

FOOD STANDARDS AGENCY CONSULTATION
Title: THE FEED (SPECIFIED UNDESIRABLE SUBSTANCES)
(ENGLAND) REGULATIONS 2009

CONSULTATION SUMMARY PAGE

Date consultation launched:	Closing date for responses:
23 March 2009	15 June 2009

Who will this consultation be of most interest to?

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

What is the subject of this consultation?

A draft Statutory Instrument to transpose Commission Directive 2009/8/EC setting maximum permitted levels for the carry-over of residues of coccidiostats -- substances intended to help prevent coccidiosis, or infestations of the gastro-intestinal tract by certain single-celled micro-organisms (protozoa), mainly in poultry -- into feed for other species.

What is the purpose of this consultation?

To seek stakeholder views on whether the draft Statutory Instrument appropriately and proportionately transposes the Annex to the Commission Directive, setting out the tolerances for the carry-over of these products.

Responses to this consultation should be sent to:

Name Joseph Nicholas
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FOOD STANDARDS AGENCY
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Is an Impact Assessment included with this consultation?

Yes

No See Annex A for reason.



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

Dear Colleague

DETAIL OF CONSULTATION

Introduction

1. At present, there are no tolerances for the potential carry-over of technically unavoidable residues of coccidiostats in feed intended for one species of farmed livestock into feed for another. This can be a particular problem for feed business operators who are producing a range of feedingstuffs within one establishment, where a number of different feed products may be manufactured on the same production line. Commission Directive 2009/8/EC of 10 February 2009 sets maximum permitted levels for these residues, to provide harmonised Community rules in this area without posing increased risks to animal and human health. The measure requires transposition into law in England.

Proposals

2. The Directive's key features are set out in the box immediately below.

- **The maximum permitted levels for the potential carry-over of coccidiostats into feed are laid down by amendment to the Annex to Directive 2002/32 on undesirable substances in feed.**
- **These maximum permitted levels will be implemented in England by an amendment to the Feeding Stuffs (England) Regulations 2005.**
- **There is a parallel measure, which will be subject to a separate consultation, for residues of coccidiostats in animal products for human consumption, to reflect the potential for their carry-over from feed into milk, meat and eggs.**

3. Coccidiostats are substances intended to help prevent coccidiosis -- i.e., infestations of the gastro-intestinal tract by certain single-celled micro-organisms (protozoa), mainly in poultry -- which are authorised under EC Regulation 1831/2003 on feed additives. Authorisations under this Regulation typically set the conditions of use, such as the species for which the specific products are intended, their maximum inclusion rates in finished feed, and the required labelling declarations.

4. EC Regulation 183/2005 on feed hygiene lays down specific requirements for feed businesses which use coccidiostats. In particular, they must take measures to avoid any cross-contamination of their facilities (production, storage, transport and other equipment) to ensure that any residues of these products are not present in feed for species for which they are not authorised (non-target species).

5. Feed business operators will take measures to minimise the potential for cross-contamination, but in practice the presence of such residues may be technically unavoidable, in particular where feed business operators are

manufacturing a range of feedingstuffs within the same establishment and different types of feed products are being turned out on the same production line. This cross-contamination -- known as carry-over -- typically occurs where residues from one production run are incorporated in the start of the following production run. At present, there are no tolerance levels for such instances of carry-over, although there is a need for harmonised tolerance levels throughout the EU to avoid Member States setting their own, different national limits which would vary depending 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.

6. Commission Directive 2009/8/EC of 10 February 2009 lays down risk-based tolerance levels for carry-over. Two rates are set, as follows:

- 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).

The levels were set following an assessment by the European Food Safety Authority of the likely risks to animal and human health.

7. The levels are being introduced as maximum permitted levels (MPLs) for a new category of undesirable substances in Schedule 5 to the Feeding Stuffs (England) Regulations 2005 (as amended). This will transpose into national legislation the provisions of the Annex to Directive 2009/8/EC, and is without prejudice to the authorisation of these substances as feed additives under EC Regulation 1831/2003.

