EXECUTIVE NOTE

THE FEED (SPECIFIED UNDESIRABLE SUBSTANCES) (SCOTLAND) REGULATIONS 2009

SSI 2009/373

The above instrument is made under powers conferred by sections 66(1), 74A and 84 of the Agriculture Act 1970. The instrument is subject to negative resolution procedure.

Policy Objectives

1. This instrument transposes Directive 2009/8/EC, amending the Annex to Directive 2002/32 on undesirable substances. The amending Directive introduces maximum permitted levels for residues of coccidiostats and histomonostats.

2. The carry-over of residues of coccidiostats and histomonostats - substances intended to help prevent infestations of the gastro-intestinal tract by certain single-celled micro-organisms (protozoa), mainly in poultry - into feed for other species ("non-target species") is technically unavoidable where feed compounders or on-farm mixers are producing a range of feedingstuffs using the same equipment. This cross-contamination typically occurs where residues from one production run are incorporated in the next. This instrument introduces permitted tolerance levels for such instances of carry-over.

3. The tolerances for carry-over have been set at European level to ensure harmonised levels throughout the EU and thus avoid the possibility of Member States setting their own, national limits based on their differing analytical capabilities and rates of detection. The setting of different national limits could give rise to difficulties with the operation of the Single Market, particularly if the UK were to set tolerance levels lower than those of other Member States on the basis of more developed analytical capabilities, which could competitively disadvantage the UK feed industry.

Consultation

4. A public consultation took place in Scotland between March and June 2009, and involved a range of stakeholders including industry trade associations, enforcement bodies, consumer groups and others. No responses were received.

Impact

5. A Regulatory Impact Assessment, which provides more details of the impact of the measure, has been produced.

FOOD STANDARDS AGENCY SCOTLAND
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TRANSPOSITION TABLE

Commission Directive 2009/8/EC of 10 February 2009 amending Annex I to Directive 2002/32/EC of the European Parliament and the Council as regards maximum levels of unavoidable carry-over of coccidiostats or histomonostats in non-target feed (*OJ* No 40, 11.2.2009, p. 19)			
Article	**Purpose**	**Implementation**	**Responsibility**
Article 1 and the Annex	To add entries for coccidiostats and histomonostats to Annex I to Directive 2002/32/EC	Regulation 2 adding Chapter E to Schedule 5 to the Feeding Stuffs (Scotland) Regulations 2005	The Scottish Ministers through implementing Regulations

Regulatory Impact Assessment (RIA)

1. Title of Proposal

The Feed (Specified Undesirable Substances) (Scotland) Regulations 2009

Implementation of:

European Commission Directive 2009/8/EC of 10 February 2009 on the Carry-over of Coccidiostats into Feed for Non-target Species.

2. Purpose and Intended Effect of the Measure

2.1 Objectives

a) To ensure the proportionate management of any potential risks to animal and human health which may arise from the presence of residues of coccidiostats and histomonostats.

b) To introduce risk-based tolerance levels for these residues which will reduce the burdens on industry.

c) To ensure harmonisation across the EU and avoid any single-market problems which may arise from Member States setting their own national levels.

d) To link the permitted tolerances to enforcement provisions which will enable competent authorities to ensure in a proportionate manner the safety of feed products put into circulation.

2.1.1 EC Directive 2009/8/EC requires implementation by 1 July 2009 and the measure requires to be transposed into law in Scotland.

2.2 Rationale for Government Intervention

2.2.1 Where feed business operators are producing feedingstuffs for a range of species in the same establishment and farmers are mixing feed on their own holdings, there may be technically unavoidable residues of coccidiostats and histomonostats. These are substances intended to help prevent infestations of the gastro-intestinal tract by certain single-celled micro-organisms (protozoa), mainly in poultry. Because feed production processes cannot be directly observed by consumers, they cannot assess the potential risks for themselves and make informed choices about them. Government intervention is therefore necessary to set harmonised tolerance levels for these residues to help protect animal health and the health of human consumers of animal products.

