

# **PARTIAL REGULATORY APPRAISAL**

## **1. TITLE OF THE REGULATORY PROPOSAL**

### **THE FEEDING STUFFS (AMENDMENT) (WALES) (NO. 2) REGULATIONS 2003**

#### **Implementation of:**

**(a) European Parliament and Council Directive 2002/2/EC of 28 January 2002 amending Council Directive 79/373/EEC on the circulation of compound feedingstuffs and repealing Commission Directive 91/357/EEC; and**

**(b) European Parliament and Council Directive 2002/32/EC of 7 May 2002 on undesirable substances in animal feed.**

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

### **2(a) Issue and Objectives**

#### **(i) Directive 2002/2 (Ingredient Listing of Compound Feeds)**

Since 1991, the ingredients of compound animal feeds have had to be declared in descending order by weight, either by category of ingredient or by specific ingredient.

In 2000, the Commission introduced a proposal deleting the category option for feed for farmed livestock and requiring all compound feed ingredients to be declared in descending order by weight, together with the amount in terms of percentage by weight. The Commission justified this approach on the grounds of improving traceability of feed materials and transparency for farmers.

Member States, including the UK, supported the deletion of the category option, but not the declaration of ingredients by percentage. It was argued that full percentage declaration was not required for human food, that there had been no calls for it from farming organisations, and that it would add little to the other nutritional and analytical information required under EU animal feed law. Feed manufacturers were also opposed on the grounds that it could compromise commercially sensitive research and recipe information.

Full percentage declaration by weight was nevertheless supported by the European Parliament, although the Council and Commission subsequently compromised on declaration in five percentage bands. The proposal then remained deadlocked for over a year, and seemed set for formal conciliation procedures until the then Presidency unexpectedly revived a previous Presidency's compromise proposal for full percentage listing with a tolerance of +/-15% to allow for variations in the declared analyses. This

approach gained qualified majority support in Council and was subsequently accepted by the European Parliament.

## **(ii) Directive 2002/32 (Blending Down of Undesirable Substances)**

Controls on undesirable substances in animal feed have been progressively strengthened over the years. The most 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.

Under Directive 1999/29 on undesirable substances in animal nutrition, certain establishments are permitted to dilute feed materials with levels of contamination above the specified MPLs by combining them with uncontaminated material ("blending down") to ensure that the finished feed MPLs are observed. This provision is restricted to manufacturers who have been approved under Directive 95/69 (the Establishments Directive). Approval is subject to a prior check by the authorities that such establishments have the equipment and facilities to process material effectively and safely. Directive 1999/29 requires that material containing levels of undesirable substances above the MPLs be accompanied by a document stating the amount of undesirable substance in the material, that the consignment is intended for manufacturers of compound feedingstuffs who fulfil the conditions in Directive 95/69, and that it must not be fed unprocessed to livestock.

Directive 2002/32 amends Directive 1999/29 principally by removing the provisions that permit material above MPLs to be blended down, which means that all feed materials put into circulation must now observe the MPLs for finished feeds. Investigations must be carried out in cases where MPLs are breached, and also where the level of contamination is below the MPL but could be "significant" – the threshold action levels for significant contamination have still to be laid down, but there are provisions in place for doing so. There is also a provision to define the criteria for the acceptability of processes for detoxifying feed. Other amendments include the extension of the provisions of Directive 1999/29 to products used in animal feeds (e.g. feed additives) and the removal of a derogation which meant that MPLs did not apply to fodder used on-farm.

## **2(b) Risk Assessment**

### **(i) Directive 2002/2 (Ingredient Listing of Compound Feeds)**

The Directive is aimed at providing farmers with complete information on the constituents of compound animal feeds, including the amounts. It is essentially user information rather than a safety measure. It will tell farmers exactly what is in a manufactured compound feed and therefore allow them better to formulate and utilise rations to meet the nutritional needs of their livestock. The suggestion is that without this information, animals would be less well fed and therefore not perform to their optimum. As such, the overall aims are laudable, although it is questionable whether the absence of this information poses any real risk to animal or human health.

The Commission originally contended that percentage inclusion rates would help reduce the frequency of contamination incidents, such as the high levels of dioxins in recovered vegetable oil in Belgium in 1999. The European Parliament has similarly contended that percentage declaration by weight is necessary for consumer protection, but both claims have little to support them. Percentage declaration could not have prevented what was either an accidental or criminal mixing of transformer and vegetable oils in the Belgian dioxin case, and full percentage declaration is not a requirement for human food. In addition, the tolerance limit of +/-15% is not linked to any scientific criterion and allows scope for both potential fraud and wide variations in enforcement in Member States.

