

REGULATORY APPRAISAL

1. TITLE OF THE REGULATORY PROPOSAL

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

Implementation of:

- **Commission Directive 2003/57/EC of 17 June 2003 amending European Parliament and Council Directive 2002/32/EC of 7 May 2002 on undesirable substances in animal feed (OJ No. L151, 19.6.2003, p. 38);**
- **Commission Directive 2003/104/EC of 12 November 2003 authorising isopropyl ester of the hydroxylated analogue of methionine (OJ No. L295, 13.11.2003, p. 83); and**

Enforcement provision for the following EC regulations which are directly applicable in Member States:

- **Commission Regulations (EC) 1334/2003 and 2112/2003. Commission Regulation 1334/2003 amends the conditions for authorisation of a number of additives in feedingstuffs belonging to the group of trace elements (OJ No. L187, 26.7.2003, p. 11). EC Regulation 2112/2003 corrects an error in the entry for iron in EC Regulation 1334/2003.**
- **Commission Regulations (EC) 1801/2003, 1847/2003, 2154/2003, 277/2004, 278/2004 and 490/2004 authorising a number of new substances in feedingstuffs.**

2. PURPOSE AND INTENDED EFFECT OF THE MEASURE

2(i) Issue and Objectives

2.1 These Regulations:

- **implement Commission Directive 2003/57/EC which makes changes to some existing maximum permitted levels for dioxins and introduces new ones for some classes of feed additives;**
- **implement Commission Directive 2003/104/EC, which authorises a new bioprotein product, the isopropyl ester of the hydroxylated analogue of methionine, for use in feedingstuffs; and**
- **add Commission Regulations 1334/2003 and 2112/2003 to the list in Part IX of Schedule 3 to the Feeding Stuffs (Wales) Regulations 2001 and make consequential amendments to Part V of the Schedule. These Regulations amend the permitted maximum inclusion rates in feed for a number of trace elements (iron, cobalt, copper, manganese and zinc).**
- **add Commission Regulations (EC) 1801/2003, 1847/2003, 2154/2003, 277/2004, 278/2004 and 490/2004 to the list in Part IX of Schedule 3 to the Feeding Stuffs (Wales) Regulations 2001 and make consequential amendments to Part V of the Schedule. These Regulations authorise or provisionally authorise new enzyme and micro-organism products and**

provisionally authorise a new use of an already authorised additive for use in feed.

Devolution

2.2 These Regulations will apply only in Wales. Separate but parallel Regulations will be made in England, Scotland and Northern Ireland.

Background

Commission Directive 2003/57/EC

2.3 An important safeguard for the protection of animal and human health is the setting of maximum permitted levels (MPLs) for a range of contaminants including heavy metals, nitrates, aflatoxins, dioxins and certain pesticides. The previous amendment to Community legislation on undesirable substances, Directive 2002/32/EC – which was implemented in Wales last year in the Feeding Stuffs, the Feeding Stuffs (Sampling and Analysis) and the Feeding Stuffs (Enforcement) (Amendment) (Wales) Regulations 2003 (SI 2003/1850) – conferred additional safeguards on the integrity of the feed chain by prohibiting the dilution (through mixing with other feed materials, known as blending down) of consignments of feedingstuffs with levels of contamination above the specified MPLs.

2.4 Directive 2002/32/EC replaced Directive 1999/29/EC, the previous consolidating measure for undesirable substances in animal feed. Directive 1999/29/EC had been amended by Council Directive 2001/102/EC, which introduced maximum permitted levels for dioxins in a range of feed materials and feedingstuffs. These MPLs were transposed into legislation in Wales in 2002 by an amendment to the Feeding Stuffs (Wales) Regulations 2001, and remain in force. Due to an oversight by the Commission, these MPLs were not carried through to the full schedule in the Annex to Directive 2002/32/EC. Although it is to bring them within the scope of Directive 2002/32/EC, it has not been necessary to reflect this in our national implementing Regulations because the prohibition on blending down is general rather than specific.