2.3 Background to Reasons for Government Intervention

2.3.1 Contaminants in feed can have an adverse effect on animal health and potentially on the health of human consumers of animal products (milk, meat and eggs). Other negative consequences can include the costs of veterinary treatment (for the livestock farmer) and medical treatment (for humans). Consumers cannot assess the risks which may be associated with contaminants in animal feed because they cannot observe the potential levels of contaminants which may be present in it, and so cannot make informed choices about such risks. Government intervention is therefore necessary to help manage these risks and to address the lack of informed consumer choice.

2.3.2 Coccidiostats and histomonostats are substances intended to help prevent coccidiosis and histomoniosis, ie infestations of the gastro-intestinal tract by certain single-celled micro-organisms (protozoa), mainly in poultry. The carry-over of residues of coccidiostats and histomonostats into feed for other species ("non-target species") is technically unavoidable in those cases where feed business operators are manufacturing a range of feedingstuffs in the same establishment or where farmers are mixing feed for livestock on their own holdings using the same equipment. This cross-contamination typically occurs where residues from one production run are incorporated in the next although at present there are no tolerance levels for such instances of carry-over. Although the levels of the residues in question may be too low to pose a risk to animal or human health, it is nevertheless necessary to manage any potential risks by laying down maximum permitted levels for these residues.

2.3.3 Government intervention will also help fulfil the European Commission's goal of ensuring the adoption of harmonised tolerance levels throughout the EU, thus avoiding the possibility of Member States setting their own, different national limits based on their differing analytical capabilities and rates of detection. The setting of different national limits could give rise to difficulties with the operation of the Single Market, particularly if the UK were to set tolerance levels lower than those of other Member States on the basis of more developed analytical capabilities, which could competitively disadvantage the UK feed industry.

2.4 Background to the Intended Effect of the Measure

2.4.1 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 of inclusion in feed, and their required labelling.

2.4.2 Feed business operators may produce within one establishment a range of feedingstuffs 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 on the same production line. Livestock farmers mixing feed on their own holdings may also produce different feed products using the same equipment every time. This may result in unavoidable traces of one product remaining in the production line and thus becoming incorporated in the production of another feed product. This transfer from 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.

2.4.3 Commission Directive 2009/8/EC is intended to assist the operation 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 those residues based on their differing analytical abilities and thus the variable rates of detection of those residues which would obtain 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 risks to the human consumers of animal products which may arise from the presence of residues in the feed received by non-target species of animals.

2.4.4 The tolerance levels for these residues are being introduced at European level as an amendment to the Annex to 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 Scotland by an amendment to Schedule 5 to the Feeding Stuffs (Scotland) Regulations 2005 (as amended), and will provide enforcement authorities with the means to help confirm the safety of feed products put into circulation.

2.5 Background to Commission Directive 2009/8/EC

2.5.1 The European Food Safety Authority was asked by the Commission to undertake a risk assessment of the presence of residues of authorised coccidostats and histomonostats in feed for non-target species. It published a series of Opinions on the products concerned in 2007-2008, 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 histomonstats are not added, and feed for non-target species classifiable as "continuous food-producing animals" (such as dairy cows and laying hens).

2.5.2 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.

2.5.3 These provisions, and the parallel provisions for food for human 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 November 2008, and agreed that the tolerances should be reviewed no later than 1 July 2011. The provisions for feed were adopted by the Commission as Commission Directive 2009/8/EC of 10 February 2009.

2.6 Devolution

2.6.1 Separate but parallel transposing legislation will be required in England, Wales and Northern Ireland.

2.7 Funding

2.7.1 No additional testing costs are envisaged for business or enforcers.

2.8 Training

2.8.1 A requirement for training is not envisaged

3. Consultation

3.1 Key stakeholders representing UK stakeholder interests were kept apprised of the content of the draft Directive while it was under discussion at the Standing Committee in Brussels. The public consultation on the draft Feed (Specified Undesirable Substances) (Scotland) Regulations 2009 to transpose Commission Directive 2009/8/EC into law in Scotland asked stakeholders to comment in particular on the following issues:

- the maximum permitted levels set out in the Schedule to the draft Feed (Specified Undesirable Substances) (Scotland) Regulations 2009;
- information on the potential benefits of the introduction of maximum permitted levels for residues of coccidostats and histomonostats in feed for non-target species, quantified in monetary terms wherever possible;
- comments on the assumption that there would be no new costs associated with the introduction of these maximum permitted levels; and
- the ability of laboratories to analyse down to the maximum permitted levels to be introduced by the draft Regulations.

