**EXPLANATORY MEMORANDUM TO THE FEED (SPECIFIED UNDESIRABLE SUBSTANCES) (WALES) REGULATIONS 2009**

This explanatory memorandum has been prepared by the Food Standards Agency and is laid before the National Assembly for Wales in accordance with Standing Order 24.1.

## 1. Description

The Statutory Instrument transposes into national law in Wales Commission Directive 2009/8/EC of 10 February 2009 on the carry-over of residues of coccidiostats and histomonostats into feed for non-target species. Coccidiostats and histomonostats are substances intended to help prevent coccidiosis and histomoniosis i.e. infestations of the gastro-intestinal tract by certain single cell micro-organisms, mainly in poultry.

## 2. Legislative Background

The Powers enabling this instrument to be made are contained under section 2(2) of the European Communities Act 1972. The Welsh Assembly Ministers are designated for the purpose of section 2(2) by virtue of the European Communities (Designation) (No.2) Order 2005 (WI 2005/1971) (which function has been transferred to them by virtue of paragraphs 28 and 30 of Schedule 11 to the Government of Wales Act 2006), in respect of measures relating to feed produced for or fed to food producing animals. In so far as this instrument cannot be made under the designated powers specified above, the Welsh Assembly Ministers also have powers conferred by sections 66(1), 74A and 84 of the Agriculture Act 1970 as read with Regulation 14 of the Food Standards Act 1999 (Transitional and Consequential Provisions and Savings) (England and Wales) Regulations 2000 and with Articles 2 and 6 of the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002 in relation to the making of this instrument. There are no issues of regularity or propriety for the Welsh Assembly Government arising from making these Regulations.

## 3. Purpose and Intended Effect of the Legislation

Coccidiostats and histomonostats are authorised for use as feed additives under EC Regulation 1831/2003 on feed additives for use in animal nutrition. The authorisations lay down specific conditions for their use, such as the target animal species or categories for which they are intended, their maximum rates for inclusion on feed, and their required labelling.

Food business operators may produce within one establishment a range of feeding stuffs for a number of animal species, and in such cases it may be that different types of feed products are manufactured one after the other or on the same production line. Livestock farmers mixing feed on their own holdings may produce different feed products using the same equipment every time. This may result in technically unavoidable traces of one product remaining in the production line and this becoming incorporated in the production of another feed product. The transfer of one product to another is called ‘carry-over’, and may result in traces of substances appearing both in feed for non-target species and in resulting animal products for human consumption.

Commission Directive 2009/8/EC is intended to assist the operators of the Single Market by introducing harmonised tolerance levels for residues of coccidiostats and histomonostats. This will prevent Member States from setting their own national limits for these residues based on their differing analytical abilities and thus the variable rates of detection of those residues which would occur throughout the EU. The measure is also expected to help reduce the administrative and policy burdens on the feed industry and livestock farmers, as they will no longer be required to work to a zero tolerance for the presence of residues of these substances and will thus be permitted to undertake risk-based assessments of their likely presence in feed production runs. This will help manage any potential health risk to human consumers of animal by-products which may arise from the presence of residues of these substances in the feed received by non-target species of animals.

The tolerance levels for these residues are being introduced at European level as an amendment to the Annex to EC Directive 2002/32 on undesirable substances in feed, and are without prejudice to the authorisation of coccidiostats and histomonostats as feed additives under EC Regulation 1831/2003. The amendment to the Directive will be transposed into law in Wales by an amendment to Schedule 5 of the Feeding Stuffs (Wales) Regulations 2006 (as amended), and will provide enforcement authorities with the means to help confirm the safety of feed products put into circulation.

Background to Commission Directive 2009/8/EC

The European Food Safety Authority (EFSA) was asked by the Commission to undertake a risk assessment of the presence of residues of authorised coccidiostats and histomonostats in feed for non-target species. It published a series of Opinions on the products concerned in 2007-08, setting out the likely risks to animal and human health. These Opinions were reviewed by the Standing Committee on the Food Chain and Animal Health (Animal Nutrition Section), which agreed the following tolerances:

- 3% carry-over in feed for less sensitive non-target species: and
- 1% carry-over in withdrawal feed (i.e. feed used in the period before slaughter), feed for sensitive non-target species, feed for target species to which coccidiostats and histomonostats are not added, and feed for non-target species classifiable as ‘continuous food-producing animals’ (such as dairy cows and laying hens).

The Standing Committee also agreed to:

- Set tolerance levels for residues in premixtures (i.e. mixtures of additives intended for inclusion in a finished feed) to ensure that, when their instructions for use are correctly followed, the premixture will not contribute more than 50% of the total carry-over in the finished feed; and
- Set a specific provision for chickens reared for laying (which have longer lifespans than chickens reared for slaughter for their meat) to minimise the potential for the carry-over of residues into eggs for human consumption.

These provisions, and the parallel provisions for food for humans consumption, were put out for consultation with relevant professional stakeholder organisations while they were under discussion in the Standing committee, but no comments were received. The Standing Committee therefore voted to adopt the provisions at its meeting on 27-28 September 2008, and agreed that the tolerances should be reviewed no later than 1 July 2011. The provisions for feed were adopted as Commission Directive 2009/8/EC of 10 February 2009.

