Explanatory Memorandum to the Feed (Sampling and Analysis and Specified Undesirable Substances) (Wales) Regulations 2010

This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 24.1.

Member's Declaration

In my view the Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Feed (Sampling and Analysis and Specified Undesirable Substances) (Wales) Regulations 2010. I am satisfied that the benefits outweigh any costs.

Gwenda Thomas
Deputy Minister for Social Services
Assembly Minister in Charge of the Proposed Measure

15 September 2010

Explanatory Memorandum for the Feed (Sampling and Analysis and Specified Undesirable Substances) (Wales) Regulations 2010

1. Description

This Statutory Instrument will transpose into law in Wales Commission Directive 2009/141/EC amending certain entries in Annex I of Directive 2002/32/EC on undesirable substances in animal feed and provides for the administration and application of Commission Regulation (EC) No.152/2009, which is directly applicable in all Member States, laying down methods of sampling and analysis for the official control of feed.

2. Matters of Special Interest to the Constitutional Affairs Committee

None

3 Legislative Background

Welsh Ministers have the powers to make these Regulations under sections 66(1), 67(5), 74A, 79(9) and 84 of the Agriculture Act 1970; and pursuant to the Welsh Ministers' designations under section 2(2) of the European Communities Act 1972 in relation to: measures in the veterinary and phytosanitary fields for the protection of public health; the common agricultural policy of the European Community; and measures relating to feed produced for or fed to food-producing animals.

This instrument is subject to the negative procedure.

4 Purpose and Intended Effect of the Legislation

<u>European Regulation (EC) No.152/2009</u>
The methods and procedures for the sampling and analysis of animal feed were laid down in a number of Commission Directives which date back over thirty years and which had been amended and extended on numerous occasions. The EC Regulation primarily consolidates in a single, directly applicable European Regulation, the existing sampling and analysis methods and procedures. The EC Regulation also deletes a number of harmonised community methods of analysis, for example either because the analyte in question in no longer subject to Community legislation or because a number of other, equally validated analytical methods have become available for it.

Such deletion of certain harmonised community methods of analysis will allow laboratories greater flexibilities because they will be able to use any method which they consider suitable for the analyte in question. The EC Regulation will re-enact the qualifications required by analysts and lay down the form of certificate in which analytical results are declared. Additionally, some consequential amendments to the Agriculture Act 1970 are necessary, firstly to bring certain definitions relating to sampling and analysis into line with those in the EC Regulation, and secondly to disapply those provisions of the Act which cover territory now occupied by the EC Regulation.

The UK and other Member States supported the commission's proposals to delete a number of methods of analysis.

Methods of analysis for the following 17 analytes have been removed:

- aflatoxin B1, ascorbic and dehydroascorbic acids, avoparcin, calcium, flavophospholipol, hydrocyanic acid, magnesium, monensin sodium, pepsin activity, pepsin (hydrochloric acid soluble crude protein), potassium, sodium, spiramycin, tylosin, urease activity (of products derived from soya), virginiamycin, and zinc bacitracin.

Methods of analysis for the following 32 analytes have been retained:

- amino acids other than tryptophan, amprolium, ash insoluble in hydrochloric acid, carbonates, chlorine from chlorides, constituents of animal origin, copper, crude ash, crude fibre, crude oils and fats, crude protein, diclazuril, dioxins and dioxin-like PCBs, gossypol (free and total), halofuginone, iron, lactose, lasalocid sodium, manganese, methyl benzoquate, moisture, olaquindox, robenidine, starch, sugar, phosphorus, tryptophan, urea, vitamin A, vitamin E, volatile nitrogenous bases, and zinc.

The EC Regulation also introduces two new methods of analysis, one for carbodax and one for calculating the energy value of poultry feed. It also specifies procedures for taking samples and preparation of samples for analysis. However, the Commission has indicated that current procedures for the taking of samples are to be subject to further discussion in a technical working group, and amendments to them are therefore likely in the near future. The EC Regulation introduces a requirement that a product intended for animal feed should be considered non-compliant if the analytical result exceeds the maximum permitted level specified in Directive 2002/32 on undesirable substances.

Commission Directive 2009/141/EC

Feed material may be susceptible to contaminants by various substances. At excessive levels, such substances may have implications for animal health and/or the health of human consumers of animal products. To protect the feed and food chains, it is therefore necessary to set statutory maximum permitted levels (MPLs) for these substances and to review them periodically.

MPLs for undesirable substances in animal feed are laid down in the Annex to European Parliament and Council Directive 2002/32/EC. Commission Directive 2009/141/EC amends certain entries on the earlier Directive by extending and in some cases tightening the range of MPLs for arsenic, theobromine and certain alkaloid-containing and toxic weed seeds.

The European Food Safety Authority (EFSA) was charged a number of years ago with responsibility for reviewing the MPLs for undesirable substances to determine whether the levels were still appropriate in the light of advances in scientific knowledge and experience of the actual presence of these undesirable substances in feed and their effects on animal and human health.

The amendments made by Commission Directive 2009/141/EC are a result of the EFSA review process, and are as follows:

- arsenic -- new limits are being introduced for feed additives, which have not hitherto been subject to MPLs for arsenic. (Feed additives -- e.g. vitamins, trace elements, binders, preservatives -- are substances added to feed to, among other things, favourably affect its characteristics, or the characteristics of animal products, or to satisfy the animals' nutritional needs.) The existing limits for various products of marine origin, such as seaweed and fishmeal, and for feedingstuffs intended for fish, are being raised (with the proviso that their content of inorganic arsenic -- the more toxic form -- must remain below a specified level);
- theobromine -- the existing, higher limit for this alkaloid substance in feed for cattle is being removed (so that the level for bovines will in future be the same as for other farmed livestock). New, lower limits will be introduced for feed for pigs and feed for dogs, rabbits and horses;
- alkaloid-containing and toxic weed seeds -- existing entries are being consolidated, bringing various different species of plants together beneath a reduced number of headings.