Enforcement authorities were asked to comment in particular on the potential impact on their work of the new maximum permitted levels, including the frequency of sampling and analysis, quantified in monetary terms wherever possible.

3.2 The consultation was sent to 122 stakeholders and the 32 Scottish local authorities, and was also published on the Food Standards Agency's website. No responses were received to the public consultation in Scotland.

4. Options

4.1 The proposal is to make regulations to transpose Commission Directive 2009/8/EC into national law, setting maximum permitted levels for the carry-over of residues of coccidiostats and histomonostats.

There would appear to be two options available:

- Option 1: do nothing. This would mean retaining the existing "zero tolerance" for residues of coccidiostats and histomonostats; or.

- Option 2: Make appropriate Regulations to transpose Commission Directive 2009/8/EC into national law.

4.2 Option 1 – Do nothing.

4.2.1 Retention of the existing zero tolerance for the carry-over of technically unavoidable residues of coccidiostats and histomonostats is not proportionate to the risks as assessed by the European Food Safety Authority and could have continuing cost implications for UK feed business operators, who would be required to maintain their existing level of vigilance to ensure that such residues are wholly excluded. Users of the feed would be assured that it is free of all such residues and thus safe for its intended uses, but operators might also have to use additional equipment or maintain separate production lines for different types of feedingstuffs, with the continuing costs associated with this. These costs could include those associated with the disposal of production runs of feed found to contain residues of coccidiostats and histomonostats.

4.2.2 Doing nothing could also give rise to the possibility of infraction proceedings by the Commission under Article 226 of the Treaty. This could lead to action against the UK, as Member State, by the Commission in the European Court of Justice and, if the Commission was successful, potentially unlimited daily fines for non-transposition of the measure.

4.3 Option 2 – Transpose Commission Directive 2009/8/EC into national law

4.3.1 Transposition of Commission Directive 2009/8/EC would be commensurate with the UK's obligations under the Treaty of Rome. In addition section 57(2) of the Scotland Act provides that the Scottish Ministers may not make subordinate legislation so far as that legislation is incompatible with Community Law.

4.3.2 Transposition would introduce measures which are proportionate to the potential risks to animal and human health. It would also 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 the tolerances were determined, and are thus safe for their intended uses.

5. Costs and benefits

5.1 **Sectors and groups affected**

5.1.1 Feed compounders producing feed for more than one species, farmers mixing feed on their own holdings and enforcement officers.

5.1.2 We consider that the proposals will have no impact on racial equality, social or environmental issues.

5.2 Costs

5.2.1 **Option 1**

5.2.1.1 These costs are described at paras 4.2.1 and 4.2.2 above.

5.2.2 Option 2

5.2.2.1 Costs associated with option 2 are as follows:

5.2.2.2 The potential costs of Commission Directive 2009/8/EC of 10 February 2009 are assessed as minimal, because the Directive is not introducing any new burdens 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.

5.2.2.3 Feed business operators and local authorities will both need to familiarise themselves with the requirements of the new measure, which it is estimated will incur a one-off time cost. It is assumed that it will take one person from each animal feed manufacturing premise and each local authority 1 hour to complete such familiarisation. The associated time cost estimates are detailed in the table below. It is estimated, through the application of appropriate hourly wage rates, that familiarisation with the requirements of the new measure will cost feed business operators around £6,500 in total and local authorities around £9,000 in total across the UK.

One-off Familiarisation Costs to Businesses and Local Authorities			
Region	Familiarisation Costs		Total
	Local Authorities	Feed Manufacturing Premises	
UK	**£9,200**	**£6,437**	**£15,638**
England	£7,631	£4,751	£12,382
Scotland	£628	£536	£1,164
Wales	£432	£460	£891
Northern Ireland	£510	£690	£1,200

Notes: Wage rates have been obtained from the Annual Survey of Household Earnings 2008 (http://www.statistics.gov.uk/statbase/product.asp?vlnk=15187). Costs to the 469 Local Authorities use the hourly wage for an Environmental Health Officer (used as a proxy for a Trading Standards Officer) of £19.62 (including 30% uplift for overheads); costs for the 420 feed manufacturing premises use the hourly wage for 'Managers In Farming, Horticulture, Forestry And Fishing' of £15.33 (including 30% uplift for overheads).
The number of feed manufacturing premises has been obtained from the UK Inter Departmental Business Survey.

