

**EXPLANATORY MEMORANDUM TO**  
**THE FEED (SPECIFIED UNDESIRABLE SUBSTANCES) (ENGLAND)**  
**REGULATIONS 2007**

**2007 No. 3008**

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

**2. Description**

2.1 This instrument transposes Directive 2006/77/EC of 29 September 2006, amending Annex I to Directive 2002/32 on undesirable substances. The amending Directive revises the maximum permitted levels for a range of organochlorine compounds, which are classified as undesirable substances (contaminants) in animal feed.

2.2 The opportunity is also being taken to correct an omission which occurred during consolidation of the Feeding Stuffs (England) Regulations 2005, relating to a sub-group of permitted protein sources consisting of two by-products from the production of amino acids by fermentation, which were omitted from Schedule 6.

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

3.1 None.

**4. Legislative Background**

4.1 EC feed legislation includes provisions which lay down maximum permitted levels (MPLs) for certain undesirable substances in animal feed. Essentially, these are either naturally occurring environmental contaminants present at low levels in feed and food, particularly vegetable crops drawing nutrients directly from the soil, or process contaminants which may be introduced into the feedingstuff either during or as a consequence of its treatment, manufacture or storage. Examples include arsenic, cadmium, aflatoxin B1 and dioxins. The legislation which establishes these limits has been in place for many years; it was last consolidated as European Parliament and Council Directive 2002/32/EC of 7 May 2002. The MPLs prescribed in this Directive are implemented in Schedule 5 to the Feeding Stuffs (England) Regulations 2005.

4.2 Commission Directive 2006/77/EC, which amends Directive 2002/32/EC and which these Regulations transpose into law in England, revises certain of these MPLs by: setting new limits for aldrin and dieldrin, two insecticides which were prohibited from use some time ago but persist in the environment (particularly in fish oil). It also sets new limits for endosulphan (a pesticide found chiefly in the atmosphere, soil and sediment) in crude vegetable oil, and replaces the term “fats” by the term “fats and oils”.

4.3 Action to implement Commission Decision 2006/77/EC in the UK had to be deferred because of the timing of elections in Scotland and Wales. The then MS(PH) agreed that, to ensure a common coming-into-force date for the measure in all parts of the UK, public consultation on the draft Regulations should be deferred until after the Scottish and Welsh elections in May 2007.

## **5. Territorial Extent and Application**

5.1 This instrument applies to England. Separate but parallel legislation will be made for Scotland, Wales and Northern Ireland.

## **6. European Convention on Human Rights**

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, a statement is not required.

## **7. Policy background**

### *Policy*

7.1 MPLs for undesirable substances in animal feeds are an important measure to protect the feed and food chain. However, the MPLs for many undesirable substances were adopted some time ago and are in need of review in the light of recent scientific evidence and experience. The European Food Safety Authority (EFSA) has therefore been undertaking a detailed review and setting out its risk assessments in a series of published Opinions. A number of these Opinions covered a range of organochlorine compounds, chiefly pesticides, and suggested various amendments to their existing MPLs. The suggested amendments were subsequently voted on by the Standing Committee on the Food Chain and Animal Health and adopted as Commission Directive 2006/77/EC of 29 September 2006.

7.2 As explained in paragraph 4.1 above, the opportunity is also being taken via these Regulations to rectify the omission from Schedule 6 to the Feeding Stuffs (England) Regulations 2005 of a sub-group of permitted protein sources. The rectification of this omission will end a disparity between the Regulations and the relevant Directive which authorised these products and thus resolve any potential confusion on the part of the feed industry and enforcement authorities.

### *Consultation*

7.3 The public consultation in England took place between May and August 2007, and involved a range of stakeholders including industry trade associations, enforcement bodies, professional associations, consumer groups and others. Three responses were received, only one of which was substantive. However, this concerned what it saw as the potential effects on local authority financial resources of any extra work undertaken in the short term to ensure that the amended MPLs are observed by the feed industry, and made no comment on the amended MPLs themselves. No changes to the draft Regulations were considered necessary as a result of the consultation.

## *Guidance*

7.4 The Food Standards Agency does not consider that guidance on the new MPLs is necessary as these provisions are self-explanatory and have already been subject to public consultation. The feed industry has long established procedures in place to ensure its compliance with the MPLs for undesirable substances.

