

**YMGYNGHORIAD YR ASIANTAETH SAFONAU BWYD**  
**Teitl: RHEOLIADAU BWYD ANIFEILIAID**  
**(SYLWEDDAU ANNYMUNOL PENODEDIG) (CYMRU)**  
**2009**

**TUDALEN CRYNODEB YMGYNGHORIAD**

<b>Dyddiad lansio'r ymgynghoriad:</b>	<b>Dyddiad cau ar gyfer ymatebion:</b>
24 Mawrth 2009	16 Mehefin 2009

**I bwy fydd yr ymgynghoriad hwn o fwyaf o ddiddordeb?**

Cymysgwyr bwyd anifeiliaid yn cynhyrchu bwydydd i ragor nag un rhywogaeth, ffermwyr yn cymysgu bwyd anifeiliaid ar eu daliadau eu hunain, a swyddogion gorfodi.

**Beth yw testun yr ymgynghoriad hwn?**

Offeryn Statudol drafft i drosi Cyfarwyddeb Comisiwn 2009/8/EC yn gosod uchafswm y lefelau a ganiateir ar gyfer cario-drosodd gweddillion cocsidiostatau -- sylweddau a fwriedir i gynorthwyo i atal cocsidiosis, neu heigiadau o'r llwybr treulio gan rai micro-organebau cell sengl (protosoa), yn bennaf mewn dofednod -- i mewn i fwydydd anifeiliaid ar gyfer rhywogaethau eraill.

**Beth yw diben yr ymgynghoriad hwn?**

Ceisio sylwadau rhanddeiliaid ynglŷn ag a yw'r Offeryn Statudol drafft yn trosi'n briodol a chymesurol Atodiad Cyfarwyddeb y Comisiwn, gan bennu'r goddefiadau ar gyfer cario-drosodd y cynhyrchion hyn.

**Dylid anfon yr ymatebion i'r ymgynghoriad hwn at:**

Vicki Reilly  
Cangen Amaethyddiaeth a Chynhyrchu  
Sylfaenol  
YR ASIANTAETH SAFONAU BWYD  
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**Oes Asesiad Effaith wedi'i gynnwys gyda'r ymgynghoriad hwn?**

Oes

Nac Oes  Gweler Atodiad A am y rheswm.

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www.salt.gov.uk

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CYMRU

At: Pawb sydd â Diddordeb

24 Mawrth 2009

## **RHEOLIADAU BWYD ANIFEILIAID (SYLWEDDAU ANNYMUNOL PENODEDIG) (CYMRU) 2009**

Annwyl Gydweithiwr

### **MANYLION YR YMGYNGHORIAD**

#### **Cyflwyniad**

1. Ar hyn o bryd nid oes goddefiadau ar gyfer cario-drosodd posibl ar weddillion cocsidiostatau sy'n dechnegol anochel mewn bwyd anifeiliaid a fwriedir ar gyfer un rhywogaeth da byw a ffermir i fwyd rhywogaeth arall. Gall hon fod yn broblem arbennig i weithredwyr busnes bwyd anifeiliaid sy'n cynhyrchu amrediad o fwydydd anifeiliaid o fewn un sefydliad, lle y gall nifer o wahanol gynhyrchion bwyd anifeiliaid gael eu cynhyrchu ar yr un llinell gynhyrchu. Mae Cyfarwyddeb y Comisiwn 2009/8/EC 10 Rhagfyr 2009 yn gosod uchafswm lefelau a ganiateir ar gyfer y gweddillion hyn, er mwyn darparu rheolau Cymunedol cytûn yn y maes hwn heb beri cynnydd yn y perygl i iechyd anifeiliaid ac iechyd pobl. Mae angen trosi'r mesur i gyfraith yng Nghymru.

