EXPLANATORY MEMORANDUM TO

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

2009 No. 2825

1. This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 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. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 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.

4.2 The tolerance levels for residues of coccidiostats and histomonostats 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 England by an amendment to Schedule 5 to the Feeding Stuffs (England) Regulations 2005 (as amended), and will provide enforcement authorities with the means to help confirm the safety of feed products put into circulation.

5. Territorial Extent and Application

5.1 This instrument applies to England. Separate but parallel legislation is being made in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- What is being done and why

7.1 The European Food Safety Authority (EFSA) was asked by the Commission to undertake a risk assessment of the presence of residues of coccidostats and histomonostats in feed for non-target species and published a series of Opinions 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 tolerances of 3% for carry-over in feed for less sensitive non-target species and 1% for 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).

7.2 The Standing Committee also agreed to set tolerance levels for residues in premixtures to ensure that the premixture will not contribute more than 50% of the total carry-over in the finished feed; and to set a specific provision for chickens reared for laying (which have longer lifespans than chickens reared for their meat) to minimise the potential for the carry-over into eggs for human consumption.

7.3 These provisions were put out for consultation with relevant stakeholder organisations while they were under discussion in the Standing Committee, but no comments were received. The provisions were eventually adopted as Commission Directive 2009/8/EC of 10 February 2009.

7.4 The measure is expected to help reduce the administrative and policy burdens on the feed industry and livestock farmers, which will no longer be required to work to a zero tolerance for the presence of residues and will thus be permitted to undertake risk-based assessments of their likely presence in feed production runs. This could mean that consignments of feed which previously would have breached the zero tolerance requirement will no longer have to be disposed of outside the feed chain, which could lead to a reduction of the costs of compliance with the legislation. However, the potential benefit is difficult to assess because the number of consignments of feed currently disposed of due to the presence of residues of coccidiostats and histomonostats is unknown.

7.5 It was also thought that the introduction of tolerance levels could reduce the need for sampling and testing and feed products, and thus the costs of such analyses. Here again, however, the potential benefit is difficult to assess because the current level of testing exclusively for coccidiostats and histomonostats is unknown.

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 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.

- Consolidation

7.6 The Feeding Stuffs (England) Regulations 2005 mentioned in paragraph 4.2 above have previously been amended a number of times, but are not being consolidated on this occasion because five of the EC Directives they implement have recently been consolidated into a single EC Regulation which will apply in Member States from September 2010. The 2005 Regulations will be revoked and remade in considerably altered form to give effect to this development.

8. Consultation outcome

8.1 Ten responses were received to the public consultation on the draft Regulations. All were content with or had no comments on the proposed tolerances for carry-over, although questions were asked about the ability of laboratories to analyse for these substances. However, the Food Standards Agency considers that relevant laboratories will be identifiable through the list maintained by the United Kingdom Accreditation Service (UKAS), which is responsible for laboratory auditing and accreditation.

8.2 Questions were also asked about enforcement procedures and a suggestion made that there should be a formal interface between local authority trading standards departments, which are responsible for testing for the presence of undesirable substances, and Defra's Veterinary Medicines Directorate (VMD), which is responsible for testing for the presence of residues of veterinary and medicinal substances. It was also suggested that there should be a formal protocol for sampling and analysis of these substances, to ensure the consistency and repeatability of results when testing at very low levels, and for the enforcement action to be taken when the MPLs are found to have been breached or the analysed levels are just below the maxima.

8.3 The Food Standards Agency considers that these issues are best addressed by the Animal Feed Law Enforcement Liaison Group (AFLELG), which comprises representatives of UK enforcement authorities and government departments and meets twice a year to discuss feed enforcement issues. AFLELG has held a preliminary discussion of the issues arising from this measure; further discussion will cover procedures for the exchange of information and the co-ordination of enforcement action. If necessary, an appropriate amendment can be made to the existing Memorandum of Understanding between LACORS (the Local Authorities Coordinators of Regulatory Services), the body which represents local authority trading standards departments, and VMD.

8.4 However, the Agency does not consider that a formal enforcement protocol is required, as local authorities are already aware of the need to base enforcement action

on representative samples and are familiar with the application of existing provisions to their sampling and analysis work. The main purpose of sampling will be to establish that manufacturers' feed safety management systems are sufficient to prevent breaches of the tolerance levels, and where any are found the principal response will be to determine why those systems failed and what remedial action should be taken.