2.5 Directive 2003/57/EC also introduces a new, higher, limit for fish protein hydrolysates containing more than 20% fat, of 2.25 ng WHO-PCDD/F-TEQ/kg. These products are currently subject to the same MPL as for fishmeal, of 1.25 ng WHO-PCDD/F-TEQ/kg. A second change will increase the maximum permitted level for dioxins for fresh (i.e. unprocessed) fish used for the direct feeding of pets and zoo and circus animals from 1.25 ng/kg WHO-PCDD/F-TEQ to 4 ng/kg WHO-PCDD/F-TEQ, to equate it with the MPL for fresh fish for human consumption. Thirdly, the current, provisional dioxin MPL of 0.5 ng WHO-PCDD/F-TEQ/kg for kaolinitic clays authorised for use in feed as binders is being raised to 0.75 ng WHO-PCDD/F-TEQ/kg. The provisional dioxin MPL is contained in an EC Regulation made under the Feed Additives Directive (70/524/EEC), but as MPLs for undesirable substances in feed additives are now within the scope of Directive 2002/32, the EC Regulation will be repealed so that the MPL for these minerals can also be listed in the Annex to Directive 2002/32/EC. The new MPL will also be extended to other minerals – calcium sulphate dihydrate, vermiculite, natrolite-phonolite, synthetic calcium

aluminates and clinoptilolite of sedimentary origin – which are also authorised for use in feed as binders, anti-caking agents and coagulants.

Commission Directive 2003/104/EC

2.6 Council Directive 82/471/EC established rules for the authorisation and labelling of certain products for use in feed. 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.

2.7 Directive 2003/104/EC adds a new product, the isopropyl ester of the hydroxylated analogue of methionine, to the Annex. This product, which is intended for use in feeds for dairy cows, is a derivative of the essential amino acid methionine, modified to make the substance easier to take up by animals' digestive systems.

Commission Regulation 1334/2003

2.8 Trace elements are added to feedingstuffs to help animals meet their nutritional needs, and must be specifically authorised for this use. The authorisation includes details of the form of the additive, its maximum rate of inclusion in complete and complementary feeds, and the species and age of the animals for which it may be used. Many of the authorisations were agreed some years ago, and now require updating in the light of advances in scientific knowledge and having regard to the potential impact on human health of high levels of certain additives.

2.9 Until 2000, the Commission had been working with Member State experts on proposed new maximum inclusion rates for authorised trace elements. These discussions were put in abeyance while the Scientific Committee on Animal Nutrition (SCAN) was asked to review the use of copper and zinc. SCAN adopted its opinions on these two trace elements in February and March 2003. The Commission responded by suggesting levels of its own for these trace elements, which in some instances differed markedly from those recommended by SCAN. The Commission also proposed its own, lower inclusion rates for three additional trace elements: iron, cobalt and manganese. These proposals were adopted by a qualified majority, and are reflected in Regulations 1334/2003.

Timetable

2.10 Member States were required to transpose Directive 2003/57/EC no later than 29 February 2004 into domestic legislation, and bring it into force with effect from 1 March 2004. Directive 2003/104/EC is required to be transposed and brought into force no later than 20 May 2004.

2.11 Regulation 1334/2003 applies directly in Member States as from 26 January 2004 (with a transitional period expiring on 26 April 2004 for the use of existing stocks of animal feed labelled according to the current rules).

Risk Assessment

Commission Directive 2003/57/EC

2.12 The increased MPL for dioxins in fish protein hydrolysates containing more than 20% fat reflects both unavoidable environmental levels of this contaminant and the behaviour of the dioxin molecule. Dioxins are hydrophobic (i.e. water-avoiding), and thus tend to concentrate in fatty tissue; a product with more than 20% fat will accordingly have a higher level of dioxins than other fishmeal. It is therefore appropriate for the MPL for fish protein hydrolysates to be adjusted to permit their continued use in the feed chain. It should be noted, however, that the new, higher MPL is still below the MPL of 4 ng/kg WHO-PCDD/F-TEQ for fish for human consumption.

2.13 The increase in the MPL for dioxins in fresh fish used for the direct feeding of pets, zoos and circus animals, to match the MPL for fish for human consumption, is justified because these animals do not at any point enter the human food chain. This increase does not therefore pose any risk to consumer health or the environment.