8. There is a parallel measure for the carry-over of residues of coccidiostats into food for human consumption. These tolerances are being introduced by an EC Regulation which will be directly applicable in all Member States and on which Agency colleagues responsible for food contaminants legislation are consulting as part of a consolidation of that legislation.

Consultation Process

9. Key stakeholders were kept apprised of the content of the draft Directive while it was under discussion at the Standing Committee in Brussels. We are now formally consulting on the draft Feed (Specified Undesirable Substances) (England) Regulations 2009 to transpose the Directive's provisions into law in England. (There will be separate but parallel consultations in Scotland, Wales and Northern Ireland.) The issues on which we would like stakeholders' views are set out in the box immediately below. Comments from small businesses are particularly requested.

1. **Comments on the maximum permitted levels set out in the Schedule to the draft Feed (Specified Undesirable Substances) (England) Regulations 2009.**
2. **Information on the potential benefits of the introduction of maximum permitted levels for residues of coccidostats in feed for non-target species. It would be helpful if these benefits could be quantified in monetary terms, wherever possible.**
3. **Comments on the assumption that there will be no new costs associated with the introduction of these maximum permitted levels.**
4. **The ability of laboratories to analyse down to the maximum permitted levels to be introduced by the draft Regulations.**
5. **Comments from enforcement authorities in particular on the potential impact on their work of the new maximum permitted levels, including any potential reduction in the frequency of sampling and analysis. It would be helpful to have this quantified in monetary terms, wherever possible.**
6. **Any other comments stakeholders may have on the draft Feed (Specified Undesirable Substances) (England) Regulations 2009.**

10. All comments received will be summarised and published on the Food Standards Agency website as part of the post-consultation action unless stakeholders particularly request that their comments be treated as confidential. Comment may be made by post, by fax, or by e-mail.

Other Relevant Documents

11. The Directive which the draft Regulations are intended to transpose is published on the Commission's website at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:040:0019:0025:EN:PDF>

Responses

12. **Responses are requested no later than 15 June 2009.** Please state, in your response, whether you are responding as a private individual or on behalf of an organisation or company (including details of any stakeholders your organisation represents).

13. Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Keith Millar', written in a cursive style.

K MILLAR
Head of Animal Feed Unit
Food Safety: Hygiene and Microbiology Division

Enclosures

Annex A: Standard Consultation Information
Annex B: Impact Assessment
Annex C: List of Interested Parties
Annex D: The draft Feed (Specified Undesirable Substances) (England) Regulations 2009

STANDARD CONSULTATION INFORMATION

Queries

1. If you have any queries relating to this particular consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of Personal Data and Confidentiality of Responses

2. In accordance with the Food Standards Agency's principle of openness, our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The Agency will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which can be found on the Agency's website at <http://www.food.gov.uk/multimedia/pdfs/dataprotection.pdf> Please note that return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000 and the Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the Food Standards Agency. However, we will take your views into account when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further Information

5. A list of interested parties to whom this letter is being sent appears at Annex B. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. A Welsh version of the consultation package can be found at www.food.gov.uk

7. Please contact us for alternative versions of the consultation documents in Braille, or other languages or audiocassette.

8. Please let us know if you need paper copies of the consultation documents or of anything specified under the **Other Relevant Documents** section of the consultation letter.

9. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at:
<http://www.berr.gov.uk/files/file47158.pdf> The Consultation Criteria are available at
<http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44458.html>

10. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. The Impact Assessment for this consultation is at Annex B.

11. For details about the consultation process (not about the content of this particular consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 2C, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8630.

Comments on the Consultation Process Itself

12. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by completing the Consultation Feedback Questionnaire at
<http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc>

13. If you would like to be included in future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire. The Questionnaire can also be used to update us about your existing contact details.

Summary: Intervention & Options

Department /Agency:
Food Standards Agency

Title:
Impact Assessment of COMMISSION DIRECTIVE
2009/8/EC OF 10 FEBRUARY 2009 ON THE CARRY-
OVER OF COCCIDIOSTATS INTO FEED FOR NON-
TARGET SPECIES

Stage: Consultation

Version: 1

Date: 9 March 2009

Related Publications: Consultation Letter

Available to view or download at:

<http://www.>

Contact for enquiries: Joseph Nicholas, Animal Feed Unit

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, technically unavoidable residues of coccidiostats may be present. 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.

