

PARTIAL REGULATORY APPRAISAL

1. TITLE OF THE REGULATORY PROPOSAL

THE FEEDING STUFFS (SAMPLING AND ANALYSIS) AND THE FEEDING STUFFS (ENFORCEMENT) (AMENDMENT) (WALES) REGULATIONS 2003

Implementation of:

Commission Directive 2002/70/EC of 26 July 2002 establishing requirements for the determination of levels of dioxins and dioxin-like PCBs in feedingstuffs.

2. PURPOSE AND INTENDED EFFECT OF THE MEASURES

2(i) Issue and Objectives

This measure introduces criteria for methods of analysis for use by authorities for the enforcement of maximum permitted levels (MPLs) of dioxins and dioxin-like PCBs in animal feeds.

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.

Until recently, however, there were no legal limits on the levels of dioxins which might be present 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 of MPLs for dioxins in feed. (A parallel measure introduced MPLs for dioxins in food for human consumption.) While accepting the need for MPLs, the UK argued during negotiation of the measure that the most effective way to reduce exposure to dioxins is through source-directed measures to reduce their release into the environment, as this is the main route by which dioxins are incorporated in feed and food. Source-directed measures already taken in the UK have reduced emissions by 70% over the last nine years.

The UK was also concerned by the absence of MPLs for PCBs, as data from UK surveys shows that dioxin-like PCBs contribute at least the same toxic load as dioxins in most foods and should be included in control measures, including those for feed. 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. A strategy was subsequently adopted in October 2001.

2(ii) Risk Assessment

One of the concerns raised during negotiation of the measures which introduced MPLs for dioxins in feed and food was the absence of agreed criteria for EU-wide methods of sampling and analysis for the presence of dioxins to effectively enforce the MPLs. In addition, sampling for dioxins is expensive, at around £1,000 per sample; and there are few laboratories which are accredited to undertake such work.

Nevertheless, agreed harmonised methods of sampling and analysis for dioxins are key to the consistent and effective enforcement of the maximum permitted levels (MPLs) for dioxins in a range of feed materials and feedingstuffs introduced by Council Directive 2001/102/EC of 27 November 2001. Commission Directive 2002/70/EC therefore lays down the requirements for laboratories, sample preparation, analytical procedures and the reporting of results.

The introduction of statutory procedures will help reduce both inconsistency in the sampling and analysis of feedingstuffs for the presence of dioxins and also uncertainty or dispute in the interpretation of the results, particularly in those cases where they are close to the specified MPL for the feed material in question. This will benefit both industry and consumers, who will gain from improved confidence in the testing regime employed. Not adopting harmonised testing procedures could undermine effective enforcement of the MPLs for dioxins, consumer confidence in the protection and animal and human health conferred by those MPLs, and could throw up barriers to trade because the UK feed industry might not be able to demonstrate the compliance of its products with EU requirements.

3. OPTIONS, BENEFITS AND ISSUES OF EQUITY AND FAIRNESS

3(i) Options

There would appear to be three possible options:

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

3(ii) Benefits

Option 1

Non-implementation or partial implementation of Directive 2002/70 could represent a significant cost saving to local authorities, who are responsible for enforcement of feedingstuffs legislation, including the sampling and analysis of animal feed. Sampling for dioxins is expensive, at an average cost of £1,000 per time, and there are few laboratories accredited to undertake such work. Although the Directive does not specify any limit of determination at which feedingstuffs should be analysed for

dioxins, the existence of EU-agreed methods of testing for this contaminant might lead to the expectation that local authorities will incorporate such analyses as a routine part of their enforcement activities.

However, both non-implementation and partial implementation could give rise to perceptions that feed safety and consumer protection measures were being ignored. Non-implementation or partial implementation would also result in legal proceedings against the UK in the European Court of Justice, as the terms of the Directive require implementation of all provisions. The costs of non-implementation would include the costs of infraction proceedings to the UK Government. There might also be a loss of EU markets to UK companies, which might be unable to market feeds in other Member States because they could not demonstrate compliance with EU requirements.

Option 2

Full implementation of Directive 2002/70 would meet the UK's mandatory obligation to implement EC measures. UK manufacturers and suppliers could benefit from this because the routine testing for dioxins by local authorities which might result from implementation of the Directive would demonstrate that their feed products were free of such contamination, and thus in turn help confirm the safety and integrity of the feed chain. However, it is not possible to put a financial value on these benefits.