9. Guidance

9.1 The Food Standards Agency does not currently consider that any guidance in respect of the interpretation of the measure's provisions is necessary, as they are self-explanatory. However, the question of whether guidance may be required for enforcement officers will be kept under review by AFLELG.

10. Impact

10.1 The likely impact on business is summarised at paragraph 7.4 above. No impact on charities or voluntary bodies is anticipated.

10.2 The likely impact on the public sector is summarised at paragraph 7.5 above.

10.3 An Impact Assessment is attached to this memorandum.

11. Regulating small business

11.1 The legislation will apply to small businesses, which will not be exempted from the measure because it is not introducing any new burdens for business.

12. Monitoring & review

12.1 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 European Food Safety Authority 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.

13. Contact

Tim Franck or Joseph Nicholas in the Animal Feed Branch at the Food Standards Agency are available to deal with any queries regarding the instrument -- telephone 020 7276 8471 or 020 7276 8462 or email <tim.franck@foodstandards.gsi.gov.uk> or <joseph.nicholas@foodstandards.gsi.gov.uk>

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 (England) Regulations 2005	S of S for Health through implementing Regulations

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	**Impact Assessment of THE FEED (SPECIFIED UNDESIRABLE SUBSTANCES) (ENGLAND) REGULATIONS 2009**	
Stage: Post-Consultation	**Version:** 2	**Date:** 13 October 2009
Related Publications: Ministerial Submission		

Available to view or download at:

http://www.

Contact for enquiries: Joseph Nicholas, Animal Feed Branch **Telephone:** 020 7276 8462

What is the problem under consideration? Why is government intervention necessary?

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 to help prevent infestations of the gastro-intestinal tract by certain single-celled micro-organisms (protozoa), mainly in poultry. Consumers cannot directly observe these feed production processes to assess the potential risks and make informed choices about them. Government intervention to set harmonised tolerance levels to protect the health of animals and human consumers of animal products is thus required.

What are the policy objectives and the intended effects?

1. 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.
2. To introduce risk-based tolerance levels for these residues which will reduce the burdens on industry.
3. To ensure harmonisation across the EU and avoid any single-market problems which may arise from Member States setting their own national levels.
4. 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.

What policy options have been considered? Please justify any preferred option.

1. Do nothing. The status quo would therefore be continued, i.e. no residues of coccidiostats and histomonostats would be tolerated in feed for species for which they were not intended.
2. Make Regulations to transpose Commission Directive 2009/8/EC of 10 February 2009 into national law. This is the preferred option because it would set risk-based tolerance levels, ensure harmonisation across the EU, and be commensurate with the UK's obligations under the Treaty.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

Maximum permitted levels for undesirable substances are frequently reviewed by the European Food Safety Authority in the light of their actual incidence and current scientific evidence. The results are discussed and voted upon in the Standing Committee on the Food Chain and Animal Health (Animal Nutrition Section). EFSA is required to review these particular levels no later than 1 July 2011.

Ministerial/CEO Sign-off For Final Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister:

Gillian Merron .....Date: ***21st October 2009***

Summary: Analysis & Evidence

Policy Option: 2	Description: Implementation of Commission Directive 2009/8/EC

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ 16,000	**1**
Average Annual Cost (excluding one-off)	
£ 45,000	

Description and scale of **key monetised costs** by 'main affected groups' One-off familiarisation costs to animal feed manufacturers and local authorities (£16,000). Annual administrative costs of additional sampling for local authorities (£45,000).

Total Cost (PV) **£ 225,000**

Other **key non-monetised costs** by 'main affected groups' Possible increased frequency of feed sampling to ensure residues remain within the new maximum permitted levels; possible costs to laboratories of investment in new analytical equipment.

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ Not known	
Average Annual Benefit (excluding one-off)	
£ Not known	

Description and scale of **key monetised benefits** by 'main affected groups' None quantified. Quantified monetary information on the potential benefits was sought as part of the public consultation, but none was forthcoming from any group of stakeholders.

Total Benefit (PV) **£**

Other **key non-monetised benefits** by 'main affected groups' Reduction of the quantities of feed which have to be disposed of outside the feed chain because of the increased tolerances; reduction in the costs of compliance with the legislation.