2.14 The current, provisional MPL for kaolinitic clays was laid down in 1999 following the discovery of very high levels of dioxins in clays from certain sources. However, subsequent monitoring has provided data to demonstrate that these additives either are not routinely contaminated with dioxins or that the levels of dioxins which they do contain are below the analytical limit of quantification. Although lower levels are in practice achievable, it was deemed inappropriate to have a lower MPL for these additives, which are incorporated in feed at lower quantities compared to other materials. It was therefore agreed to align the MPL for these substances with that for most feed materials, at 0.75 WHO-PCDD/F-TEQ/kg. At the same time, it is appropriate to extend this MPL to other minerals – calcium sulphate dihydrate, vermiculite, natrolite-phonolite, synthetic calcium aluminates and clinoptilolite of sedimentary origin – which are also authorised for use in feed as binders, anti-caking agents and coagulants, but which are not currently subject to the same controls, to bring them within the scope of Directive 2002/32/EC.

Commission Directive 2003/104/EC

2.15 When used in feed, the biologically available form of methionine will provide particular advantages for farmers raising dairy cattle. The product has already been assessed for safety, quality and efficacy.

Commission Regulation 1334/2003

2.16 The justification advanced by the Commission for the revised, lower maximum rates of inclusion for the trace elements iron, cobalt, copper, manganese and zinc is that advances in scientific and technical knowledge related to animal nutrition means that these rates can be reduced for environmental reasons, as required by the relevant articles of the Feed Additives Directive (70/524/EEC). The revised rates are

claimed to be better suited to the target species' actual nutritional needs and, through excretion from their digestive systems, to entail less burden to the environment.

Business Sectors Affected

2.17 The business sectors which will be chiefly affected by these measures are importers of feed materials, agricultural merchants, manufacturers of feed additives, feed compounders and pet food manufacturers. There could also be some impact on zoos, safari and wildlife parks, marine aquaria and circuses. The approximate number of such businesses in the UK (and Wales where figures are available) is as follows:

	UK	Wales
Manufacturers of additives and premixtures	40	Not available
Distributors of additives and premixtures	2,400	Not available
Manufacturers of prepared feed for farm animals (feed compounders)	405	20
Manufacturers of prepared pet foods	130	11
Importers and agricultural merchants	70	Not available
Farmers	150,000	36,746 ^a
Zoos, safari and wildlife parks and marine aquaria	400	Not available
Circuses	20	N/A

^a Includes main or minor holdings

2.18 The manufacturers of additives and premixtures, and the merchants and compounders who trade in or use these products, may benefit from the increase in the dioxin MPL for kaolinitic clays, as they may be able to obtain supplies of this material from a wider variety of sources than at present. On the other hand, there may be disbenefits to them from the application of this new MPL to calcium sulphate dihydrate, vermiculite, natrolite-phonolite, synthetic calcium aluminates and clinoptilolite of sedimentary origin, as this could restrict the range of sources from which supplies of these minerals are currently obtained and require them to increase the frequency of any sampling and analysis to ensure the MPL is not breached.

2.19 Feed compounders and manufacturers of prepared pet foods may benefit from the increase in the dioxin MPL for fish protein hydrolysates containing more than 20% fat. A likely consequence of this increase is that less of the material than hitherto will be rejected for breaching the MPL, which could in turn lead to reductions in the price of the material to feed compounders and the manufacturers of prepared pet foods.

2.20 The increase in the dioxin MPL for fresh fish for non-food producing animals may also be of benefit to pet owners and the operators of zoos, safari and wildlife parks, marine aquaria and circuses as they too may gain from an increase in available supplies and thus a reduction in price. However, as this lies outside the feed chain for livestock production and ultimately the health of those consuming animal products, it will not be addressed in detail in this Regulatory Appraisal.

2.21 The authorisation for the isopropyl ester of the hydroxylated analogue of methionine for use in dairy cattle may lead to slight cost reductions for UK farmers.

2.22 The revised maximum inclusion rates for the trace elements iron, cobalt, copper, manganese and zinc will affect feed compounders and the manufacturers of additives and premixtures, who may need to reformulate their products to satisfy the new requirements.

2.23 Stakeholders, including bodies representing compounders and others who use fish protein hydrolysates containing more than 20% fat, and manufacturers and merchants of additives and premixtures which contain trace elements, kaolinitic clays and other minerals used as binders, anti-caking agents and coagulants, were invited to comment on these issues. They were particularly requested to provide financial and other information on the potential impact on their activities of the amendments to dioxin MPLs and trace element inclusion rates introduced by these draft Regulations. However, no comments on the potential impact of these measures were forthcoming.