## **8. Impact**

8.1 A Regulatory Impact Assessment, which provides more details of the impact of the measure, is attached to this memorandum. A Regulatory Impact Assessment rather than an Impact Assessment has been completed because, at the time of the launch of the public consultation on the draft Regulations in May, the new Impact Assessment procedures had still be be finalised by the Cabinet Office.

## **9. Contact**

Tim Franck or Joseph Nicholas at the Food Standards Agency can answer queries regarding the instrument. Telephone: 020-7276-8471 or 020-7276-8462, e-mail: [tim.franck@foodstandards.gsi.gov.uk](mailto:tim.franck@foodstandards.gsi.gov.uk) or [joseph.nicholas@foodstandards.gsi.gov.uk](mailto:joseph.nicholas@foodstandards.gsi.gov.uk)

## TRANSPOSITION TABLE

<b>Commission Directive 2006/77/EC of 29 September 2006 amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for organochlorine compounds in animal feed (OJ No L271, 30.9.2006, p. 53)</b>			
<b>Article</b>	<b>Purpose</b>	<b>Implementation</b>	<b>Responsibility</b>
Article 1 and the Annex	To amend the entries for organochlorine compounds in Annex I of Directive 2002/32/EC	Regulation 2(3) and Schedule 1, substituting the entries for organochlorine compounds in the Annex (including the footnotes) for those in Chapter D of Schedule 5 to the Feeding Stuffs (England) Regulations 2005.	S of S for Health through implementing Regulations

## **FULL REGULATORY IMPACT ASSESSMENT**

### **1. TITLE OF PROPOSAL**

The Feed (Specified Undesirable Substances) (England) Regulations 2007.

#### **Implementation of:**

European Commission Directive 2006/77/EC of 29 September 2006 amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for organochlorine compounds in animal feed (*Official Journal* No. L271, 30.9.2006, p.53).

### **2. PURPOSE AND INTENDED EFFECT OF THE MEASURE**

#### **Objectives**

2.1 Commission Directive 2006/77/EC is intended to help sustain and enhance feed safety, and thus the protection of the health of human consumers of animal products as well as animal health. The measure revises the maximum permitted levels (MPLs) for a range of organochlorine compounds, chiefly pesticides, which are classified as undesirable substances (contaminants). This principally involves (a) setting new limits in relation to aldrin and dieldrin; (b) setting new limits in relation to endosulphan in crude vegetable oil; and (c) replacing the term “fats” by the term “fats and oils”. These levels are to be transposed in a Schedule to the draft Feed (Specified Undesirable Substances) (England) Regulations 2007.

#### **Background**

2.2 An important safeguard in the protection of animal and human health is the setting of statutory limits for undesirable substances in animal feed. European Parliament and Council Directive 2002/32, the most recent consolidation of Community legislation on undesirable substances in feeds, prohibited the dilution (through mixing with other feed materials) of consignments of feed with levels of contamination above the specified MPLs. When this Directive was adopted the European Commission agreed that these MPLs should be reviewed in the light of current experience and up-to-date scientific evidence. When reviewing these MPLs, the Commission takes into account the prohibition of any dilution.

2.3 These reviews are being conducted by a scientific panel of the European Food Safety Authority (EFSA), which produces Opinions setting out its risk assessments of a range of undesirable substances. Directive 2006/77/EC represents the adoption of some of these Opinions in Community feed law.

#### **Rationale for Government Intervention**

2.4 Feed containing a relatively high proportion of fish oil in its formulation has been found to contain significant levels of aldrin and/or dieldrin, two insecticides the use of which was prohibited some time ago but which persist in the environment.

Because of higher rates of bio-accumulation in the aquatic food chain, fish derived products, particularly fish oil, have the highest levels of these insecticides. Based on both this and available monitoring data, EFSA has recommended that there should be separate, lower, MPLs for fats and oils and fish feed than for all other feedingstuffs. A similar amendment is being made to MPLs for camphechlor, a pesticide.

2.5 Endosulphan is a pesticide found chiefly in the atmosphere, soil and sediment. Direct uptake from soil to plant as well as transport in plants is assessed by EFSA as negligible, but it is readily absorbed through the gastro-intestinal tract and distributed to the kidneys and liver and to a lesser extent to other tissues. However, scientific opinion and monitoring data suggest that it is appropriate to amend the MPLs by the addition of a new MPL for this pesticide in crude vegetable oil. This recognised that data has indicated higher concentrations of endosulphan in the oil than in the oilseeds and other products derived from oilseed processing.