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.
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 coccidiostat residues 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 of Rome.

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 reviewed by EFSA in the light of their actual incidence and current scientific evidence, the results of which 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 tolerance levels no later than 1 July 2011.

Ministerial/CEO Sign-off For SELECT STAGE Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister/Chief Executive*:



Date: 12/3/09

* for Impact Assessments undertaken by non-ministerial departments/agencies and NOT being considered by Parliament

Summary: Analysis & Evidence

Policy Option: 2

Description: Implementation of Commission Directive 2009/8/EC

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups' Quantified monetary information on the potential costs will be sought as part of the public consultation.
	One-off (Transition)	Yrs	
	£		
	Average Annual Cost (excluding one-off)		
	£		Total Cost (PV) £
Other key non-monetised costs by 'main affected groups' Possible increased costs 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		Description and scale of key monetised benefits by 'main affected groups' Quantified monetary information on the potential benefits will be sought as part of the public consultation.
	One-off	Yrs	
	£		
	Average Annual Benefit (excluding one-off)		
	£		Total Benefit (PV) £
Other key non-monetised benefits by 'main affected groups' Reduction of administrative and policy burdens on the feed industry and enforcement authorities, so reducing the costs of complying with the legislation.			

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	Net Benefit Range (NPV) £	NET BENEFIT (NPV Best estimate) £
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What is the geographic coverage of the policy/option?			UK		
On what date will the policy be implemented?			1 July 2009		
Which organisation(s) will enforce the policy?			Local Authorities		
What is the total annual cost of enforcement for these organisations?			£		
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?			£		
What is the value of changes in greenhouse gas emissions?			£		
Will the proposal have a significant impact on competition?			No		
Annual cost (£-£) per organisation (excluding one-off)		Micro	Small	Medium	Large
Are any of these organisations exempt?		No	No	N/A	N/A

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

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 (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.

1.2 The carry-over of residues of coccidiostats -- substances intended to help prevent coccidiosis, i.e. 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 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. Intended Effect of the Measure

2.1 Coccidiostats 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 unavoidable traces of one product remaining in the production line and thus becoming incorporated in the production of another feed product. This transfer, or carry-over, from one product to another is called "cross-contamination", 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, and the draft Regulations to transpose it into national law in England, are intended to assist the operation of the Single Market by preventing Member States setting their own, different national limits for technically unavoidable residues of coccidiostats based on their differing analytical abilities and thus their rates of detection of those residues. The measure is also 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 of these substances and will thus be permitted to undertake risk-based assessments of their likely presence in their 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 of coccidiostats 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 Directive 2002/32 on undesirable substances in feed, and is without prejudice to the authorisation of coccidiostats as feed additives under EC Regulation 1831/2003. The amendments to the Directive will be transposed 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 was asked by the Commission to undertake a risk assessment of the presence of residues of authorised coccidostats 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) which would ensure that, when their instructions for use were correctly followed, the premixture would 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 by the Commission 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; 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 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.

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 of Rome and 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 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. 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, which 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. This could in turn lead to a reduction of the costs of compliance with the legislation. Local authorities may also benefit from the introduction of risk-based tolerance levels because of a reduced need for their officers to sample and test feed products, and thus a reduction in the costs associated with such analyses. However, further information on these potential benefits will be sought as part of the public consultation on the transposition of the measure.

5.2 The measure is generally 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). 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 it is considered that the Directive will not be 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 in feed for non-target species. However, further information on any potential costs will be sought as part of the public consultation on the transposition of the measure.

7. Administrative Burden Costs

7.1 Information on whether there are any administrative burdens will be sought as part of the public consultation on the transposition of the measure.

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 results of the public consultation which will be undertaken on the draft Feed (Specified Undesirable Substances) (England) Regulations 2009 to transpose Commission Directive 2009/8/EC into law in England will be summarised once that consultation has been concluded.