Issues of Equity and Fairness

2.24 These changes are unlikely to disadvantage the UK feed industry relative to the feed industries of other EU Member States and third countries, as the revised MPLs and trace element inclusion rates will apply to feed both manufactured in the EU and imported from third countries, which has to conform to EU feed legislation to be legally sold here.

2.25 Consumers of animal products could indirectly benefit from these revisions, particularly from the extension of the dioxin MPL for kaolinitic clay to other minerals authorised for use binders, anti-caking agents and coagulants.

2.26 Stakeholders were also invited to comment on these issues, and were requested in particular to provide financial and other information on the potential impact of the amendments to dioxin MPLs and trace element inclusion rates introduced by these draft Regulations. However, no comments on these potential aspects of the measures were received.

3. OPTIONS

There would appear to be three possible options:

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

Non-Implementation or Partial Implementation

3.1 Directive 2003/57/EC Non-implementation or partial implementation of Directive 2003/57/EC would mean the retention of the existing dioxin MPL for fish protein hydrolysates, which could restrict the use of this material by excluding from the feed chain any which contained more than of 1.25 ng WHO-PCDD/F-TEQ/kg. It would also mean retention of both the existing, lower MPL for fresh fish for non-food producing animals and the current provisional MPL of 0.5 ng WHO-PCDD/F-TEQ/kg for kaolinitic clays used as binders; and, more significantly, mean that other minerals authorised for use as binders, anti-caking agents and coagulants would continue not to be subject to controls on the levels of dioxin they contain.

3.2 However, non-implementation or partial implementation of Directive 2003/57/EC 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 delayed or ignored. Non-implementation or partial implementation of Directive 2003/57/EC would also result in undoubtedly successful legal proceedings against the UK in the European Court of Justice, as the terms of the Directive require implementation of all its provisions. 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.

3.3 Directive 2003/104/EC Non-implementation or partial implementation of Directive 2003/104/EC would mean that this new product would not be authorised for use in feed in Wales, to the relative disadvantage of UK dairy farmers. Non-implementation or partial implementation would probably not disadvantage the UK feed industry, as it is thought that the product is unlikely to be manufactured in this country. However, the product has already been subject to a safety assessment and there is therefore no policy reason not to authorise it for use in the UK. In addition, non-implementation would leave the UK open to legal proceedings against it by the Commission in the European Court of Justice.

3.4 EC Regulation 1334/2003 EC Regulations are directly applicable irrespective of Member States' actions. However, UK practice has been to link feed additive Regulations to enforcement powers by listing them in Part IX of Schedule 3 to the Feeding Stuffs Regulations. The omission of Regulation 1334/2003 from that list would mean that it could not be enforced in the UK and therefore that the current inclusion rates for the trace elements iron, cobalt, copper, manganese and zinc would be retained by default. Alternatively, the UK could adopt the rates for copper and zinc adopted by SCAN, which could be justified on the grounds that they had been subject to a full scientific evaluation whereas the rates for cobalt, iron and manganese had been proposed by the Commission without a full risk assessment. The UK could also consider adopting some but not all of the inclusion rates listed in the Regulation, perhaps in consultation with the feed industry to determine which would cost less to implement and/or which would be most appropriate for the target species.

Full Implementation

3.5 Full implementation would be consistent with the UK's obligations as a member of the EU. Full implementation, particularly of Directive 2003/57/EC, will adjust the dioxin MPL for fish protein hydrolysates to reflect the unavoidable

presence of dioxins in fatty tissue. It will modify the current, provisional, MPL for kaolinitic clays in the light of environmental monitoring and extend the MPL to other minerals authorised for use in feed; and will relax the dioxin MPL for fish for non-producing animals to reflect the fact that such animals do not enter the human food chain at any point and therefore pose no risk to consumers or public health.

Delayed Implementation

3.6 Delayed implementation, like non-implementation or partial implementation, could also give rise to concerns that measures intended to enhance the safety and integrity of the feed chain and the protection of consumers were being delayed. Delayed implementation would also leave the UK open to infraction proceedings until the measures had been implemented in full.