2.6 Scientific opinion and available monitoring data indicate that no changes are necessary to the existing maximum levels for hexachlorocyclohexanes and endrin.

2.7 Many of the organochlorine compounds for which MPLs are set -- aldrin, dieldrin, chlordane, DDT, endrin, heptachlor, hexachlorine and hexachlorocyclohexanes (HCH) -- have separate, lower, MPLs for fats than for other feedingstuffs and feed materials. EFSA has recommended that the term "fats" in the list of feedingstuffs potentially contaminated with these substances should be replaced by the term "fats and oils". This is to indicate clearly that the MPL applies to all fats and oils, including animal fat, vegetable oils and fish oil.

2.8 In transposing Commission Directive 2006/77/EC into national law, the opportunity is also being taken to rectify the omission from Schedule 6 to the Feeding Stuffs (England) Regulations 2005 of a sub-group of permitted protein sources, consisting of two by-products from the production of amino acids by fermentation. The rectification of this omission is necessary to clarify that these two amino acid by-products can legally continue to be used in animal feed. Two other minor typing errors made during the consolidation are also being corrected.

### **3. CONSULTATION**

#### **Within Government**

3.1 The Food Standards Agency in England, Scotland, Wales and Northern Ireland undertook separate consultations on the proposed measures. The views of Agriculture Departments throughout the UK were sought.

#### **Public Consultation**

3.2 Key stakeholders were kept informed of developments during negotiations on the revised MPLs. 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 relevant data.

3.3 There were three responses to the public consultation in England. Only one was substantive, and mainly commented on what it saw as the potential additional resource requirements to be met by local authorities as a consequence of the action necessary to ensure that the revised MPLs are observed by the feed industry. The other two responses essentially amounted to no comment.

## **4. OPTIONS**

4.1 There appear to be two possible options:

- (a) non-implementation of the measure; or
- (b) full implementation of the measure.

### **Non-Implementation**

4.2 Non-implementation could give rise to concerns that a measure intended to enhance the safety and integrity of the feed chain and the protection of consumers and of animal health was being ignored. Non-implementation could also lead to legal proceedings against the UK in the European Court of Justice, as the terms of the measure require the implementation of all of its 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 on export markets as not complying with EC feed law, even if they had in fact complied with the revised MPLs set out in the Directive. Consequently, this might lead to UK manufacturers losing market share in other Member States.

### **Full Implementation**

4.4 Full implementation of the proposed measure would provide additional safeguards on feed safety and 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 to sell the full range of their products on other markets in the EU.

## **5. COSTS AND BENEFITS**

### **Sectors and Groups Affected**

5.1 The provisions of Directive 2006/77/EC will directly affect the UK feed industry, which will need to ensure that its products comply with the amended MPLs. Quantification of this impact is difficult because the amendments are marginal and because, as a matter of routine, the feed industry will already be carrying out sampling and analysis work to ensure that its products comply with existing levels. In addition, the UK feed industry is highly fragmented and the impact of the measures will vary greatly among feed producers -- the compound feed production sector in particular is more concentrated and is dominated by two large companies.

5.2 There may be a one-off administrative cost to all businesses due to a need for each to familiarise itself with the requirements of the new legislation. Applying a standard wage rate (plus 30% overheads) derived from the annual survey conducted by the Office for National Statistics of £16.30 per hour for managers in agriculture and services to the figure for the total number of business operating in the UK feed industry -- see the figures in paragraph 7.2 below -- gives a one-off cost of £5,950. Set against the figures for annual turnover shown in paragraph 7.2, this cost appears insignificant.

5.3 The rectification of the omission from Schedule 6 to the Feeding Stuffs (England) Regulations 2005 of two amino acid by-products from the list of permitted protein sources will end the disparity between the Regulations and the relevant Directive which authorised them and thus resolve any potential confusion on the part of the feed industry and enforcement authorities.

5.4 It is possible that local authorities may wish to undertake additional sampling and analysis of feed products to ensure that they comply with the new and revised MPLs, at least in the short term. The Local Authorities Coordinators of Regulatory Services (LACORS), the co-ordinating body for local authority trading standards departments, estimates the potential extra cost of this work in England as £20-£30,000 per year. However, the question of whether such additional work is actually undertaken will depend on the relative priority given to enforcement of the amended levels by both local authorities themselves and the annual National Control Plan published by the Food Standards Agency, which sets out the checks it expects them to undertake. The current Plan does not include any requirement to sample for the presence of organochlorine compounds.

