EXPLANATORY MEMORANDUM TO

THE FEEDING STUFFS AND THE FEEDING STUFFS (SAMPLING AND ANALYSIS) (AMENDMENT) (ENGLAND) REGULATIONS 2006

2006 No.113

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

2. Description

This instrument transposes Commission Directives 2005/6/EC and 2005/7/EC on procedures for the sampling and analysis of undesirable substances (i.e. contaminants) in animal feed, and Commission Directive 2005/8/EC, which amends existing and introduces new permitted maximum levels for certain of these undesirable substances.

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

None.

4. Legislative Background

4.1 The Feeding Stuffs (England) Regulations 2005 implement harmonised EC measures on the marketing, labelling and composition of animal feedingstuffs. They include provisions intended to safeguard animal and human health, including maximum permitted levels for certain undesirable substances. These are naturally occurring contaminants such as lead, mercury and fluorine, and process contaminants such as dioxins.

4.2 The Feeding Stuffs (Sampling and Analysis) Regulations 1999 (as amended) implement harmonised EC procedures for the sampling and analysis of animal feed, including the precise methods to be used in taking samples and conducting analyses, and the form of reporting on the results of such analyses.

4.3 Commission Directives 2005/6/EC and 2005/7/EC introduce measurement uncertainty and correction for recovery in the reporting of analytical results, which is necessary because of inherent uncertainties in analytical procedures. Commission Directive 2005/6/EC therefore introduces general provisions relating to these procedures in the interpretation and reporting of analyses of undesirable substances in general, and Commission Directive 2005/7/EC introduces them to the analysis of dioxins and dioxin-like polychlorinated biphenyls (PCBs) in particular.

4.4 The maximum permitted levels (MPLs) for many undesirable substances were established some years ago. In accordance with more recent approaches to risk analysis, a review is being undertaken in the light of current scientific data on actual

background levels by the relevant scientific panel of the European Food Safety Authority, which has proposed a number of changes. Commission Directive 2005/8/EC introduces an upper limit for mercury in calcium carbonate, amends the existing entry for fluorine in complementary feedingstuffs, and amends the existing MPL for lead in green fodder by inserting a footnote to clarify what the term encompasses.

4.5 A transposition note showing how the measures have been given effect in the Feeding Stuffs and the Feeding Stuffs (Sampling and Analysis) (Amendment) (England) Regulations 2006 is attached to this Explanatory Memorandum.

5. Extent

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

6. European Convention on Human Rights

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

7. Policy background

7.1 Requirements for laboratories, sample preparation, analytical procedures and the reporting of results for the analysis of both dioxins and dioxin-like PCBs were introduced by Commission Directive 2002/70/EC. The procedures for the analysis of these and other undesirable substances now need refining to introduce measurement uncertainty and correction for recovery.

7.3 All analytical results have a variability known as the measurement uncertainty, which, due to uncertainties inherent in the measurement procedures, has to be estimated to calculate the range within which the true value of the concentration of the analyte being determined will lie. Correction for recovery allows for the adjustment of analytical measurement to compensate for the likelihood that not all of the analyte will have been extracted from the sample prior to analysis.

7.4 Commission Directive 2005/6/EC inserts into the first of the Community's sampling and analysis Directives, 71/250/EEC, general provisions relating to these procedures for analytical results to be reported under the Undesirable Substances Directive, 2002/32/EC. Commission Directive 2005/7/EC amends Commission Directive 2002/70/EC by inserting into its annexes provisions relating to these procedures in the analysis of dioxins and dioxin-like PCBs in particular.

7.5 Commission Directive 2005/8/EC makes three amendments to existing MPLs for undesirable substances. Firstly, it extends the existing MPLs for mercury by adding an MPL for mercury in calcium carbonate (a mineral used as a source of calcium because it is essential for the normal growth and function of animals) in which this toxic heavy metal occurs and which, if not controlled, could have adverse effects on the health of animals and humans who consume animal products.

Secondly, it amends the existing MPLs for fluorine in complementary feeds by replacing two existing entries with one relating the MPL to whether the phosphorus content, with which fluorine typically co-exists, is greater or lesser than 4% of the feed. (Consumers and farmed livestock are not generally exposed to high levels of fluorine, but MPLs are necessary to help prevent adverse effects on teeth and bones.) Thirdly, the Directive amends the existing MPL for lead in green fodder by inserting a footnote to clarify what the term encompasses. UK domestic legislation currently uses the words "grass meal, lucerne meal or clover meal" instead of "green fodder", the term used in the Undesirable Substances Directive. The term used in domestic legislation is more restrictive than that used in the Directive and so needs to be replaced.