Option 3

Delaying implementation might defer any implementation costs. However, this would still leave the UK open to infraction proceedings and there could be concerns that a measure to ensure the safety and integrity of the feed chain was being delayed.

3(iii) Issues of Equity and Fairness

Directive 2002/70 concerns sampling and analysis undertaken for official control purposes, and its scope has resource implications for enforcement authorities (local authorities and Port Health Authorities) because of the expense of testing for dioxins by currently validated methods. However, the Directive will clearly contribute to enforcement of the MPLs for dioxins in animal feedingstuffs through ensuring consistency in methods of testing.

4. COMPLIANCE COSTS FOR BUSINESS

4(i) Business Sectors Affected

Commission Directive 2002/70/EC relates only to testing, and in consequence enforcement authorities rather than industry will be most affected. The Directive does not require industry to carry out additional sampling, or to adopt the methods of analysis it lays down, although it is possible that industry may wish to conform to the Directive's provisions as part of the testing normally undertaken to satisfy the general

4(ii) Compliance Costs for "Typical" Businesses

Because the measure concerns the methods to be used for sampling and analysis, business is unlikely to be directly affected by it. The costs of compliance will therefore fall largely on enforcement authorities. **Businesses are invited to comment on the potential costs to them of more frequent testing for dioxins.**

5. IMPACT ON SMALL BUSINESSES

Approximately one-third of the companies which manufacture prepared animal feed claim small company status, but – as before – it is not clear whether and if so to what extent business will be affected by this measure. **A number of small businesses are being contacted directly as part of this consultation, and invited to give an estimate to them of the potential costs which may be associated with it.**

6. ENFORCEMENT COSTS

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 contaminants.

The high cost of analysis for dioxins has resource implications for these bodies; Port Health Authorities could be disproportionately affected because of the large volumes of imports with which some deal. However, the Directive does not specify a level for the sampling and analysis of feedingstuffs, and enforcement bodies should not therefore be faced with any new burden. They will nevertheless need to make risk-based judgements on the relative priorities of enforcing this and other feedingstuffs legislation, bearing in mind that any programme to test for breaches of dioxin MPLs could take up a significant proportion of the enforcement budget.

There are few laboratories in the UK accredited for analysis of dioxins. Under the Agriculture Act 1970, agricultural analysts are responsible for undertaking analyses of samples, but our understanding is that few are equipped to carry out this work in respect of dioxins. The draft Regulations therefore amend the Act by requiring analysis for dioxins to be undertaken by any laboratory which complies with the requirements specified in the Directive. **We would be grateful for comments on this amendment by agricultural analysts, the Laboratory of the Government Chemist, and other laboratories.**

Currently validated methods of analysis for dioxins are time-consuming and cost around £1000 per sample, although the Agency has been advised (but has not confirmed) that this cost is falling. In addition, the new legislation also provides for bio-assay techniques which meet the relevant quality criteria and which should help alleviate the financial burden on enforcement bodies. CALUX, a potential new screening method which could reduce the cost of analysis of each sample to around £250, is currently being validated in an exercise co-ordinated by the Dutch

Agricultural Research Station in Wageningen, the EU Joint Research Centre and the Central Science Laboratory, York; the validation is expected to be completed by the end of 2003. Nevertheless, the cost of an analysis is at the discretion of the laboratory offering the service and is likely to be dependent on the volume of samples tested.

Equipping a laboratory to carry out screening analyses would entail a capital cost of around £20,000 for high-resolution gas chromatography mass spectrometry equipment, plus additional sums for staff training to gain experience in the methodology. A complication here is that local authorities would first need to determine their intended levels of sampling of feedingstuffs for dioxins to help laboratories to determine whether to invest in the capital equipment, staff training and other consumables necessary to establish facilities for dioxins testing.

Comments and views from laboratory analysts and local authorities on these issues are therefore being invited as part of the consultation on the draft Regulations. Information is sought in particular on the implications (short and long-term) the legislation will have on the annual costs of testing for dioxins, if possible with a breakdown of the potential policy costs (those arising from prescribed changes to achieve policy goals) and the implementation costs (those arising from inspection and monitoring arrangements, from familiarisation and from adjustments to facilitate compliance). Supplementary information about the implications that dioxins testing may have on testing for other contaminants is also invited.