5.5 The provisions of the Directive, which will enhance feed safety, will also have a beneficial impact on the consumers of animal products.

5.6 Voluntary organisations and charities are unlikely to be affected by the provisions of the Directive.

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

## **Benefits**

### **(i) Economic**

5.8 Full implementation of the measure will be of direct benefit to UK manufacturers, who will be able to continue to sell their products into the feed chain in the UK and other Member States. In 2006, the value of UK exports of animal feed to Member States totalled £230 million. This was roughly 75% of the total value of UK exports of animal feed to all countries, which totalled £307 million.

5.9 Through the extension of controls on undesirable substances, there will be greater health benefits for farmed livestock and human consumers of animal products. This should provide purchasers of feed with more confidence in the products they buy, helping to promote sales by UK manufacturers. However, because the amended MPLs have been set on a precautionary basis, for scientific



rather than economic reasons, it is difficult to quantify the potential benefit in financial terms.

## **(ii) Environmental**

5.10 Full implementation of the Directive could be of some indirect benefit to the environment, as reductions in the quantities of contaminants ingested by farmed livestock and other animals would ensure reductions in the quantities subsequently excreted onto pasture land also used by wildlife. However, it is difficult to quantify this in financial terms.

## **(iii) Social**

5.11 Full implementation of the new and revised MPLs for these undesirable substances will be advantageous for pets and their owners. Apart from potential improvements in the health of pets, their owners may benefit financially through paying less in veterinary fees. As with the potential environmental impact, it is difficult to quantify these benefits in financial terms.

5.12 Other than pet owners and their pets, most of the measures introduced by the Directives will be socially neutral, as they do not disadvantage any particular group of consumers of animal products.

## **Costs**

### **(i) Economic**

5.13 Full implementation could have some costs for UK feed producers in the short term because they may wish to undertake additional sampling and analysis work to ensure that their feed products conform to the amended MPLs. However, as explained in paragraph 5.1, the feed industry carries out sampling and analysis as a matter of routine to ensure that its products comply with existing levels, and the nature of the amendments means that any increases in the price of feed to livestock farmers are likely to be marginal. Livestock producers unable to pass on the higher costs to their customers could possibly be disadvantaged. In any case, the amendments will not alter the existing need for all feed business operators and users to keep sources of supply under review to ensure that potential sources of contamination are kept to a minimum.

### **(ii) Environmental**

5.14 Non-implementation of the Directive could mean no reductions in the levels of contaminants being potentially consumed by farmed livestock, and other animals. This would lead to no decrease in the amounts of contaminants being excreted by animals onto pasture land. However, it is difficult to quantify this in financial terms.

### **(iii) Social**

5.15 Non-implementation of the Directive would lead to no decrease in detrimental health effects for pets and thus no decrease in veterinary fees for pet owners. On a broader scale, non-implementation could be socially disadvantageous due to greater levels of undesirable substances in the feed and food chains. Once again, this is difficult to quantify in financial terms.

### **Sustainable Development**

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

### **Administrative Burdens**

5.17 Businesses and local authorities may incur some additional minor administrative costs in relation to sampling and analysis work, as explained in paragraphs 5.4 and 5.13.

## **6. SMALL FIRMS IMPACT TEST**

6.1 Approximately three-quarters 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.

6.2 Despite seeking their views, no information was forthcoming from either feed trade associations or small businesses directly on the potential impact of the measure in response to the public consultation on the draft Regulations.

## **7. COMPETITION ASSESSMENT**

7.1 Detailed information on the number, size, market share and geographical location of businesses operating in the animal feed sector is not available, as statistical data of this nature has not been collected for some years. It is therefore not possible to give an accurate picture of the sector's economic position. However, it is known that national production of compound feed is characterized by two large companies which account for approximately 50% of the sector, with the remainder accounted for by compounders that do not manufacture or distribute on a national basis but have significant capacity in certain parts of the UK, and by co-operative or farmer-controlled compounders that have other interests in addition to feed manufacture, such as wholesaling and retailing.