8. Impact

8.1 There were five responses to the public consultation in England. Three agreed with the implementation of the three Directives, with one suggesting that the introduction of measurement uncertainty and correction for recovery could have some costs but being unable to quantify these. A fourth response also suggested that there could be additional costs, particularly to laboratories for accreditation and validation of methods, but again was unable to provide specific figures. The Food Standards Agency is assessing the potential costs to analysts of accreditation under a separate measure on Official Feed and Food Controls, and the issue of any costs associated with the new procedures can be addressed as part of that exercise. The fourth response also requested deferment of the implementation of one of the measures, but the consultee was advised that this was not a realistic option as failure to meet EC implementation deadlines could attract infraction proceedings from the European Commission. The fifth response made no substantive comments.

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

9. Contact

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ANNEX 1

REGULATORY IMPACT ASSESSMENT

1. TITLE OF PROPOSAL

The Feeding Stuffs and the Feeding Stuffs (Sampling and Analysis) (Amendment) (England) Regulations 2005

Implementation of:

- **Commission Directive 2005/6/EC of 26 January 2005 amending Directive 71/250/EEC as regards reporting and interpretation of analytical results required under Directive 2002/32/EC (*OJ* No. L24, 27.1.2005, p. 33);**

- **Commission Directive 2005/7/EC of 27 January 2005 amending Directive 2002/70/EC establishing requirements for the determination of levels of dioxins and dioxin-like PCBs in feedingstuffs (*OJ* No. L27, 29.1.2005, p. 41), and**

- **Commission Directive 2005/8/EC of 27 January 2005 amending Annex 1 to Directive 2002/32/EC of the European Parliament and Council on undesirable substances in animal feed (*OJ* No. L27, 29.1.2005, p. 44).**

2. PURPOSE AND INTENDED EFFECT OF THE MEASURE

Objectives

2.1 Commission Directives 2005/6/EC, 2005/7/EC and 2005/8/EC are intended to sustain and enhance feed safety, and thus the protection of the health of human consumers of animal products (meat, milk and eggs).

2.2 To implement the Directives, these Regulations:

- make a number of small technical amendments to entries in Schedules 2 and 3 to the Feeding Stuffs (Sampling and Analysis) Regulations 1999 (as amended). Schedule 2 lays down the procedures to be followed in taking and analysing samples of animal feedingstuffs and Schedule 3 concerns the declarations to be made on the certificate of analysis;

- amend the existing entries in Schedule 2 to the Feeding Stuffs (Sampling and Analysis) Regulations 1999 (as amended) for the analysis of dioxins and dioxin-like polychlorinated biphenyls (PCBs). This amendment introduces provisions which take into account measurement uncertainty and correction for recovery. Measurement uncertainty, which is normally expressed as an expanded uncertainty, has to be estimated to calculate the range within which the true value of the concentration of the analyte being determined will lie. Correction for recovery allows the data to be corrected for incomplete extraction of the analyte from the sample; and

- amend the existing maximum permitted levels (MPLs) in the Feeding Stuffs Regulations 2005 for a number of naturally occurring contaminants. There will be a new limit for the presence of mercury in calcium carbonate, a widely used mineral feedingstuff; the existing MPLs for fluorine in mineral mixtures for ruminants and complementary feedingstuffs will be altered to link the MPLs to the phosphorus content of such feeds; and the entry for the MPL for lead in green fodder will have an annotation added to make clear what green fodder encompasses.

Background

(i) Directives 2005/6/EC and 2005/7/EC

2.3 Dioxins are ubiquitous toxic substances produced during various combustion and incineration processes and are also unwanted by-products in the manufacture of certain chemicals. Polychlorinated biphenyls (PCBs) have been used since the early 1930s, mainly in electrical equipment, but their manufacture and general use stopped in the 1970s and is no longer permitted in the UK. However, both dioxins and PCBs are persistent organic pollutants which degrade slowly and so are widespread in the environment and accumulate in the food and feed chain. Current levels of dioxin and PCB contamination generally reflect historical emissions.