## 4. Implementation

It is intended that these Regulations will come into force on 23 November 2009. This Statutory Instrument applies only to Wales. Separate but parallel legislation will be made for England, Scotland and Northern Ireland.

Enforcement of the new tolerance levels in Wales will be the responsibility of the Local Authority trading standards officers. This is unchanged from the existing arrangements for the enforcement of animal feed legislation.

There is a parallel measure for the presence of residues of coccidiostats and histomonostats in animal products (meat, milk and eggs) for human consumption.

## 5. Consultation

Key Stakeholders were kept appraised of the content of the draft Directive while it was under discussion in the Standing Committee in Brussels.

Interested parties, including industry representatives and farming unions were invited to comment on the draft Regulations. Details are included in the Regulatory Impact Assessment below.

## 6. Regulatory Impact Assessment

### 6.1 Options

In respect of this legislation, the ‘do nothing’ option is not an option, as it would ultimately lead to infraction proceedings against the National Assembly for Wales by the European Commission. Therefore, the ‘make the legislation’ option, to implement the changes required to comply with the European Legislation, is being proposed. Transposition of the Directive would be of benefit to the UK feed industry, which would be able to take advantage of the new tolerances for technically unavoidable residues of coccidiostats and histomonostats while ensuring that its feed products conform to the risk-based principles on which these tolerances have been determined, and are thus safe for their intended uses.

### 6.2 Costs and Benefits

The potential benefits of transposing Commission Directive 2009/8/EC include the relaxation of the existing requirements to operate a zero tolerance principle for the potential presence of coccidiostats and histomonostats, which could mean that consignments of feed which previously would have breached requirements will no longer have to be disposed of outside the feed chain. This could in turn lead to a reduction of the costs of compliance with the

legislation. However, the number of consignments of feed currently disposed of due to the presence of coccidiostats and histomonostats above the current zero tolerance is unknown, and therefore its benefit is non-monetised.

It was initially thought that local authorities might also benefit from the introduction of risk-based tolerance levels because it could reduce the need for their officers to sample and test feed products, and thus in turn reduce the costs associated with such analyses. However, the current level of testing exclusively for coccidiostats and histomonostats is unknown, and therefore benefits arising from a lower level of testing under Commission Directive 2009/8/EC are non-monetised. Further information about these potential benefits, including their possible financial value, was sought as part of the public consultation on the transposition of the measure, but none was forthcoming from either industry or enforcement authorities.

Nevertheless, the measure is generally perceived as proportionate to the potential risk to animal and human health, as the maximum permitted levels are based on an independent risk assessment carried out by the European Food Safety Authority (EFSA) and endorsed by the Commissions Standing Committee on the Food Chain and Animal Health. This will ensure that both animal health and the health of consumers of livestock products are adequately protected.

It is not anticipated that any additional costs will arise from the implementation of Commission Directive 2009/8/EC, because the Directive is not introducing any new burden for the feed industry. This assumption is made on the basis that feed business operators are already sampling and testing to ensure compliance with the existing zero tolerance requirement for the presence of coccidiostats and histomonostats in feed for non-target species. In addition, it is likely that one additional annual sample for each feed manufacturing premises required to test for the presence of coccidiostats and histomonostats could be obtained from routine sampling conducted for other purposes.

6.4 Competition Assessment

The Food Standards Agency's preliminary assessment is that the Feed (Specified Undesirable Substances) (Wales) Regulations 2009 will have little direct impact on competition in the UK feed industry.

6.5 Consultation

Key stakeholders across the UK, including 17 in Wales, were consulted on the draft Regulations to transpose Commission Directive 2009/8/EC into law in Wales.

Ten responses were received UK-wide to the public consultation (with a nil response from Wales). Two were received from individuals with an interest in animal nutrition issues, one from a local authority enforcement officer, and the remainder from trade associations or feed businesses. All were content or had no comments on the proposed tolerance for carry-over of coccidiostats and histomonostats into feed for non-target species. Some questions were raised about the capability of laboratories to analyses the presence of

residues, particularly at very low levels, and the need for formal enforcement agreements between Local Authority trading standards departments and the Veterinary Medicines Directorate (which is responsible for testing for the presence of residues of veterinary and medicinal substances). The Food Standards Agency considers that these issues can best be addressed through the Animal Feed Law Enforcement Liaison Group, which brings together representatives of bodies with an interest in animal feed law and can consider procedures for the exchange of information and the co-ordination of enforcement action.

6.6 Post Implementation Review

Commission Directive 2009/8/EC requires that the tolerance levels for residues of coccidiostats and histomonostats be reviewed in the light of developments in scientific and technical knowledge no later than 1 July 2011. This review will be undertaken by the European Food Safety Authority and the results reported via the Standing Committee on the Food Chain and Animal Health, where amendments would be put to a vote by the Member States.

6.7 Summary

Commission Directive 2009/8/EC introducing harmonised tolerances for residues of coccidiostats and histomonostats will be implemented in Wales by the Feed (Specified Undesirable Substances) (Wales) Regulations 2009. There will be separate but parallel Regulations for England, Scotland and Northern Ireland. The Regulations will amend the Feeding Stuffs (Wales) Regulations 2006 (as amended) by introducing new tolerance levels as Chapter E of Schedule 5 to the Regulations (the schedule which lists the maximum permitted levels for undesirable substances laid down in the Annex to European Parliament and Council Directive 2002/32/EC of 7 May 2002).