8.2 Stakeholders will be asked in particular to comment 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 in feed for non-target species. It would be helpful if these benefits could be quantified in monetary terms, wherever possible;
- comments on the assumption that there will be no new costs associated with the introduction of these maximum permitted levels;
- the ability of laboratories to analyse down to the maximum permitted levels to be introduced by the draft Regulations;
- comments from enforcement authorities in particular on the potential impact on their work of the new maximum permitted levels, including any potential reduction in the frequency of sampling and analysis. It would be helpful to have this quantified in monetary terms, wherever possible; and
- any other comments stakeholders may have on the draft Feed (Specified Undesirable Substances) (England) Regulations 2009.

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 draft Feed (Specified Undesirable Substances) (England) Regulations 2009 can be classified as a simplificatory measure because the introduction of tolerances for technically unavoidable residues of coccidiostats 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 will be implemented in England by the draft Feed (Specified Undesirable Substances) (England) Regulations 2009. (There will be separate but parallel Regulations for Scotland, Wales and Northern Ireland.) The Regulations are intended to 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 be reviewed in the light of developments in scientific and technical knowledge no later than 1 July 2011.

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	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
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

Competition Assessment

1 Detailed information on the number, size, market share and geographical location of businesses operating in the animal feed manufacturing sector is not available, as statistical data of this nature has not been collected for some years. It is therefore not possible to give an accurate picture of the sector's economic position. However, it is known that national production of compound feed is characterised by two large companies which account for approximately 50% of the sector, with the remainder accounted for by compounders that do not manufacture or distribute on a national basis but have significant capacity in certain parts of the UK, and by co-operative or farmer-controlled compounders that have other interests in addition to feed manufacture, such as wholesaling and retailing.

2 Information collated by the Inter-Departmental Business Register, a database of the Office of National Statistics, showed that as at September 2008 there were 415 companies in the UK recorded as engaged in the "manufacture of prepared animal feeds", although this figure would have included firms producing pet food as well as feed for farmed livestock and horses. However, it excludes firms producing fish meal and oil seed cake. Data on total turnover and number of employees engaged in the sector does not appear to be collected.

3 The Food Standards Agency's preliminary assessment is that the draft Regulations 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

4. 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 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 will be sought as part of the public consultation.

Sustainable development

5. 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 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.

Health Impact Assessment

6. 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

7. It is considered that the draft Regulations are unlikely to have any implications for or impact on race equality issues.

Disability equality issues

8. It is considered that the draft Regulations are unlikely to have any implications for or impact on disability equality issues.

Gender equality issues

9. It is considered that the draft Regulations are unlikely to have any implications for or impact on gender equality issues.

Human Rights

10. It is considered that the draft Regulations are unlikely to have any implications for or impact on human rights issues.

Rural Proofing

11. It is considered that the draft Regulations are unlikely to have any implications for rural areas in general.

LIST OF INTERESTED PARTIES

Bruce Cottrill, ADAS
Advisory Committee on Animal Feedingstuffs
Andrew Eldridge, Advisory Committee on Organic Standards
Judith Nelson, Agricultural Industries Confederation
George Perrott, Agricultural Industries Confederation
Ian Scott, Animal Health Distributors Association
John Millward, Animal Medicines Inspectorate
Andrew Mackie, Association of Public Analysts
Peter Rotheram, Association of Port Health Authorities
David Clarke, Assured Food Standards
Philippa Wiltshire, Assured Food Standards
Mr D Frei, Beth-Din
Ruth Evans, Brewing, Food & Beverage Industry
Harry Evans, British Association of Feed Supplement and Additive Manufacturers
Roger Earl, British Association of Green Crop Driers
Keith Cutler, British Cattle Veterinary Association
Mark Williams, British Egg Industry Council
Natalie Evans, British Chambers of Commerce
Claire Williams, British Equestrian Trade Association
Deidre Carson, British Equine Veterinary Association
Paula Foote, British Free Range Egg Producers Association
Sue Knowles, British Goat Society
David Collins, British Institute of Agricultural Consultants
Marcus Bates, British Pig Association
Peter Bradnock, British Poultry Council
Andrew Opie, British Retail Consortium
Andrea Martinez-Inchausti, British Retail Consortium
Alistair Carson, British Society of Animal Science
Helen Edge, British Society of Animal Science
David Bassett, British Trout Association
Celia Bennett, British Veterinary Association
Jenny Morris, Chartered Institute of Environmental Health
Peter Stephenson, Compassion in World Farming
Jill Johnstone, Consumer Focus
Wendy Cave, Co-operative Group (CWS) Limited
Henry Aubrey-Fletcher, Country Land and Business Association
Ed Komorowski, Dairy UK Limited
Robin Manning, Department for Environment, Food and Rural Affairs
Clare Druce, Farm Animal Welfare Network
Nick Winch, Federation of Small Businesses
Bill Harris, Feed Fat Association
Karen Green, Fishmeal Information Network
Tim Lobstein, Food Commission
Lynn Insall, Food and Drink Federation
Keneth Chinyama, Food and Drink Federation