2.4 Until recently, there were no statutory limits on the levels of dioxins permitted in either animal feedingstuffs or foods for human consumption. The discovery of elevated levels of dioxins in citrus pulp pellets imported from Brazil in 1998, and the mixing of used transformer oils with recovered vegetable oils intended for use in feed in Belgium in 1999, prompted the introduction in 2001 of MPLs for dioxins in a range of feed materials (materials fed singly or used as ingredients) and manufactured feeds. These MPLs were incorporated in a subsequent consolidation of the Undesirable Substances Directive, 2002/32/EC, specifying MPLs for a range of process and environmental contaminants whose presence in animal feed is technically unavoidable.

2.5 The UK accepted the need for MPLs, but was concerned about the absence of MPLs for dioxin-like PCBs, as UK survey data shows that these contribute at least the same toxic load as dioxins and should therefore be included in control measures for feed and food. The UK also argued that source-directed measures to reduce the release of dioxins to the environment, the main route by which dioxins are incorporated in feed and food, is the most effective way to reduce exposure to them. In recognition of these concerns, the Commission agreed to develop both a strategy to reduce environmental dioxin emissions and criteria for Community methods of analysis for dioxins.

2.6 A strategy for the reduction of emissions was subsequently adopted in October 2001, and criteria for Community methods of analysis covering both dioxins and dioxin-like PCBs were adopted in July 2002 as Directive 2002/70/EC. One of the two new Directives, 2005/7/EC, to be implemented by these Regulations amends the annexes to Directive 2002/70/EC by introducing provisions relating to measurement uncertainty and correction for recovery in the analysis of dioxins. The other new Directive, 2005/6/EC, inserts into the first of the Community's sampling and analysis Directives, 71/250/EEC, a general provision relating to recovery for uncertainty in the interpretation and reporting of analytical results required under Directive 2002/32/EC on undesirable substances in general.

(ii) Directive 2005/8/EC

2.7 An important safeguard in the protection of animal and human health is the setting of MPLs for undesirable substances. Directive 2002/32/EC, the most recent consolidation of Community legislation on undesirable substances, prohibited the dilution (through mixing with other feed materials, known as blending down) of consignments of feed with levels of contamination above the specified maximum permitted levels.

2.8 During negotiations on the prohibition on blending down enacted by Directive 2002/32/EC, the Commission agreed that the existing MPLs for undesirable substances, many of which had been established some years previously and never subject to a proper risk assessment, should be reviewed by the Scientific Committee on Animal Nutrition (SCAN). In the event, SCAN was unable to complete this work before the prohibition took effect. The work is now being carried forward by a scientific panel of the European Food Safety Authority (EFSA) which took over SCAN's responsibilities, and is reviewing both existing MPLs and examining new data on other undesirable substances not currently subject to controls. The measures in Directive 2005/8/EC represent one of the results of this continuing review.

Rationale for Government Intervention

(i) Directives 2005/6/EC and 2005/7/EC

2.9 Commission Directive 2002/70/EC introduced requirements for laboratories, sample preparation, analytical procedures and the reporting of results, so establishing the framework for the harmonised methods of sampling and analysis which are key to consistent and effective enforcement. However, these procedures now need refining to introduce measurement uncertainty and correction for recovery in the reporting of analyses of feed for the presence of dioxins.

2.10 All analytical results have a variability known as the measurement uncertainty, which can be described as the range of values that can be placed on a measured value, due to uncertainties in the measurement procedures. If there are several factors capable of introducing errors into the measurement procedure, the total measurement uncertainty can be difficult to derive. There is no such thing as a perfect measurement, although some measurements are so precise that the errors which contribute to uncertainty are negligible.

2.11 Correction for recovery allows the adjustment of analytical measurement to compensate for the likelihood that not all of the analyte will have been extracted from the sample prior to analysis. For example, if it can be shown by an internal standard that the recovery of an analyte is 95%, the measurement value can be divided by 0.95 to correct for recovery.

(ii) Directive 2005/8/EC

2.12 Some of the undesirable substances subject to a maximum limit are naturally occurring environmental contaminants (such as lead, mercury and fluorine) which would ordinarily be present at low levels in feed and food products, particularly vegetable crops drawing nutrients directly from the soil. However, the MPLs for these contaminants were established some years ago, and have not been subjected to a thorough risk assessment. A

review of these levels in the light of current scientific data on actual background levels is therefore appropriate.