## **(ii) Directive 2002/32 (Blending Down of Undesirable Substances)**

From the point of view of public safety and animal health it is important that MPLs for undesirable substances are observed. For example, there are occasional instances of aflatoxin in consignments of imported feed materials. There have also been a number of major contamination incidents over the past few years, e.g. the contamination with dioxins of vegetable oils used in feed in Belgium and dioxin contamination of a copper premixture imported into the UK from the USA.

The Commission made the proposal to prohibit blending down in the wake of the Belgian dioxin incident. There is clearly some risk in allowing feed materials to be put into circulation above MPLs, but we are unaware of any problems associated with the current arrangements which permit approved establishments to blend down contaminated consignments. In negotiations, the UK argued that a ban on blending down under supervision in the EU was not a complete solution, as third country blending arrangements are beyond the scope of the Directive. This argument was supported by the independent Advisory Committee on Animal Feedingstuffs (ACAF), which was also concerned that no scientific risk assessment had been carried out.

Industry, particularly importers and feed manufacturers, have expressed some concern about the potential effect of this measure on trade. There could be more rejected consignments; trade from some countries could cease because they are unable to supply materials with contamination levels below the specified MPL (a particular problem where aflatoxins are concerned); and compounders will be more restricted in the ingredients available to them (a particular problem in the light of the prohibitions on the use of animal material as a consequence of BSE).

During negotiations, the Commission made a commitment that its scientific committees would review the existing MPLs, taking into account the implications of the prohibition on blending down. This is supposed to be completed before the Directive comes into force.

Removal of the provision that permitted Member States not to apply MPLs to fodder used on farm closes a loophole that had potential safety implications. The UK had not applied this derogation, and had no objection to its deletion.

### **3. OPTIONS, BENEFITS AND ISSUES OF EQUITY AND FAIRNESS**

#### **3(a) Options**

There would appear to be three possible options:

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

#### **3(b) Benefits**

##### **Option (i)**

Non-implementation of Directive 2002/2 would be consistent with the position taken by the UK during negotiations on the measure that full ingredient listing by percentage weight of ingredient is unnecessary from both a consumer protection and animal health perspective, and would add little to the other nutritional and analytical information required under EU animal feed law.

Non-implementation of Directive 2002/32 might be justified on the grounds that MPLs, where properly set and observed, provide an adequate safeguard for the protection of both animal and human health. In addition, establishments which have the necessary facilities to blend down contaminated consignments of feed could continue to be approved for this activity under existing legislation; and threshold levels for action where contamination is below current MPLs, but considered to be “significant”, could continue to be based on the MPLs themselves.

Partial implementation of Directive 2002/2 could involve the deletion of the option to declare by category, which the UK supported in negotiations, allied perhaps to the original Council compromise on declaration in five percentage bands (<2%, 2-5%, 5-15%, 15-30%, and >30%). Partial implementation of Directive 2002/32 could involve stricter controls on contaminated feed materials, e.g. the option to blend down could be restricted to consignments with levels of contamination which exceed the MPL by no more than (say) 10-15%, with automatic destruction required for those more grossly contaminated.

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 undoubtedly successful legal proceedings against the UK in the European Court of Justice, as the terms of both Directives 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 as their feed products might be perceived as less safe by other Member States.

### **Option (ii)**

Full implementation of Directives 2002/2 and 2002/32 would meet the UK's mandatory obligation to implement EC measures. This might benefit UK manufacturers and suppliers because (a) compliance with the new labelling declaration could demonstrate greater transparency and openness about their products; and (b) the removal of the option to blend down would eliminate a potential risk from the feed chain, in turn helping to confirm its safety and integrity. However, it is not possible to put a financial value on these benefits.

### **Option (iii)**

Delaying implementation might defer any implementation costs. However, this would still leave the UK open to infraction proceedings and there might be concerns that feed safety measures were being delayed.