Theobromine is a substance similar to caffeine, and is toxic to many non-human species. The alkaloids in question are naturally occurring organic compounds which can have an adverse effect on farmed livestock.

2. Consultation

Key stakeholders were kept appraised of the content of the two EU measures while they were under discussion in the Standing Committee in Brussels, although few comments were received on either.

The Food Standards Agency consulted stakeholders for 8 weeks on the draft Feed (Sampling and Analysis and Specified Undesirable Substances) (Wales) Regulations 2010, this consultation closed 19 April 2010. Eighteen key welsh stakeholders were invited to comment, however, no responses were received in Wales.

Eight responses were received UK-wide, three of which were either non-committal or made broad general expressions of support for the implementation of the two EU measures. One raised a series of questions about sampling procedures and the application and interpretation of MPLs for undesirable substances, but did not comment directly on the draft Regulations. The remaining four responses, from professional associations, were more substantive, chiefly commenting on the potential cost calculations, the qualifications of analysts and the methods of taking samples. Some minor amendments were made to the finalised Statutory Instrument. A summary of the responses received is attached at Annex I.

3. Regulatory Impact Assessment

5.1 Options

Two options have been considered: option 1 which is do nothing; and option 2 which is to make regulations to provide for the administration of Commission Regulation (EC) No.152/2009 and the transposition of Commission Directive 2009/141/EC.

Do nothing would mean that existing national measures or methods and procedures for the sampling and analysis of feed would be retained, as would the existing maximum permitted levels for arsenic, theobromine and certain alkaloid-containing or toxic weed seeds.

It is recommended that option 2 be pursued and that the Feed (Sampling and Analysis and Specified Undesirable Substances) (Wales) Regulations 2010 be made to provide for the administration of European Regulation (EC) No.152/2009 and the transposition of Commission Directive 2009/141/EC. It is also commensurate with the UK's legal obligation under the Treaty of the Functioning of the EU to apply EU legislation in its territory.

5.2 Costs and Benefits

5.2.1 European Regulation (EC) No.152/2009

The Regulation deletes 17 methods of analysis, which could have some benefits for feed businesses, enforcement authorities and analytical laboratories as they will then be free to use any other procedures which can be applied to the analyte in question and they consider will be equally effective. However, it has not been possible to quantify the potential benefits to this, as there is no requirement to collect data on methods of analysis used by laboratories.

Because the Regulation is primarily consolidatory, costs are likely to limited to reading and familiarisation by local authority Trading Standards Officers, analytical laboratories and feed business operators.

It is thought that there is unlikely to be any new administrative burdens or policy savings associated with the regulations.

5.2.2 Commission Directive 2009/141/EC

The extended limits relating to arsenic are likely to be of benefit to feed businesses because they increase existing limits for this substance in products of marine origin and in feed for fish. This could in future allow businesses using products of marine origin or manufacturing feed for fish, to obtain ingredients from sources which are currently excluded from the supply chain because their arsenic loading exceeds the statutory maxima. Feed businesses using materials which might potentially contain traces of certain weed seeds such as Indian mustard might also benefit from the deletion of the specific entry for this plant. However, it has not been possible to quantify the potential benefits of these changes.

The tightened maximum permitted levels of theobromine and certain alkaloid-containing and toxic weed seeds could impose some constraints on the sources of supply of feed materials which potentially contain or are contaminated with these substances. However, it has not been possible to quantify the potential costs of these restraints.

As with Regulation 152/2009, it has been assumed that only a one-off familiarisation cost will apply.

It is thought that the Commission Directive may have some additional administrative burdens for feed businesses and enforcement authorities because the extended and in some cases tightened MPLs may require additional testing to ensure conformity.

Further information about the potential administrative burdens associated with both measures was sought as part of the consultation on the Feed (Sampling and Analysis and Specified Undesirable Substances) (Wales) Regulations 2010, but no comments were received.

Consultees' responses to the benefits and cost calculations concerned the potential costs associated with European Regulation 152/2009 on sampling and analysis; no respondents made any comments on the potential costs associated with Commission Directive 2009/141, or on the potential benefits of both measures.

6. Competition Assessment

Data compiled by the Office for National Statistics for the Inter-Departmental Business Register shows that in 2009 there were 405 premises manufacturing prepared feed for farm animals in the UK, with 15 such premises in Wales. These figures include 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 cakes. The FSA's assessment is that the Feed (Sampling and Analysis and Specified Undesirable Substances) (Wales) Regulations 2010 will have little direct impact on competition in the UK feed industry.

7. Small Firms Impact Test

Those parts of the Feed (Sampling and Analysis and Specified Undesirable Substances) (Wales) Regulations 2010 which concern sampling and analysis will have little direct or indirect impact on small firms. Those parts of the Regulations covering amended MPLs for arsenic, theobromine and certain alkaloid-containing and toxic weed seeds may have a marginal impact on small firms. This is because the increase in the level for arsenic in some products and the consolidation of the levels for weed seeds into fewer entries may entail less testing to confirm feed products' compliance with these MPLs, and therefore a reduction in the cost of both testing and disposing of non-compliant products.

8. Post Implementation Review

There is no requirement in either of the two EU measures for a review to be undertaken within a fixed period of procedures for sampling and analysis or of the MPLs for the undesirable substances in question. However, procedures for sampling and analysis are re-visited from time to time by the Standing Committee of the Food Chain and Animal Health, while MPLS for undesirable substances are kept under review by EFSA. Both of these bodies will make recommendations for further amendments as considered appropriate.