4. BENEFITS AND COSTS

Non-Implementation or Partial Implementation

Non-Implementation

4.1 Directive 2003/57/EC Non-implementation of Directive 2003/57/EC would mean the retention of the existing, more restrictive dioxin MPLs for both fish protein hydrolysates containing more than 20% fat – which would remain in the same category as all other forms of fishmeal instead of being assigned a separate category of their own – and kaolinitic clays, which might be of benefit to both animal and consumer health. The cost, however, would be that fish protein hydrolysates with levels of dioxin above the current MPL would not be available for feed use and would have to be disposed of, which would have costs to both the feed industry and the environment.

4.2 Directive 2003/104/EC Non-implementation of Directive 2003/104/EC would mean that a new and potentially useful form of methionine would not be available for use in feed in Wales . Farmers of dairy cattle would be denied the benefits of using this product.

4.3 EC Regulation 1334/2003 Non-implementation of EC Regulation 1334/2003 would mean that the current inclusion rates for iron, cobalt, copper, manganese and zinc would be retained by default and therefore that feed compounders and the manufacturers of additives and pre-mixtures which contained these trace elements would avoid the need to reformulate their products to meet the new, lower rates. However, non-implementation would have disadvantages for feed compounders and the manufacturers of additives and premixtures, as they would not be compliant with the new requirements and thus would not be able to sell their products into other EU markets.

Partial Implementation

4.4 Directive 2003/57/EC Partial implementation of Directive 2003/57/EC could entail the adoption of the new, higher MPL for kaolinitic clays, which would also allow scope to apply this MPL to other minerals authorised as binders, anti-caking agents and coagulants, with consequent benefits to the safety of the feed chain and indirectly to the human consumers of animal products. There would be benefits to both animal and public health from the bringing of these minerals within the scope of dioxin controls.

4.5 Directive 2003/104/EC Partial implementation of Directive 2003/104/EC would not be practical, as the measure concerns the authorisation of one new product for use in feed for one target species (dairy cattle).

4.6 EC Regulation 1334/2003 Partial implementation of EC Regulation 1334/2003 could entail the adoption of the rates for copper and zinc supported by SCAN, which have been subject to a full scientific evaluation and might therefore be considered to be more robust than the rates for cobalt, iron and manganese proposed by the Commission. However, as with non-implementation, UK manufacturers of additives and premixtures which contain these trace elements at the rates of inclusion other than those specified would not be able to sell their products into other markets in the EU.

Full Implementation

4.7 Directive 2003/57/EC Full implementation of Directive 2003/57/EC would adjust the MPLs for fish protein hydrolysates containing more than 20% fat, kaolinitic clays, and fish for consumption by non-food producing animals, so reflecting and responding to current and emerging knowledge. It would also apply the dioxin MPL for kaolinitic clays to a range of other minerals authorised for use as binders, anti-caking agents and coagulants, bringing a range of additives within the scope of these controls and thus providing further assurance for the purchasers of animal feed and, indirectly, the ultimate consumers of animal products.

4.8 Directive 2003/104/EC Full implementation of Directive 2003/104/EC would allow the use of the isopropyl ester of the hydroxylated analogue of methionine to be used in feed for dairy cows in Wales.

4.9 EC Regulation 1334/2003 Full implementation of EC Regulation 1334/2003 would mean that the inclusion rates for the trace elements iron, cobalt, copper, manganese and zinc were better matched to the target species of animals and, through excretion from the animals' digestive systems, would entail less burden to the environment.

Delayed Implementation

4.10 Delayed implementation could defer any costs associated with the implementation and enforcement of the measures, including costs associated with

the disposal outside the feed chain of material with levels of contamination above the specified MPLs, any testing to ensure that the additional minerals to which a dioxin MPL applies are compliant with it, and the potential expense of product reformulation to manufacturers of additives and premixtures which contain iron, copper, cobalt, manganese and zinc.

5. COSTS FOR BUSINESS, CHARITIES & VOLUNTARY ORGANISATIONS

Compliance Costs

5.1 Charities and voluntary organisations will not be affected by these measures.

5.2 There could be some additional costs to business in the early stages of complying with Directive 2003/57/EC, because of a perceived need to verify that the additional minerals to which dioxin MPLs now apply are free of such contamination; there could also be some savings to business as a consequence of the relaxation of the MPLs for fish protein hydrolysates and kaolinitic clays. Any costs or savings from the relaxation of the dioxin MPL for unprocessed fresh fish for direct consumption by non-food producing animals – pets and zoo and circus animals – are likely to fall to the owners and exhibitors of such animals rather than the feed industry.