5.2.2.4 Information on whether there are likely to be any administrative burdens associated with the implementation of the EC measure was sought as part of the public consultation on its transposition. No information was received in response to the consultation in Scotland. However, a response to the parallel consultation in England suggested that the additional administrative burdens to local authorities would amount to no more than half-an-hour to an hour's additional work per year on the basis that, as a matter of routine, no more than one sample would need to be taken each year to confirm that the tolerance levels were not being exceeded.

5.2.2.5 In addition, it is likely that the one annual sample required to test for the presence of coccidiostats and histomonostats could be obtained from routine sampling conducted for other purposes. This would imply that no additional sampling costs would be incurred other than that of additional laboratory analysis.

5.2.2.6 The estimates of the additional administrative costs of the measure to local authorities are detailed in the table below. The cost of additional paperwork is calculated by applying an hourly wage rate to the midpoint (45 minutes) of the half-an-hour to an hour range described in paragraph 5.2.2.4, and multiplying this by the number of local authorities in each UK region, yielding costs in the region of £7,000. Discussions between the Food Standards Agency and the Veterinary Medicines Directorate suggest that the additional laboratory analysis required to test for coccidiostats and histomonostats in animal feed would cost around £45 per sample. In order to account for additional costs such as transportation to and from the laboratory, it is assumed the overall cost of a test would double to £90 per sample. Assuming one sample per year is taken for each animal feed manufacturing premises, the annual cost of laboratory analysis to local authorities is estimated to be around £38,000 across the UK.

Additional Administrative Burden of Commission Directive 2008/9/EC on Local Authorities

Region	Paperwork	Laboratory Analysis	Total
UK	**£6,900**	**£37,800**	**£44,700**
England	£5,723	£27,900	£33,623
Scotland	£471	£3,150	£3,621
Wales	£324	£2,700	£3,024
Northern Ireland	£383	£4,050	£4,433

Notes: Wage rates have been obtained from the Annual Survey of Household Earnings 2008 (http://www.statistics.gov.uk/statbase/product.asp?vlnk=15187). Costs use the hourly wage for an Environmental Health Officer (used as a proxy for a Trading Standards Officer) of £19.62 (including 30% uplift for overheads); the number of feed manufacturing premises has been obtained from the UK Inter Departmental Business Survey.

5.3 Benefits

5.3.1 Option 1

5.3.1.1 As the European Commission has now set maximum permitted levels for the carry-over of residues of coccidiostats and histomonostats, there are no benefits in maintaining the status quo.

5.3.2 Option 2

5.3.2.1 The potential benefits of option 2 -- i.e. the transposition of Commission Directive 2009/8/EC of 10 February 2009 -- include the relaxation of the existing requirement 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 that requirement 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 level is unknown, and therefore this benefit is non-monetised.

5.3.2.2 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.

5.3.2.3 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 European Commission's 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.

6. Small Firms Impact Test

6.1 The draft Regulations might be of benefit to small and medium-sized enterprises because the current costs of compliance with the existing zero tolerance for residues of coccidiostats and histomonostats are likely to bear more heavily on them than on larger companies. Further information on the potential impact of the draft Regulations on small businesses was sought as part of the public consultation and the Federation of Small Businesses was included in the consultation on these proposals. However, no information was received, and it is not, therefore, clear whether such benefits may be realised.