We would also be grateful if enforcement bodies could provide the information necessary to complete the table below:

	Number of samples tested in 2001		Total annual cost (£)	
	Dioxins/PCBs	Other contaminants	Dioxins/PCBs	Other contaminants
Local authorities				
Analysts				

7. TOTAL COSTS

The information presently available to the Food Standards Agency is insufficient to estimate total costs. **This draft Regulatory Appraisal is being circulated to feed industry representatives and enforcement authorities with a request to provide as much detail on potential costs and other impacts before the measure is implemented in law.**

8. COMPETITION ASSESSMENT

8(i) Competition Filter

Information available to the Food Standards Agency suggests that the measure may have little impact on competition in the UK market, as it relates to the sampling and analysis of feed products rather than their composition or manufacture. However, a competition filter has been conducted in line with guidance from the Office of Fair Trading, with the following results:

Question		Answer (Yes or No)
Q1	In the market affected by the new measures, does any firm have more than 10% market share?	Yes (but see section 8(ii) below)
Q2	In the market affected by the new measures, does any firm have more than 20% market share?	Yes (but see section 8(ii) below)
Q3	In the market affected by the new measures, do the largest three firms together have at least 50% market share?	Yes (but see section 8(ii) below)
Q4	Would the costs of the measures affect some firms substantially more than others?	No
Q5	Are the measures likely to affect the market structure, changing the number or size of firms?	No
Q6	Would the measures lead to higher set-up costs for new or potential firms that existing firms do not have to meet?	No
Q7	Would the measures lead to higher ongoing costs for new or potential firms that existing firms do not have to meet?	No
Q8	Is the market characterised by rapid technological change?	No
Q9	Would the measures restrict the ability of firms to choose the price, quality, range or location of their products?	Yes (but see section 8(ii) below)

8(ii) Competition Assessment

The market share disclosed by the answers to questions 1 to 3 inclusive will be unaffected by this measure.

The answer to question 9 derives from the possibility that feed merchants and compounders, particularly those sourcing their materials from abroad, could choose to reduce the range of materials used and feedingstuffs produced in order to exclude imports of feed materials from regions where contamination with dioxins is a known problem.

Comments are invited as part of the consultation on the draft Regulations.

9. RESULTS OF CONSULTATION

The results of the consultation will be made available on the website of the Food Standards Agency and discussed in more detail in the final version of the Regulatory Appraisal.

10. ENFORCEMENT, SANCTIONS, MONITORING AND REVIEW

(i) Enforcement and Sanctions

Enforcement of feedingstuffs legislation is the responsibility of Port Health Authorities, the Trading Standards Departments of local authorities in Great Britain, and the Department of Agriculture and Rural Development in Northern Ireland. The penalties for non-compliance with the legislation are set out in the Agriculture Act 1970 and the Feeding Stuffs Regulations.

(ii) Monitoring and Review

The Directive will be implemented in Wales by the Feeding Stuffs (Sampling and Analysis) and the Feeding Stuffs (Enforcement) (Amendment) (Wales) Regulations 2003. There will be separate but parallel regulations for England, Scotland, and Northern Ireland. The Food Standards Agency welcomes feedback from the feed industry, enforcement authorities and other stakeholders on their experience of and the effectiveness of the new legislation. The Agency will also consider developing guidance to enforcement authorities on the implementation of the legislation.

11. SUMMARY AND RECOMMENDATIONS

Option	Total Cost	Total Benefit
Non-implementation or partial implementation	Costs of infraction proceedings (which would be ongoing); possible loss of EU markets for UK feed manufacturers	Cost savings to local authorities, which might not feel under any obligation to test for the presence of dioxins in feed
Full implementation	Not yet known	Ensuring the safety and integrity of the feed chain through testing for dioxins by agreed Community methods
Delayed implementation	Costs of infraction proceedings (which would be ongoing)	Cost savings to local authorities until the implementation of the measure

The potential costs to enforcement authorities of sampling and analysing for dioxins, and the impact this could have on other feed enforcement work, could be significant.

Nevertheless, the measure has been formally adopted at European level, and the UK would accordingly need very strong reasons not to implement it in domestic legislation. For this reason, we recommend that Commission Directive 2002/70/EC be implemented in Wales by the Feeding Stuffs (Sampling and Analysis) and the Feeding Stuffs (Enforcement) (Amendment) (Wales) Regulations 2003.

12. TIMETABLE

Member States are required to transpose Directive 2002/70 into domestic legislation no later than 28 February 2003, with the same date for it coming into force.

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