2.13 The range of existing MPLs for mercury is being amended by the addition of an MPL for calcium carbonate. Mineral products such as this are used extensively in the feed industry as sources of calcium, magnesium, etc., because they are essential for the normal growth and function of animals. However, deposits of calcium carbonate can occur in combination with the toxic heavy metal mercury, which can have an adverse effect on the health of both animals and humans who consume animal products such as milk, meat and eggs. It is therefore important to set limits for mercury in calcium carbonate.

2.14 The existing range of MPLs for fluorine in feedingstuffs includes two entries for (a) mineral mixtures for ruminants and (b) fluorine in complementary feeds (that is, feeds which themselves are insufficient to provide a complete daily ration for an animal and which therefore require to be mixed with other materials before feeding). Although consumers and farmed livestock are not generally exposed to unacceptably high levels of fluorine, it is necessary to set maximum limits 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.

2.15 The entries for fluorine in complementary feeds are currently linked to the percentage value of the phosphorus content of the feedingstuff because these elements typically co-exist in certain feed materials. In consequence, it is technically impossible to have lower limits for fluorine for products with high levels of phosphorus. The two existing entries for fluorine are therefore to be replaced by an entry for fluorine in complementary feedingstuffs which relates the fluorine MPL to whether the phosphorus content is greater or lesser than 4% of the feedingstuff.

2.16 Directive 2005/8/EC also amends the existing MPL for lead in green fodder by inserting a footnote to clarify that "green fodder includes products intended for animal feed such as hay, silage, fresh grass, etc.". However, although the term "green fodder" has been used in the Undesirable Substances Directive since its insertion by an amendment in 1994, the wording "grass meal, lucerne meal or clover meal" was used when this amendment was implemented in UK domestic legislation. This wording is inconsistent with the Undesirable Substances Directive and will be replaced with that in Directive 2005/8/EC.

3. CONSULTATION

Within Government

3.1 The Food Standards Agency in Scotland, Wales and Northern Ireland undertook separate consultations on the draft Regulations to implement Directives 2005/6/EC, 2005/7/EC and 2005/8/EC in their respective countries. Consultation by the Food Standards Agency in Wales and Northern Ireland involved, respectively, the National Assembly for Wales and the Department of Agriculture and Rural Development for Northern Ireland. The views of Agriculture Departments (the Scottish Environment and Rural Affairs Department and the Department for Environment, Food and Rural Affairs) and the DTI's Small Business Service were also be sought as part of the consultation exercise, but no comments were received.

Public Consultation

3.2 All stakeholders were invited to comment on the draft Regulations to transpose these three measures into national legislation, and to provide any financial or other data which they considered might support their arguments, whether or not in favour of their implementation.

3.3 The Food Standards Agency in London received five responses to the public consultation in England. Three respondents indicated their full agreement to the implementation of the three Directives, although one -- the Agricultural Industries Confederation, a feed industry trade association -- suggested that there could be some additional costs associated with the introduction of measurement uncertainty and correction for recovery in the reporting of analyses of animal feed. However, this respondent was unable to quantify these potential costs.

3.4 The fourth response, from the Association of Public Analysts, suggested that the cost to laboratories for accreditation, validation of methods and calculation of measurement uncertainty could be significant, but did not provide specific figures to support its argument despite a subsequent request for quantification to help inform this Regulatory Impact Assessment. However, the Food Standards Agency is assessing the potential costs to analysts of accreditation under a separate measure on Official Feed and Food Controls, and the issue of any costs associated with the new procedures can be addressed as part of that exercise.

3.5 The Association of Public Analysts also requested that the implementation of Directive 2005/6/EC be deferred (to an unspecified future date), so that its requirements could be phased in alongside the accreditation and validation associated with another measure (EC Regulation 882/2004, which came into force on 1 January 2006). However, the Association has been advised that deferment is not a realistic option, as failure to meet the deadline for implementation could attract infraction proceedings from the European Commission.