Key Assumptions/Sensitivities/Risks

Time required for familiarisation with the new requirements is 1 hour per business premise and each local authority.

Price Base Year 2008	Time Period Years 5	**Net Benefit Range** (NPV) **£ -225,000**	**NET BENEFIT** (NPV Best estimate) **£ -225,000**

What is the geographic coverage of the policy/option?			UK	
On what date will the policy be implemented?			Mid-November 2009	
Which organisation(s) will enforce the policy?			Local authorities	
What is the total annual cost of enforcement for these organisations?			£ 45,000	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ N/A	
What is the value of changes in greenhouse gas emissions?			£ N/A	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro **0**	Small **0**	Medium **0**	Large **0**
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** **£** N/A

Evidence Base (for summary sheets)

1. Reasons for Government Intervention

1.1 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 (borne by 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.

1.2 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 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.

1.3 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, 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. Intended Effect of the Measure

2.1 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.

2.2 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 technically 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.

2.3 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 these 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 human consumers of animal products which may arise from the presence of residues of these substances in the feed received by non-target species of animals.

2.4 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 animal 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 England by an amendment to Schedule 5 to the Feeding Stuffs (England) Regulations 2005 (as amended), and will provide enforcement authorities with the means to help confirm the safety of feed products put into circulation.

3. Background to Commission Directive 2009/8/EC

3.1 The European Food Safety Authority (EFSA) 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).

3.2 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.

3.3 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 as Commission Directive 2009/8/EC of 10 February 2009.

4. Policy Options for the UK

4.1 There would appear to be two options available to the UK:

- 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.

Option 1: do nothing

4.2 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 EFSA 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.

4.3 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 by the Commission in the European Court of Justice and, if the Commission were successful, potentially unlimited daily fines for non-transposition of the measure.

Option 2: transpose Commission Directive 2009/8/EC into national law

4.4 Transposition of Commission Directive 2009/8/EC would be commensurate with the UK's obligations under the Treaty and would introduce measures which are proportionate to the potential risks to animal and human health. Transposition 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 have been determined, and are thus safe for their intended uses.

5. Potential Benefits of Commission Directive 2009/8/EC

5.1 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.

5.2 It was initially thought that the introduction of risk-based tolerance levels could reduce the need for sampling and testing feed products for residues of coccidiostats and histomonostats, 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 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 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. Potential Costs of Commission Directive 2009/8/EC

6.1 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, which was confirmed by one of the industry stakeholders who responded to the consultation. However, this stakeholder also suggested that to ensure compliance with the measure it might be necessary to increase sampling frequency above that required for current quality assurance purposes. Although this could have some additional marginal costs, no figures were provided in support of this suggestion.

6.2 It was also suggested that on-farm mixers producing feed containing coccidiostats and histomonostats for use on their own holding might need to purchase sampling equipment because the introduction of tolerance levels for carry-over could lead to a relaxation of the thoroughness of their previous equipment cleaning regimes. However, any such relaxation might lead to a breach of the requirements of the EC Feed Hygiene Regulation, which among other things sets standards for the cleanliness of equipment and to which on-farm mixers will continue to adhere.

6.3 Were any farmers to purchase sampling equipment of their own, it seems likely that such a purchase would be a one-off capital cost rather than a continuing cost. However, no figures were provided in support of the suggested purchase. In addition, the Food Standards Agency is aware from other sources that the actual number of farmers registered to mix these substances on their own holdings is very small, at around 30 farms, and the potential impact of any such capital costs -- if actually incurred -- would therefore be very limited.

6.4 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 Inter Departmental Business Survey (see the Competition Assessment in the Annex).

7. Administrative Burden Costs

7.1 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. One response to the consultation 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.

7.2 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.

7.3 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 7.1, 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 Inter Departmental Business Survey (see the Competition Assessment in the Annex).

8. Consultation

8.1 Key stakeholders were kept apprised of the content of the draft Directive while it was under discussion in the Standing Committee in Brussels. The public consultation on the draft Feed (Specified Undesirable Substances) (England) Regulations 2009 to transpose Commission Directive 2009/8/EC into law in England 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) (England) Regulations 2009;
- information on the potential benefits of the introduction of maximum permitted levels for residues of coccidiostats 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.