James McCulloch, The George Group
Michael Putnam, The George Group
Paul Curtis, Grain and Feed Trade Association
June Pearson, Grain and Feed Trade Association
Masood Khawaja, Halal Food Authority
Jeremy Boxall, LEAF (Linking Environment and Farming)
Les Bailey, Local Authorities Coordinators of Regulatory Services
Muhammad Abdul Bari, Muslim Council of Britain
Jill Hewitt, National Association of Agricultural Contractors
Eva Neary, National Association of British and Irish Millers
Tim Brigstocke, National Cattle Association (Dairy)
Monica Hall, National Council of Women
Stella Nicholas, National Consumer Federation
Helen Ferrier, National Farmers Union
Hannah Moule, National Farmers Union
Jana Osborne, National Federation of Women's Institutes
Stephen Dawson, National Office of Animal Health
Neville Chandler, National Renderers Association
Peter Morris, National Sheep Association
Janet Nunn, Pet Care Trust
Michael Bellingham, Pet Food Manufacturers Association
Monika Prenner, Pet Food Manufacturers Association
John Avizienius, Royal Society for the Prevention of Cruelty to Animals
Lynda Simmons, Seed Crushers and Oil Processors Association
Mabel Foye, Society of Feed Technologists
Francis Blake, Soil Association
Jeanette Longfield, SUSTAIN
Margerie Hall, Townswomen
Sandy Driskell, Trading Standards Institute
Yvette Layzell, Trading Standards Institute
Syed Aziz Pasha, Union of Muslim Organisations of UK and Eire
John Perry, United Kingdom Association of Fish Meal Manufacturers
Nikki Robertson, UK Renderers Association
Nick Renn, Veterinary Medicines Directorate
Janis McDonald, Veterinary Medicines Directorate
Sue Archer, Women's Food and Farming Union

STATUTORY INSTRUMENTS

2009 No.0000

AGRICULTURE, ENGLAND

**The Feed (Specified Undesirable Substances) (England)
Regulations 2009**

<i>Made</i>	- - - -	<i>Nth Month 2009</i>
<i>Laid before Parliament</i>		<i>Nth Month 2009</i>
<i>Coming into force</i>	- -	<i>2009</i>

The Secretary of State makes the following Regulations in exercise of the powers conferred on him by sections 66(1), 74A and 84 of the Agriculture Act 1970(a), as read with regulation 14 of the Food Standards Act 1999 (Transitional and Consequential Provisions and Savings) (England and Wales) Regulations 2000(b) and with Articles 2 and 6 of the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002(c).

There has been consultation during the preparation of these Regulations in accordance with the requirements of section 84(1) of the Agriculture Act 1970 or as appropriate of Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council (d) laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Title and Commencement

1. These Regulations may be cited as the Feed (Specified Undesirable Substances) (England) Regulations 2009 and come into force on [—] 2009.

Amendments to the Feeding Stuffs (England) Regulations 2005

2. At the end of Schedule 5 (prescribed limits for undesirable substances) to the Feeding Stuffs (England) Regulations 2005(e) add the entries set out in the Schedule to these Regulations.