3.6 The Association also stated that in its opinion a provision in the draft Regulations did not correctly replicate the intentions of Directive 2005/6/EC, in that it would apply measurement uncertainty and correction for recovery to the results of all analyses of feedingstuffs, irrespective of the analyte, rather than solely to analyses of undesirable substances. This same point was made in the fifth response to the consultation, from the Local Authorities Coordinators of Regulatory Services, the umbrella body for local authority trading standards departments which are responsible for the enforcement of feedingstuffs legislation. However, the provision in the draft Regulations inserted a footnote to the certificate of analysis, advising on the procedure for completion of the certificate in respect of undesirable substances, and would not affect completion of the certificate where any other analytes are concerned. Nevertheless, the relevant provision in the finalised Regulations has been amended to clarify that the footnote applies only to the analysis of undesirable substances.

4. OPTIONS

4.1 There were two possible options:

(a) non-implementation of the measures; and
(b) full implementation of the measures.

Non-Implementation

(i) Directives 2005/6/EC and 2005/7/EC

4.2 Non-implementation of these two Directives would mean that measurement uncertainty and correction for recovery would not be introduced into the interpretation and reporting of analytical results of undesirable substances in general and of dioxins and dioxin-like PCBs in particular.

(ii) Directive 2005/8/EC

4.3 Non-implementation of Directive 2005/8/EC would mean that there would be no new, separate MPL for mercury in calcium carbonate, and that the existing MPLs for fluorine in mineral mixtures for ruminants and complementary feedingstuffs would remain unchanged.

Consequences of Non-Implementation

4.4 Non-implementation of the provisions of Directives 2005/6/EC and 2005/7/EC which take into account expanded measurement uncertainty and correction for recovery might lead to enforcement officers responding to particular sampling results with action which could ultimately prove erroneous. Non-implementation of Directive 2005/8/EC could 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 or ignored. It could also mean that UK producers of calcium carbonate and complementary feedingstuffs could lose market share in the EU, as they might no longer be able to sell these feed products into other EU markets.

4.5 Non-implementation of these three Commission Directives could lead to legal proceedings against the UK in the European Court of Justice, as the terms of the measures require the implementation of all their provisions. The costs of non-implementation could include the costs of infraction proceedings to the UK Government as well as any financial penalties imposed.

Full Implementation

(i) Directives 2005/6/EC and 2005/7/EC

4.6 Implementation will provide clearer guidance for enforcement officers in cases where sampling has generated analytical results showing levels of apparent contamination very close to or just at the relevant MPL, by allowing such results to be refined to determine whether or not the MPL has in fact been breached. In any case, it is likely that a state-of-the-art laboratory will already be reporting such "borderline" results using expanded measurement uncertainty and correction for recovery.

(ii) Directive 2005/8/EC

4.7 Full implementation of Directive 2005/8/EC 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, particularly calcium carbonate and complementary feedingstuffs, in other EU copuntries.

5. COSTS AND BENEFITS

Sectors and Groups Affected

5.1 The provisions of Directives 2005/6/EC and 2005/7/EC will have most effect on laboratories analysing samples of animal feedingstuffs taken by local authority trading standards departments, which will have to apply the calculations for expanded measurement uncertainty and correction for recovery. (It is estimated that there are 19 public analyst laboratories in England.) The provisions of Directive 2005/8/EC will have most effect on the feed industry, which will be required to ensure that its products comply with the new or revised MPLs for mercury in calcium carbonate and fluorine in complementary feedingstuffs.

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

Benefits

(i) Economic

5.5 Non-implementation of Directives 2005/6/EC and 2005/7/EC has no identifiable economic benefits. However, full implementation of these two measures would mean that analytical results will be required to be reported and interpreted as prescribed under EC legislation, a clear advantage where enforcement officers are taking legal action on the basis of official sampling data.

5.6 Non-implementation of Directive 2005/8/EC may entail some savings for UK feed producers, as they would not be subject to the new MPL for mercury in calcium carbonate or the amended MPL for fluorine in complementary feedingstuffs, with the additional work of sampling and analysis which might be required to ensure that these feeds conformed to the new requirements.

5.7 However, full implementation could also have benefits for UK feed producers, as they would be able to continue selling the full range of their products, particularly calcium carbonate and complementary feedingstuffs, in other EU countries. Full implementation could also have health benefits for farmed livestock and human consumers of animal products, through the extension of controls on the undesirable substances mercury and fluorine and thus enhancements to feed safety.

(ii) Environmental

5.8 There do not appear to be any identifiable environmental benefits or disbenefits from either the non-implementation or full implementation of Directives 2005/6/EC and 2005/7/EC.