8.2 Ten responses were received in all -- two 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 either content with or had no comments on the proposed tolerances, expressed as maximum permitted levels, for the carry-over of coccidiostats and histomonostats into feed for non-target species. The comments received on the potential benefits and costs associated with the introduction of these MPLs are summarised in sections 5 to 7 above. Two stakeholders raised the issue of whether laboratories have the capability to undertake analyses of these substances and are suitably accredited; the Food Standards Agency considers that laboratories with the capacity to undertake such work will be readily identifiable through the list maintained by the United Kingdom Accreditation Service (UKAS), which is responsible for the auditing and accreditation of laboratories. No comments were received from stakeholders representing laboratories and public analysts.

8.3 Two stakeholders also raised questions over procedures for the enforcement of the measure's provisions, suggesting that in their view there will be a need for a formal interface between local authority trading standards departments, which are responsible for testing for the presence of undesirable substances, and Defra's Veterinary Medicines Directorate (VMD), which is responsible for testing for the presence of residues of veterinary and medicinal substances. One of these two stakeholders also suggested that there may also be a need for a formal protocol for (a) the sampling and analysis of these substances, in particular to ensure the consistency and repeatability of results when testing at very low levels, and (b) for the enforcement action to be taken when the MPLs are found to have been breached or the analysed levels are just below the maxima.

8.4 The Food Standards Agency has considered the issues raised in paragraph 8.3, and has agreed that they will best be addressed by the Animal Feed Law Enforcement Liaison Group (AFLELG). This body comprises representatives of UK enforcement authorities and government departments with an interest in animal feed law, and meets twice a year to discuss enforcement related issues, to identify common problems and to agree a consistent and co-ordinated approach to feed law enforcement. AFLELG has already held a preliminary discussion of the issues arising from this measure; further discussions will cover procedures for the exchange of information between local authorities and VMD and the co-ordination of enforcement action where concern has been caused by individual results. Consideration will also be given to making an appropriate amendment to the existing Memorandum of Understanding between LACORS (the Local Authorities Coordinators of Regulatory Services), the body which represents local authority trading standards departments, and VMD.

8.5 However, the Food Standards Agency does not consider it necessary to draw up formal enforcement protocols for this new area of work, as local authorities are already aware of the need to base enforcement action on representative samples and are familiar with the application of existing provisions to their sampling and analysis work. The main purpose of surveillance sampling will be to establish that manufacturers' feed safety management systems are sufficiently robust to prevent breaches of the tolerance levels, and where any are found the principal response will be to determine why those systems failed and what remedial action should be taken.

9. Enforcement

9.1 Enforcement of the new tolerance levels in England will be the responsibility of local authority trading standards departments. This is unchanged from the existing arrangements for the enforcement of animal feed legislation.

10. Simplification

10.1 The Feed (Specified Undesirable Substances) (England) Regulations 2009 can be classified as a simplificatory measure because the introduction of tolerances for technically unavoidable residues of coccicidostats and histomonostats is expected to help reduce the costs of compliance with EC animal feed legislation.

11. Implementation and Review

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

Specific Impact Tests: Checklist

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	Not applicable	No
Sustainable Development	No	Yes
Carbon Assessment	Not applicable	No
Other Environment	Not applicable	No
Health Impact Assessment	No	Yes
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

Annexes

Competition Assessment

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 regions the UK distribution of premises by size is applied to the total number of animal feed manufacturing premises in each region.

2. The Food Standards Agency's preliminary assessment is that the Feed (Specified Undesirable Substances) (England) 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 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.

Small Firms Impact Test

3. 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; however, no such information was forthcoming, and it is not therefore clear whether such benefits may in fact be realised.

Sustainable development

4. 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.

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

Health Impact Assessment

5. The tolerances laid down in the draft Regulations were assessed by the European Food Safety Authority prior to their adoption by the Standing Committee. The Agency considers them to be proportionate to the risk to human health.

Race equality issues

6. The Agency considers that the draft Regulations are unlikely to have any implications for or impact on race equality issues.

Disability equality issues

7. The Agency considers that the draft Regulations are unlikely to have any implications for or impact on disability equality issues.

Gender equality issues

8. The Agency considers that the draft Regulations are unlikely to have any implications for or impact on gender equality issues.

Human Rights

9. The Agency considers that the draft Regulations are unlikely to have any implications for or impact on human rights issues.

Rural Proofing

10. The Agency considers that the draft Regulations are unlikely to have any particular implications for rural areas.