Signed by authority of the Secretary of State for Health

- (a) 1970 c.40. Section 66(1) contains definitions of the expressions “the Ministers”, “prescribed” and “regulations”. The definition of “the Ministers” was amended by the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272), Schedule 5, paragraph 1. Functions of “the Ministers”, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46). By virtue of S.I. 1999/3141, functions of the Secretaries of State for Wales and Scotland previously exercisable in relation to England ceased to be so exercisable and were transferred to the Minister of Agriculture, Fisheries and Food. Section 74A was inserted by the European Communities Act 1972 (1972 c. 68), Schedule 4, paragraph 6.
- (b) S.I. 2000/656.
- (c) S.I. 2002/794.
- (d) OJ No. L31, 1.2.2002, p.1, as last amended by Regulation (EC) No. 202/2008 (OJ No. L60, 5.3.2008, p.17).
- (e) S.I. 2005/3281, as amended by S.I. 2006/113, S.I. 2006/2808, S.I. 2006/3120, S.I. 2007/3008, S.I. 2008/1523 and S.I. 2009/28.

Date

Dawn Primarolo
Minister of State
Department of Health

SCHEDULE

Regulation 2

Entries to comprise Chapter E of Schedule 5 to the Feeding Stuffs (England) Regulations 2005

<i>Column 1: Undesirable substances</i>	<i>Column 2: Products intended for animal feed</i>	<i>Column 3: Maximum content in mg/kg of feeding stuffs referred to a moisture content of 12%</i>
CHAPTER E		
Lasalocid sodium	Feed materials	1.25
	Compound feeding stuffs for: — dogs, calves, rabbits, equine species, dairy animals, laying birds, turkeys (> 12 weeks old) and chickens reared for laying (> 16 weeks old)	1.25
	— chickens for fattening, chickens reared for laying (< 16 weeks old) and turkeys (< 12 weeks old) for the period before slaughter in which the use of lasalocid sodium is prohibited	1.25
	— other animal species Premixtures for use in feed in which the use of lasalocid sodium is not authorised	3.75 (1)
Narasin	Feed materials	0.7
	Compound feeding stuffs for: — turkeys, rabbits, equine species, laying birds and chickens reared for laying (> 16 weeks old)	0.7
	— chickens for fattening for the period before slaughter in which the use of narasin is prohibited	0.7
	— other animal species Premixtures for use in feed in which the use of narasin is not authorised	2.1 (1)
Salinomycin sodium	Feed materials	0.7
	Compound feeding stuffs for: — equine species, turkeys, laying birds and chickens reared for laying (> 12 weeks old)	0.7
	— chickens for fattening, chickens reared for laying (< 12 weeks old) and rabbits for fattening for the period before slaughter in which the use of salinomycin sodium is prohibited	0.7
	— other animal species Premixtures for use in feed in which the use of salinomycin sodium is not authorised	2.1 (1)
Monensin sodium	Feed materials	1.25
	Compound feeding stuffs for: — equine species, dogs, small ruminants (sheep and goats), ducks, dairy cattle and other bovines, laying birds, chickens reared for laying (> 16 weeks old) and turkeys (>16 weeks old)	1.25