5.3 There may be some additional costs to business of reformulating products to comply with the requirements of Regulation 1334/2003.

5.4 Stakeholders were invited to identify and comment on any possible additional costs to them of the amendments to dioxin MPLs and trace element inclusion rates introduced by these draft Regulations. However, no comments were received.

Financial Implications for Wales

5.5 There are no financial implications for the Welsh Assembly Government or for Local Authorities arising from the making of these Regulations. Neither Directive 2003/57/EC, Directive 2003/104/EC nor Regulation 1334/2003 specify any additional levels of sampling and analysis for the enforcement of dioxin MPLs and trace element inclusion rates in feed. There is therefore no new burden on enforcement authorities. They will, however, need to make risk-based judgements on the relative priorities of this and other aspects of animal feed enforcement when deciding how to use their resources.

5.6 The business sectors which will be chiefly affected by these measures are importers of feed materials, agricultural merchants, manufacturers of feed additives, feed compounders and pet food manufacturers. There could also be some impact on zoos, safari and wildlife parks, marine aquaria and circuses. The approximate number of such businesses in the UK is shown at 2.17, with figures, where available for Wales.

5.7 Stakeholders were invited to identify and comment on any possible additional costs which may have to be borne by typical businesses as a consequence of the amendments to dioxin MPLs and trace element inclusion rates introduced by these draft Regulations. As there were no responses to the consultation in Wales, it has not been possible to identify the exact financial impact this legislation will have on Welsh Industry. Only 4 responses were received to the consultation exercise across the UK (see 10.3 – 10.5 below) but none of these commented on the financial impact of this legislation.

Costs for Typical Businesses

5.8 It is possible that additional costs for typical businesses of complying with the new dioxin MPLs could be minimal, in line with the reasoning advanced in 5.2 above. There may be higher costs for typical businesses from the reformulation of additives and premixtures to meet the new trace element inclusion rates.

5.9 Stakeholders were again invited to identify and comment on any possible additional costs which may have to be borne by typical businesses as a consequence of the amendments to dioxin MPLs and trace element inclusion rates introduced by these draft Regulations. Once again, however, no comments on these issues were forthcoming.

6. CONSULTATION WITH SMALL BUSINESSES (THE “LITMUS TEST”)

6.1 Approximately one-third of the companies which manufacture animal feed claim small company status. This includes many of the manufacturers of additives and premixtures, who could be significantly affected by the revised trace element inclusion rates. The amendments to the dioxin MPLs, although not major, could also have a significant impact on small businesses.

6.2 Small business stakeholders were covered in the consultation exercise, but none responded.

7. COMPETITION ASSESSMENT

7.1 The proposed changes to the Regulations will have some negative and some positive impacts on different types of businesses. It is expected that the potential negative impact on competition will be concentrated on the feed industry, and that the possible impact on farmers will not be strong enough to affect competition.

7.2 The UK feed industry is highly fragmented with over 340 companies. 70 of the largest accounted for 21% of the market and 185 for 55% of market value in 2002. Compound feed production is more concentrated, being dominated by 2 large companies (neither of which are based in Wales) who account for nearly 50% of the market.

7.3 The proposed changes to the Regulations may affect some feed producers more than others, depending on whether or not the materials they use meet the revised dioxin MPLs and whether or not they have to reformulate their products to

meet the revised trace element inclusion rates. This may potentially alter the market structure in the feed industry, if the resulting costs are high.

7.4 Overall, however, it is believed that the possible negative impact of the new dioxin MPLs on competition in the feed industry will not be very large.

7.5 Stakeholders, particularly feed industry interests, were invited to comment on this assessment, and assured by the Food Standards Agency that any data supplied for public consumption would be anonymised prior to publication. Businesses which considered competition in their sector might be significantly affected by the proposed Regulations were also invited to comment. However, no comments were received on the potential impact of these measures on competition in the feed or farming industries.

8. ENFORCEMENT AND SANCTIONS

Enforcement

8.1 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. Enforcement includes the taking of samples of animal feed and the testing of them for the presence of various ingredients.