## **3(c) Issues of Equity and Fairness**

Directive 2002/2 will provide more information on the composition of compound animal feed. The main beneficiaries will be farmers, who require information on the composition of compound feeds in order to know what ingredients they include and meet the nutritional needs of their livestock. On the other hand, such information should be commensurate with need and not be overburdensome for industry. There has been no demand from farmers for percentage inclusion rates, so it is questionable as to whether it is fair to impose this on manufacturers, particularly the smaller compounders. Percentage declarations are not required for human food. Moreover, there is no direct link here with safety or public health issues, such as BSE, where there are already extensive controls in place. Nevertheless, the lack of harmonised legislation could result in barriers to trade and distortion of competition within the EU Single Market.

Directive 2002/32 will have more impact on importers and feed manufacturers, although farmers and the consumers of animal products will benefit indirectly. Feed manufacturers may also benefit directly, as the provisions of the Directive also apply to feed products intended for export to third countries, and removal of the option to blend down may in turn remove any concern about potential contamination of UK feed products. In addition, the requirement to investigate the reasons for breaches of the MPLs, and to take action where levels of contamination are considered "significant", may help identify the sources of any persistent problems in third countries exporting to the EU, thus allowing importers and feed manufacturers to avoid supplies from these countries in the future or even assist the third country exporters to eliminate the problem.

## 4. COMPLIANCE COSTS FOR BUSINESS

### 4(a) Business Sectors Affected

The business sectors likely to be affected by these two measures are importers of feed materials, agricultural merchants, feed compounders and pet food manufacturers. The approximate number of such businesses across the UK is as follows:

Manufacturers of additives and premixtures	40
Distributors of additives and premixtures	2,400
Manufacturers of prepared feed for farm animals	405
Manufacturers of prepared pet foods	130
Importers and agricultural merchants	70
Farmers	150,000

Information on the total value of the trade in animal feedingstuffs, including exports, is not currently available. **Consultees are invited to provide information on this as part of the consultation process.**

### 4(b) Compliance Costs for "Typical" Businesses

Industry interests and enforcement authorities, who will principally be affected by these two measures, were consulted during the negotiations and asked to indicate areas of cost compliance which caused them concern. Industry in particular considered that the likely costs of Directive 2002/2 would be disproportionate to any benefits, but did not supply figures for expected additional costs.

The Food Standards Agency considers that the likely costs of compliance with Directive 2002/2 for larger compounders will not be significant, as they should already possess the necessary integrated computer systems to declare percentage inclusion rates of ingredients. There are likely to be non-recurring compliance costs for smaller compounders who need to purchase or upgrade software and hardware, but it is not possible to quantify these at this stage. **Feed industry representatives are asked to provide information on such costs as part of the consultation on the draft Regulations.**

**Feed industry representatives are also asked to provide information on the likely costs of the removal of the option to blend down feed materials with levels of contamination above the MPLs. The Food Standards Agency would be particularly interested to have information on the potential costs of switching (on a temporary or permanent basis) to more expensive supplies of assured feed materials in substitution for supplies from regions of the world**

where assurance schemes do not operate and where contamination may accordingly be more likely.

## 5. IMPACT ON SMALL BUSINESSES

### Small Business Litmus Test

Approximately one-third of the companies which manufacture prepared animal feed claim small company status. **As part of the consultation on the draft Regulations, a number of small companies are being asked to provide information on the potential costs to them of these measures.**

## 6. ENFORCEMENT COSTS

Local authorities, who are responsible for the enforcement of animal feedingstuffs legislation in Great Britain, were kept informed of progress during negotiation of the measures but have yet to comment on the likely costs to them. As advised in section 2(b) above, the tolerance limit of +/-15% for percentage ingredient declarations allowed in Directive 2002/2 is not linked to any scientific criterion and allows scope for both potential fraud and wide variations in enforcement in Member States. The Food Standards Agency will work with the Local Authorities Coordinators of Regulatory Services to draw up guidance for enforcement authorities and other stakeholders on the application of the new legislation. **In the meantime, local authorities are invited to provide more information on likely additional enforcement costs.**

## 7. TOTAL COSTS

Information provided to the Food Standards Agency to date has not been sufficient to estimate total costs. **This draft Regulatory Impact Assessment is therefore 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 measures are implemented in law.**