7. Legal Aid Impact Test

7.1 This test is not applicable here.

8. Test Run of Business Forms

8.1 No new or additional forms will be introduced.

9. Competition Assessment

9.1 Data from the Inter Departmental Business Register indicates that there are 420 premises manufacturing prepared feeds for farm animals in the UK.[1] Using regional data on the number of employees, the premises can be categorised by size as follows:

Region	Micro	Small	Medium	Large	Total
UK	235	140	45	0	420
England	173	103	33	0	310
Scotland	20	12	4	0	35
Wales	17	10	3	0	30
Northern Ireland	25	15	5	0	45

Source: Inter Departmental Business Register (2008)
Notes: Sizes are defined by number of employees per premises as follows: Micro – less than 10 employees; Small – 10-49 employees; Medium – 50-249 employees; Large – more than 250 employees. Distribution of premises by employee size is available only at UK level, for individual countries the UK distribution of premises by size is applied to the total number of animal feed manufacturing premises in each country.

9.2 The Food Standards Agency's preliminary assessment is that the Feed (Specified Undesirable Substances) (Scotland) Regulations 2009 will have little direct impact on competition in the UK feed industry. It will not limit the number or range of businesses operating in the sector by imposing exclusive rights to supply products or by creating a

[1] The Inter Departmental Business Register data can be accessed via the Office for National Statistics, http://www.statistics.gov.uk/idbr/idbr.asp

licensing scheme for them; it will not raise the costs of feed ingredients to some suppliers relative to others or alter the costs of entering or leaving the feed market; it will not limit the ability of businesses to compete by attempting to control the prices charged, to limit the scope for innovation or to restrict the ability to advertise feed products; and it will not limit incentives to compete by exempting any businesses from general competition law or by amending existing intellectual property rights.

10. Enforcement, Sanctions and Monitoring

10.1 Enforcement

10.1.1 Enforcement of the new tolerance levels in Scotland will be the responsibility of local authority trading standards departments. This is unchanged from the existing arrangements for the enforcement of animal feed legislation. The regulations have been drafted in accordance with Better Regulation principles.

10.2 Sanctions

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

10.3 Monitoring

10.3.1 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 Regulations.

11. Sustainability

11.1 Impacts under the three pillars of sustainable development (environmental, economic and social) have been considered in the preparation of this Impact Assessment. Option 2 is the most sustainable of the two options because it is more proportionate to the actual risks to animal and human health. In addition, the relaxation of the existing requirement to operate a zero tolerance principle for the potential presence of coccidiostats and histomonostats could mean that consignments of feed which would previously have breached that requirement will no longer have to be disposed of outside the feed chain.

12. Rural Proofing

12.1 It is considered that the Regulations are unlikely to have any particular implications for rural areas.

13. Implementation and delivery plan

13.1 Commission Directive 2009/8/EC introducing harmonised tolerance levels for residues of coccidiostats and histomonostats will be implemented in Scotland by the draft Feed (Specified Undesirable Substances) (Scotland) Regulations 2009. (There will be separate but parallel Regulations for England, Wales and Northern Ireland.) The Regulations will amend the Feeding Stuffs (Scotland) Regulations 2005 by introducing the 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).

14. Post-implementation review

14.1 Commission Directive 2009/8/EC requires that the tolerance levels of 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 EFSA and the results reported via the Standing Committee on the Food Chain and Animal Health, where any amendments would be put to a vote by the Member States.

15. Summary and Recommendation

15.1 The policy objectives of Commission Directive 2009/8/EC of 10 February 2009 are:

a) To ensure the proportionate management of any potential risks to animal and human health which may arise from the presence of residues of coccidiostats and histomonostats.

b) To introduce risk-based tolerance levels for these residues which will reduce the burdens on industry.

c) To ensure harmonisation across the EU and avoid any single-market problems which may arise from Member States setting their own national levels.

d) To link the permitted tolerances to enforcement provisions which will enable competent authorities to ensure in a proportionate manner the safety of feed products put into circulation.

15.2 The preferred option is to make Regulations to transpose this Commission Directive into national law – Option 2. This would set risk-based tolerance levels, ensure harmonisation across the EU, and be commensurate with the UK's obligations under the Treaty of Rome. Option 2 is more proportionate to the actual risks to animal and human health. In addition, it is the more sustainable of the two options because the relaxation of the existing requirement to operate a zero tolerance principle for the potential presence of coccidiostats and histomonostats could mean that consignments of feed which would previously have breached that requirement will no longer have to be disposed of outside the feed chain.

16. Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs.

Signed:

Date:

Cabinet Secretary for the Environment and Rural Affairs

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