7.2 Information collated by the Inter-Departmental Business Register, a database of the Office of National Statistics, showed that at the start of 2006 there were 405 companies in the UK recorded as engaged in the “manufacture of prepared animal feeds”, with a total turnover of about £3.3 billion and total employment of about 12,000. These figures would have included firms producing pet food and feed for horses as well as feed for farmed livestock, although they exclude firms producing fish meal and oil seed cake. Other figures suggest that in 2004 one of the two large compounders referred to in the previous paragraph produced just under two million tonnes of feed, which accounted for a UK market share of 22-23%. A return from the then HM Customs and Excise for the same year showed that 70 companies had a turnover of over £5 million each, while 40 companies had turnovers of less than £50,000 each.

7.3 It should be noted that the possible marginal increases in prices arising from implementation of the Directive are unlikely to affect competition significantly in the relevant upstream markets, as these rises will tend to fall uniformly across companies and not act to raise barriers to entry significantly.

## **8. ENFORCEMENT, SANCTIONS AND MONITORING**

8.1 Enforcement of animal feed 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 activity includes taking samples of animal feed and having them analysed for the presence of undesirable substances. In general, analyses are undertaken by accredited agricultural analysts.

### **Sanctions**

8.2 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) (England) Regulations 2005. Non-compliance is to be treated as a criminal offence, and would be subject on conviction to fines and/or imprisonment.

### **Monitoring**

8.3 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 draft Regulations.

## **9. IMPLEMENTATION AND DELIVERY PLAN**

9.1 The draft Regulations to transpose Commission Directive 2006/77/EC will apply only in England. Separate but parallel Regulations will be made for Scotland, Wales and Northern Ireland.

9.2 Guidance to the feed industry or other stakeholders on the application of the new and amended maximum permitted levels is not felt to be necessary, as it is considered that the figures themselves are straightforward and not open to misunderstanding by those who have to observe or apply them.

## **10. POST-IMPLEMENTATION REVIEW**

10.1 The Food Standards Agency will carry out a review of the impact of the new and amended levels within a year of the Regulations coming into force. This will take the form of a further public consultation, including the feed industry and enforcement authorities. The results of this review will help inform the UK's response to further Opinions adopted by EFSA as part of its continuing review (summarised in paragraphs 2.2 and 2.3 above) of the current MPLs for undesirable substances.

## **11. SUMMARY AND RECOMMENDATIONS**

11.1 This Regulatory Impact Assessment has identified some potential compliance benefits and costs for the feed industry and other stakeholders, at paragraphs 5.8 to 5.15 above, although the minimalist nature of some of the amendments to MPLs to be transposed means that it is difficult to estimate the precise economic or monetary impacts or to provide quantification of them. However, as indicated in the table below, non-implementation of Commission Directive 2006/77/EC may have costs to the feed industry due to loss of market share through inability to sell its products in other Member State markets, plus costs to the UK government from infraction proceedings taken against it by the Commission. Implementation, on the other hand, may have some small costs to both the UK feed industry and enforcement authorities because of a perceived need to ensure that feed products conform to the amended requirements, at least in the short term, but may also have benefits to the feed industry because it will retain the ability to market its products in other EU Member States, and to the health of consumers of animal products through enhancement to feed safety.

11.2 For these reasons, the MS(PH) is invited to sign the Feed (Specified Undesirable Substances) (England) Regulations 2007 and the declaration below in respect of this Regulatory Impact Assessment.

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 (that 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 small additional costs for UK feed producers and local authorities attributable to a need to ensure that products conform to the new requirements. One-off administrative costs to businesses from a need to familiarise themselves with the new requirements.	Possible benefit for UK feed manufacturers, who will retain the ability to sell their products into other markets in the EU. Possible health benefits for consumers of animal products through enhancements to feed safety.

## 12. DECLARATION AND PUBLICATION

### ***Declaration***

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

Signed by the responsible Minister ***Dawn Primarolo***

Date ***22nd October 2007***

12.1 This Regulatory Impact Assessment, after signature by the responsible Minister, will be published on the website of the Food Standards Agency.

### ***Contact Point***

Ned Mazhar  
Animal Feed Unit, Food Standards Agency  
Rm 415B, Aviation House  
125 Kingsway  
London WC2B 6NH  
Telephone: 020-7276-8609  
Fax: 020-7276-8478  
E-mail: [nader.mazhar@foodstandards.gsi.gov.uk](mailto:nader.mazhar@foodstandards.gsi.gov.uk)