## 8. COMPETITION ASSESSMENT

### 8(a) Competition Filter

Information available to the Food Standards Agency suggests that the measures – particularly Directive 2002/2 on ingredient listing – could have an impact on competition in the UK market. 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)
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Q1	In the market affected by the new measures, does any firm have more than 10% market share?	Yes (see section 8(b) below)
Q2	In the market affected by the new measures, does any firm have more than 20% market share?	Yes (see section 8(b) below)
Q3	In the market affected by the new measures, do the largest three firms together have at least 50% market share?	No (but see section 8(b) below)
Q4	Would the costs of the measures affect some firms substantially more than others?	Yes (see section 4(b) above)
Q5	Are the measures likely to affect the market structure, changing the number or size of firms?	Yes (see section 8(b) below)
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?	No (but see section 8(b) below)

### **8(b) Competition Assessment**

The answers to questions 1 to 3 inclusive refer specifically to manufacturers of compound feed, who will be affected by both the requirement to declare ingredients by percentage and the prohibition on blending down. Producers and merchants of feed materials (i.e. ingredients sold and consumed singly) will be affected only by the prohibition on blending down.

UK compound feed production is dominated by two large companies, who between them have close to 50% of the compound feed market. The remainder of production is serviced by regionally-based and co-operative and farmer-controlled compounders with typically one or two mills each. Collection of regional production data was discontinued by the then Ministry of Agriculture, Fisheries and Food in 1996, and it is not therefore possible to comment on the market shares held by these smaller manufacturers.

The answers to questions 4 and 5 assume that the additional costs to smaller compound feed manufacturers both of percentage declaration of feed ingredients and the disposal of contaminated feedingstuffs which could no longer be sent for blending down could lead to some amalgamations or closures, with consequential effects on the market shares and competitive positions of the two UK-based firms. The answer to question 9 to some extent follows on from this, in that it is possible that smaller compounders could reduce the range of materials used and feedingstuffs produced, in order both to simplify the ingredient declarations they would have to make and to exclude imports of feed materials from regions where it is known that contamination is endemic in certain crop plants.

**Further information on these points is requested from stakeholders 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**

The Directives will be implemented in Wales by the Feeding Stuffs (Amendment) (Wales) (No.2) Regulations 2003. There will be separate but parallel regulations for England, Scotland, and Northern Ireland. Enforcement is by Trading Standards Departments of local authorities in Great Britain, and by the Department of Agriculture and Rural Development in Northern Ireland. Penalties for non-compliance are set out in the Agriculture Act 1970 and in the aforementioned Regulations.

## **11. SUMMARY AND RECOMMENDATIONS**

<b>Option</b>	<b>Total Cost</b>	<b>Total Benefit</b>
Non-implementation or partial implementation	Costs of infraction proceedings (which would be ongoing); possible loss of EU markets for UK feed manufacturers	Maintenance of the existing legislative framework relating to labelling of feed and the control of contaminated consignments.
Full implementation	Not yet known	Provision of full information on feed ingredients for farmers and others, and removal from the feed chain of any risks associated with the blending down of contaminated feed.
Delayed implementation	Costs of infraction proceedings	As with non-implementation (in the short term).

The introduction of full ingredient declaration by percentage weight could have a significant impact on some feed manufacturers, while adding little to the nutritional and analytical information already required under EU feed law. Although the Food Standards Agency supports proportionate and effective measures which will help protect the ultimate consumers of animal products, this particular measure is likely to have little impact on them.

Similarly, the prohibition on the blending down of feedingstuffs with levels of contamination above the specified MPLs could have a significant effect on those feed merchants and feed manufacturers who source their materials from regions of the world where high levels of a particular contaminant, such as aflatoxins, are known to be present. Although there could in consequence be restrictions on the types and quantities of ingredients used in feed, this would have little impact on the consumers of animal products.

However, both measures have been formally adopted at European level, and we would therefore need very strong reasons not to recommend their incorporation into domestic law. We accordingly recommend their implementation via the Feeding Stuffs (Amendment) (Wales) (No.2) Regulations 2003.

## **12. TIMETABLE**

Member States are required to transpose Directive 2002/2 into domestic legislation no later than 6 March 2003, with a coming into force date of 6 November 2003. Directive 2002/32 has a date of 1 May 2003 for transposition by Member States, and a coming into force date of 1 August 2003.

### ***Contact Point***

Alison Ward  
Agricultural branch  
Food Standards Agency Wales:  
1<sup>st</sup> Floor  
Southgate House  
Woods Street  
Cardiff  
CF10 1EW  
Telephone: 029 2067 8906  
Fax: 029 20678918/9  
E Mail: [alison.ward@foodstandards.gsi.gov.uk](mailto:alison.ward@foodstandards.gsi.gov.uk)