8.2 Neither Directive 2003/57/EC nor Regulation 1334/2003 specify any additional levels of sampling and analysis for the enforcement of dioxin MPLs and trace element inclusion rates in feed. The maximum limits for dioxins in some feed materials and feedingstuffs have applied since 1 July 2002 and enforcement authorities should already be carrying out tests for dioxins to ensure compliance with the EU legislation and national legislation under the Agriculture Act 1970 (as amended). There is therefore no new burden on enforcement authorities. They will, however, need to make risk-based judgements on the relative priorities of this and other aspects of animal feed enforcement when deciding how to use their resources. It is acknowledged that the current cost of analysis for dioxins is high and any programme of testing to ensure compliance with the maximum limits is therefore likely to take up a significant proportion of the budget available for enforcement of feedingstuffs legislation. It is further acknowledged that local authority sampling across a range of feed materials and feedingstuffs for a range of undesirable substances is important for effective control of the feed chain and through that the ultimate health of the consumers of animal products such as meat, milk and eggs.

8.3 The Local Authorities Co-ordinators of Regulatory Services (LACORS), the co-ordinating body for local authority trading standards departments in England and Wales, and enforcement authorities in general were invited to identify and comment on any additional costs to them. However, no comments were received.

Sanctions

8.4 The penalties for non-compliance with feedingstuffs legislation are set out in the Agriculture Act 1970 and the Feeding Stuffs Regulations (Wales) 2001 (as amended).

9. MONITORING AND REVIEW

9.1 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.

10. CONSULTATION

Public Consultation

10.1 The Food Standards Agency Wales carried out a consultation from 5 January to 29 March 2004. Stakeholders (including consumer and industry representative bodies), and farming unions were invited to comment on the draft Regulations and the draft Regulatory Appraisal and to provide information on the potential costs and benefits to them (both monetary and non-monetary) of the amendments to dioxin MPLs and trace element inclusion rates introduced by Directive 2003/57/EC and Regulation 1334/2003. A list of those consulted in Wales is at Annex 1.

10.3 A total of four responses were received in response to all the UK consultation exercises. No responses were received from Welsh Stakeholders.

10.4 One response from the Meat and Livestock Commission advised that it had no comments to make. A second response (from the Grain and Feed Trade Association) raised a minor query on the contents of the consultation package, and a third (from the Pet Care Trust) – although not commenting directly on the implications of the draft Regulations – stated that it had been difficult to locate an executive summary of the objective of the measures amongst the other documents in the consultation package. The Food Standards Agency will reflect on how the covering letter which accompanies every consultation package – and which is intended to summarise what the new measures involve – may be enhanced to ensure that it is more readily identifiable.

10.5 The fourth response, from the British Cattle Veterinary Association, gave strong support to the full implementation both of Directive 2003/57/EC making changes to some existing maximum permitted levels for dioxins and introducing new ones for some classes of feed additives, and of Directive 2003/104/EC authorising a new bioprotein product, the isopropyl ester of the hydroxylated analogue of methionine, for use in feedingstuffs. With respect to EC Regulation 1334/2003, however, the Association expressed some concern about the manner in which the Commission had determined its inclusion rates for the trace elements copper, zinc, iron, cobalt and manganese, which it suggested were arbitrary in nature and not in line with the opinions adopted by the Scientific Committee on Animal Nutrition. Nevertheless, the Association felt that the potential costs of partial implementation or non-implementation of EC Regulation 1334/2003 were not outweighed by the

benefits, and therefore offered qualified support for the full implementation of this measure.