5.9 There may be some environmental benefits from the implementation of the new MPL for mercury in calcium carbonate laid down in Directive 2005/8/EC, but any such benefits are difficult to quantify. There do not appear to be any other identifiable environmental benefits or disbenefits from either the non-implementation or full implementation of the measure.

(iii) Social

5.10 There do not appear to be any identifiable social benefits or disbenefits from either the non-implementation or full implementation of Directives 2005/6/EC and 2005/7/EC.

5.11 As far as Directive 2005/8/EC is concerned, full implementation of the amended MPL for fluorine in complementary feedingstuffs will be socially neutral because it does not disadvantage any particular group of consumers of animal products. Full implementation of the new MPL for mercury in calcium carbonate will be socially beneficial because it should help reduce inputs of this toxic element into the feed and food chains.

5.12 Stakeholders were invited to comment on the benefits which they considered might follow from either implementation or non-implementation of these three measures. Feed industry stakeholders in particular were invited to provide any financial or other data which they considered might support their case. As noted in the summary fo the consultation response at section 3 above, however, no such data was provided.

Costs

(i) Economic

5.13 Non-implementation of Directives 2005/6/EC and 2005/7/EC could result in action taken by enforcement officers being out of step with the requirements of EC legislation. It is possible that non-implementation of Directive 2005/8/EC could lead to UK feed producers losing market share elsewhere in the EU because of doubts over whether UK calcium carbonate and complementary feedingstuff products conformed to the requirements of the legislation, but this is difficult to quantify.

5.14 Full implementation of Directive 2005/8/EC could also have some costs for UK feed producers, as they may be required to undertake additional sampling and analysis work to ensure that their calcium carbonate and complementary feedingstuff products satisfy the new MPLs for mercury and fluorine. However, these potential costs are difficult to quantify.

(ii) Environmental

5.15 There do not appear to be any identifiable environmental costs associated with either non-implementation or full implementation of these three Directives.

(iii) Social

5.16 There do not appear to be any identifiable social costs associated with either non-implementation or full implementation of these three Directives.

5.17 Stakeholders were invited to comment on the costs which they considered might follow from either implementation or non-implementation of these three measures. Feed industry stakeholders in particular were invited to provide any financial or other data which they considered might support their case. However, no such data were provided.

Sustainable Development

5.18 Sustainable development -- i.e. development which meets the needs of the current generation without compromising the ability of future generations to meet their own needs -- encompasses consideration of environmental protection, prudent use of natural resources, social progress, economic growth and employment. The three Directives in question are unlikely to have an impact on any of these considerations.

6. SMALL FIRMS IMPACT TEST

6.1 Directives 2005/6/EC and 2005/7/EC will principally affect the work of Agricultural Analyst laboratories analysing samples of feed taken by local authority enforcement officials. Some of the laboratories concerned are publicly owned and not therefore subject to a small firms impact test; but some Agricultural Analyst laboratories are private concerns. However, as explained in paragraph 3.4 above, no quantified information on the potential impact on these businesses of these two Directives was forthcoming in response to the consultation.

6.2 Approximately one-third of the companies that manufacture animal feed claim small company status. Feed industry trade associations have advised the Agency 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. In this particular case, the Agency has been advised by the relevant trade associations that Directive 2005/8/EC is likely to have little if any impact on small businesses, and in any case no responses to the consultation were received from small businesses.

6.3 The advice of the Small Business Service was sought prior to the consultation. It acknowledged that the trade associations would represent the views of members involved in the production of calcium carbonate on the potential impact on them of Directive 2005/8/EC

7. COMPETITION ASSESSMENT

7.1 UK feed production is highly fragmented. National production of compound feed is characterised by two large companies which account for around 50% of the sector. The rest of the sector is thought to be accounted for by compounders which do not manufacture or distribute on a national basis but have significant capacity in certain regions or areas of the UK; and by co-operative or farmer-controlled compounders, many of which have other interests besides feed manufacture, such as wholesaling and retailing. However, specific statistical information on the number, size, market share and geographical location of feed mills and feed businesses has not been collected for some years, and it is not therefore possible to give an accurate picture of the sector's economic position.

7.2 However, a competition filter exercise conducted by the Food Standards Agency prior to the consultation suggested that the three measures to be implemented are likely to have little effect on competition in the feed industry. Directives 2005/6/EC and 2005/7/EC are not expected to impact at all on UK feed producers, while the impact on UK feed producers of Directive 2005/8/EC is expected to be marginal.