	<p>— chickens for fattening, chickens reared for laying (< 16 weeks old) and turkeys (< 16 weeks old) for the period before slaughter in which the use of monensin sodium is prohibited</p> <p>— other animal species</p> <p>Premixtures for use in feed in which the use of monensin sodium is not authorised</p>	<p>1.25</p> <p>3.75⁽¹⁾</p>
Semduramicin sodium	<p>Feed materials</p> <p>Compound feeding stuffs for:</p> <p>— laying birds and chickens reared for laying (> 16 weeks old)</p> <p>— chickens for fattening for the period before slaughter in which the use of semduramicin sodium is prohibited</p> <p>— other animal species</p> <p>Premixtures for use in feed in which the use of semduramicin sodium is not authorised</p>	<p>0.25</p> <p>0.25</p> <p>0.25</p> <p>0.75⁽¹⁾</p>
Maduramicin ammonium alpha	<p>Feed materials</p> <p>Compound feeding stuffs for:</p> <p>— equine species, rabbits, turkeys (> 16 weeks old), laying birds and chickens reared for laying (> 16 weeks old)</p> <p>— chickens for fattening and turkeys (< 16 weeks old) for the period before slaughter in which the use of maduramicin ammonium alpha is prohibited</p> <p>— other animal species</p> <p>Premixtures for use in feed in which the use of maduramicin ammonium alpha is not authorised</p>	<p>0.05</p> <p>0.05</p> <p>0.05</p> <p>0.15⁽¹⁾</p>
Robenidine hydrochloride	<p>Feed materials</p> <p>Compound feeding stuffs for:</p> <p>— laying birds and chickens reared for laying (> 16 weeks old)</p> <p>— chickens for fattening, rabbits for fattening and breeding and turkeys for the period before slaughter in which the use of robenidine hydrochloride is prohibited</p> <p>— other animal species</p> <p>Premixtures for use in feed in which the use of robenidine hydrochloride is not authorised</p>	<p>0.7</p> <p>0.7</p> <p>0.7</p> <p>2.1⁽¹⁾</p>
Decoquinat	<p>Feed materials</p> <p>Compound feeding stuffs for:</p> <p>— laying birds and chickens reared for laying (> 16 weeks old)</p> <p>— chickens for fattening for the period before slaughter in which the use of decoquinat is prohibited</p> <p>— other animal species</p> <p>Premixtures for use in feed in which the use of decoquinat is not authorised</p>	<p>0.4</p> <p>0.4</p> <p>0.4</p> <p>1.2⁽¹⁾</p>
Halofuginone	Feed materials	0.03

hydrobromide	<p>Compound feeding stuffs for:</p> <ul style="list-style-type: none"> — laying birds and chickens reared for laying (> 16 weeks old) and turkeys (> 12 weeks old) — chickens for fattening and turkeys (< 12 weeks old) for the period before slaughter in which the use of halofuginone hydrobromide is prohibited — other animal species other than chickens reared for laying (< 16 weeks old) <p>Premixtures for use in feed in which the use of halofuginone hydrobromide is not authorised</p>	<p>0.03</p> <p>0.03</p> <p>0.09</p> <p>(1)</p>
Nicarbazin	<p>Feed materials</p> <p>Compound feeding stuffs for:</p> <ul style="list-style-type: none"> — equine species, laying birds and chickens reared for laying (> 16 weeks old) — chickens for fattening for the period before slaughter in which the use of nicarbazin (in combination with narasin) is prohibited — other animal species <p>Premixtures for use in feed in which the use of nicarbazin (in combination with narasin) is not authorised</p>	<p>0.5</p> <p>0.5</p> <p>0.5</p> <p>1.5</p> <p>(1)</p>
Diclazuril	<p>Feed materials</p> <p>Compound feeding stuffs for:</p> <ul style="list-style-type: none"> — laying birds, chickens reared for laying (> 16 weeks old) and turkeys for fattening (> 12 weeks old) — rabbits for fattening and breeding for the period before slaughter in which the use of diclazuril is prohibited — other animal species other than chickens reared for laying (< 16 weeks old), chickens for fattening and turkeys for fattening (< 12 weeks old) <p>Premixtures for use in feed in which the use of diclazuril is not authorised</p>	<p>0.01</p> <p>0.01</p> <p>0.01</p> <p>0.03</p> <p>(1)</p>

(1) The maximum level of the substance in the premixture is the concentration which shall not result in a level of the substance higher than 50% of the maximum levels established in the feed when the instructions for use of the premixture are followed.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations make further amendments to the Feeding Stuffs (England) Regulations 2005 (SI 2005/3281 as already amended by SI 2006/113, SI 2006/2808, SI 2006/3120, 2007/3008, SI 2008/1523 and SI 2009/28) (“the Feeding Stuffs Regulations”).

2. These Regulations provide for the implementation of Commission Directive 2009/8/EC amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels of unavoidable carry-over of coccidiostats or histomonostats in non-target feed (OJ No. L40, 11.2.2009, p.19).

3. The Regulations amend Schedule 5 to the Feeding Stuffs Regulations by the addition of a Chapter E setting specified limits in relation to the carry-over into non-target feeding stuffs of certain zootechnical feed additives, (*regulation 2 and the Schedule*).

4. A full regulatory impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Animal Feed Unit of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH and is annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website.