11. SUMMARY AND RECOMMENDATIONS

Option	Total Cost	Total Benefit
1. Non-implementation or partial implementation	Costs of infraction proceedings (which would be ongoing, perhaps £100,000 per day).	<p><u>Non-implementation</u>: maintenance of the existing controls regime for dioxins, including the theoretical possibility of blending down consignments with levels of contamination above those permitted for finished feeds; no authorisation for the use of the new bioprotein product; retention of the current trace element inclusion rates.</p> <p><u>Partial implementation</u>: closure of the loophole which theoretically permits continued blending down, but retention of more restrictive dioxin MPLs for fish protein hydrolysates and kaolinitic clays; either different or no conditions attached to the use of the new bioprotein product; adoption of SCAN inclusion rates for copper and zinc only.</p>
2. Full implementation	Some potential additional costs to industry from testing of other minerals authorised for use as binders, anti-caking agents and coagulants to ensure compliance with newly applicable dioxin MPL.	Removal of the theoretical possibility of blending down of dioxin-contaminated feed and the extension of dioxin MPL controls to other minerals authorised for use as binders, anti-caking agents and coagulants, both of which are intended to further secure the safety and integrity of the feed chain. (The feed industry might also benefit from amendments to existing dioxin MPLs which make them more proportionate to the actual risks.) Farmers able to use the new bioprotein product in feed for dairy cattle. Adoption of the revised inclusion rates for trace elements, which are better suited to the target species' actual nutritional needs.
3. Delayed	Costs of infraction	As with non-implementation (in the

implementation	proceedings (which would be ongoing, perhaps £100,000 per day).	short term).
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11.1 Directive 2003/57/EC It is appropriate to adjust the provisional MPL for dioxins in kaolinitic clays in the light of monitoring of their actual inclusion rates, and to extend it to other minerals – calcium sulphate dihydrate, vermiculite, natrolite-phonolite, synthetic calcium aluminates and clinoptilolite of sedimentary origin – which are also authorised for use as binders, anti-caking agents and coagulants. It is also appropriate to increase the MPL for dioxins in fish protein hydrolysates containing more than 20% fat, to reflect both environmental background levels of this contaminant and the tendency of dioxin molecules to concentrate in fatty tissue, so that use of these hydrolysates in the feed chain can continue. The increase in the MPL for fresh fish fed to non-food-producing animals similarly reflects the prevailing environmental levels of dioxins.

11.2 Directive 2003/104/EC It would clearly be disadvantageous to livestock farmers in Wales to deny them access to a new bioprotein, the isopropyl ester of the hydroxylated analogue of methionine, which has already been assessed for safety, quality and efficacy.

11.3 EC Regulation 1334/2003 It is a matter of some concern that, in setting revised maximum inclusion rates for five trace elements, the Commission seems to have disregarded the opinions adopted by the Scientific Committee on Animal Nutrition in respect of copper and zinc and to have proceeded without waiting for the conclusion of its discussions with Member State experts in respect of iron, cobalt and manganese. Nevertheless, there appears to be some merit in the Commission's argument that the reduced inclusion rates are better suited to the target species' actual nutritional needs and will entail less burden to the environment. In addition, the UK feed industry will not be disadvantaged relative to other Member States or to imports of feedingstuffs from third countries, which will have to conform to the new rates in order to be marketed here.

11.4 In the light of these considerations, it is recommended that Directives 2003/57/EC and 2003/104/EC be implemented in Wales by the Feeding Stuffs, the Feeding Stuffs (Sampling and Analysis) and the Feeding Stuffs (Enforcement) (Amendment) (Wales) Regulations 2004 and that EC Regulation 1334/2003 be linked to existing enforcement powers by the same Regulations (option 2).

Contact Point

Alison Ward
Food Standards Agency Wales
11th Floor Southgate House
Wood Street
Cardiff, CF10 1EW
Telephone: 029 20678906
Fax: 029 20678918
E Mail: alison.ward@foodstandards.gsi.gov.uk

LIST OF STAKEHOLDERS CONSULTED IN WALES

ADAS Wales

The Association of Public Analysts

Farmers' Union of Wales

Federation of Small Businesses

Hybu Cig Cymru

LACORS (Welsh Officer)

Trading Standards Institute (Wales)

National Farmers Union (Wales)

Society of Directors of Public Protection

Wales Young Farmers' Club
Welsh Consumer Council
CIEH-Cymru Wales
Welsh Food Laboratories
Welsh Food Directorate
Royal Welsh Agricultural Society
Agri-Food Partnership
British Retail Consortium
Welsh Lamb and Beef Promotions
Eurofins Scientific
Countryside Council for Wales
Country Land and Business Owners Association

Welsh Food Alliance
Meat & Livestock Commission Cymru
UKASTA Wales
Minton, Treharne & Davies Ltd
Cardiff Scientific Services
Wales Assembly of Women
Wales Council for Voluntary Action
Welsh Agricultural Organisation Society
Welsh Assembly Government
Welsh Council of the Institution of Environmental Health Officers
Welsh Food Promotions

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