7.3 As detailed in section 3 above, there were no responses to the consultation which appeared to dissent from this view.

8. ENFORCEMENT, SANCTIONS AND MONITORING

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 taking samples of feed and testing them for the presence of various components including undesirable substances, which is important for effective control of the feed chain and through that the ultimate health of the consumers of animal products. In general, analyses are undertaken by accredited agricultural analysts.

8.2 However, it should be noted that none of the three Directives specify any new or revised levels of sampling and analysis for dioxins and dioxin-like PCBs. In consequence, Directives 2005/6/EC, 2005/7/EC and 2005/8/EC are expected to have little if any impact on enforcement authorities.

8.3 The Local Authorities Coordinators of Regulatory Services (LACORS), the umbrella body for local authority trading standards departments, did not raise the issue of potential extra costs to local authorities in its response to the consultation.

Sanctions

8.4 The penalties for non-compliance with feedingstuffs legislation are set out in the Agriculture Act 1970 and in subordinate legislation made under it, chiefly the Feeding Stuffs Regulations 2005, the Feeding Stuffs (Sampling and Analysis) Regulations 1999 (as amended) and the Feeding (Hygiene and Enforcement) Regulations 2005. Non-compliance is to be treated as a criminal offence, and would be subject to fines.

Monitoring

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

9. IMPLEMENTATION AND DELIVERY PLAN

9.1 The Regulations to transpose Commission Directives 2005/6/EC, 2005/7/EC and 2005/8/EC will apply only in England. Separate but parallel Regulations will be made for Scotland, Wales and Northern Ireland.

9.2 Guidance for the feed industry and enforcement authorities on the scope and interpretation of these Regulations and the three Commnission Directives they implement is not thought to be necessary. This is because the procedures for calculating the measurement uncertainty and correcting for recovery, and the new or amended maximum permitted levels for mercury, fluorine and lead in certain feedingstuffs, are set out in the Regulations themselves. However, the Food Standards Agency will provide guidance to stakeholders if requested.

10. POST-IMPLEMENTATION REVIEW

10.1 Commission Directives 2005/6/EC, 2005/7/EC and 2005/8/EC are not time-limited. However, the Food Standards Agency will review the Regulations which implement them in the light of experience of sampling and analysis using measurement uncertainty and correction for recovery and of compliance with the new maximum permitted levels for mercury and fluorine in certain feed products.

11. SUMMARY AND RECOMMENDATIONS

11.1 This Regulatory Impact Assessment suggests that there are likely to be some compliance costs and potential benefits associated with the implementation of these three Commission Directives. The main costs associated with Directive 2005/6/EC and 2005/7/EC are likely to fall on laboratories analysing samples of animal feedingstuffs taken by local authority trading standards departments, with the main costs of Directive 2005/8/EC falling on the feed industry. As mentioned above, however, it has been difficult to estimate the precise economic or monetary impacts, or to quantify the potential benefits to the feed industry and human consumers of animal products which may flow from the implementation of these measures.

11.2 When considering regulation, it is necessary to balance the potential additional costs to businesses against the need to protect consumers, in this case the human consumers of animal products. The provisions of Commission Directives 2005/6/EC, 2005/7/EC and 2005/8/EC seem proportionate to this aim.

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 (the figure would be at the Court's discretion). Possible erroneous action by enforcement officers in response to official sampling data. Less protection of the feed and food chains and possible loss of market share by UK feed producers because of non-compliance with MPLs for fluorine and mercury.	No identifiable benefits from non-implementation.

2. Full implementation	Possible small additional costs for UK feed producers attributable to a need to ensure that products conform to the new requirements.	Would ensure that UK sampling and reporting procedures are consistent with other Member States. Possible benefit for UK feed manufacturers, who will retain the ability to sell calcium carbonate and complementary feedingstuffs into other EU markets. Possible health benefits for consumers of animal products through enhancements to feed safety.

11.3 In the light of these considerations, it is recommended that Commission Directives 2005/6/EC, 2005/7/EC and 2005/8/EC be implemented in England by the Feeding Stuffs and the Feeding Stuffs (Sampling and Analysis) (Amendment) (England) Regulations 2006.

Declaration

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

Signed: Caroline Flint

Date: 23rd January 2006

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