#### **Cynigion**

2. Nodir nodweddion allweddol y Gyfarwyddeb yn y blwch sydd yn union isod.

- **Mae'r uchafswm lefelau a ganiateir ar gyfer y cario-drosodd posibl o cocsidiostatau i fwyd anifeiliaid wedi eu nodi drwy ddiwygio Atodiad Cyfarwyddeb 2002/32 ar sylweddau annymunol mewn bwyd anifeiliaid.**
- **Caiff uchafswm lefelau a ganiateir eu gweithredu yn Lloegr drwy ddiwygio Rheoliadau Bwyd Anifeiliaid (Cymru) 2006.**
- **Ceir mesur cyfochrog, yr ymgynghorir ar wahân arno, ar gyfer gweddillion cocsidiostatau mewn cynnyrch anifeiliaid ar gyfer eu bwytia gan bobl, i adlewyrchu'r potensial ar gyfer eu cario-drosodd o fwyd anifeiliaid i laeth, cig ac wyau.**



INVESTOR IN PEOPLE

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3. Mae cocsidiostatau yn sylweddau sydd wedi'u bwriadu i helpu i atal cocsidiosis - h.y. heigiad y llwybr treulio gan rai micro-organebau cell sengl (protosoa), yn bennaf mewn dofednod - a awdurdodir dan Reoleiddiad 1831/2003 yr UE ar ychwanegion mewn bwyd anifeiliaid. Mae Awdurdodiadau o dan y Rheoleiddiad hwn yn nodweddiadol yn amlinellu amodau defnydd, megis y rhywogaeth y mae'r cynhyrchion penodol wedi'u bwriadu ar eu cyfer, uchafswm eu cyfraddau cynhwysiant yn y bwyd anifeiliaid terfynol, a'r datganiadau labelu sydd eu hangen.

4. Mae Rheoleiddiad 183/2005 yr UE ar hylendid bwyd anifeiliaid yn nodi gofynion penodol ar gyfer busnesau bwyd anifeiliaid sy'n defnyddio cocsidiostatau. Yn arbennig, mae'n rhaid iddynt gymryd camau i osgoi unrhyw groeshalodiad ar eu cyfleusterau (cynhyrchu, storio, cludiant ac offer arall) i sicrhau nad oes unrhyw weddillion o'r cynhyrchion hyn yn bresennol mewn bwyd ar gyfer rhywogaethau nad dynt wedi eu hawdurdodi ar eu cyfer (rhywogaethau di-darged).

5. Bydd gweithredwyr busnes bwyd anifeiliaid yn cymryd camau i leihau'r posibilrwydd ar gyfer croeshalodiad, ond yn ymarferol efallai bod presenoldeb gweddillion o'r fath yn rhai technolegol anochel, yn arbennig pan fo gweithredwyr busnes bwyd anifeiliaid yn cynhyrchu amrediad o fwydydd o fewn yr un sefydliad a bod gwanhaol fathau o gynhyrchion bwyd yn cael eu cynhyrchu ar yr un llinell gynhyrchu. Mae'r croesghalodiad hwn - a adweinir fel cario-drosodd - yn digwydd yn nodweddiadol pan fo gweddillion o un proses gynhyrchu yn cael eu corffori i ddechrau'r broses gynhyrchu ganlynol. Ar hyn o bryd nid oes lefelau goddefiad ar gyfer digwyddiadau cario-drosodd o'r fath, er bod angen lefelau cytûn o oddefiad ledled yr UE er mwyn osgoi bod Aelod Wladwriaethau yn gosod eu terfynau cenedlaethol gwahanol eu hunain a fyddai'n amrywio, yn dibynnu ar wahanol allu dadansoddol a chyfraddau datgelu. Gallai gosod gwahanol derfynau cenedlaethol greu anawsterau gyda gweithrediad y Farchnad Sengl.

6. Mae Cyfarwyddeb Comisiwn 2009/8/GE 10 Chwefror 2009 yn nodi lefelau goddefiadau ar sail risg ar gyfer cario-drosodd. Gosodir dwy gyfradd, fel a ganlyn:

- 3% cario-drosodd mewn bwydydd ar gyfer rhywogaethau di-darged llai sensitif; a
- 1% cario-drosodd mewn bwydydd cyfnod cilio (h.y. bwyd a ddefnyddir yn y cyfnod cyn lladd), bwyd ar gyfer rhywogaethau di-darged sensitif, bwyd i rywogaethau targed na chaiff cocsidiostatau a histomonstatau eu hychwanegu, a bwyd ar gyfer rhywogaeth di-darged a ddosberthir yn "anifeiliaid cynhyrchu bwyd parhaus" (megis gwartheg llaeth ac ieir dodwy).

Gosodwyd y lefelau yn dilyn asesiad gan Awdurdod Diogelwch Bwyd Ewrop o'r risgiau tebygol i iechyd anifeiliaid a phobl.

7. Caiff y lefelau eu cyflwyno fel uchafswm lefelau a ganiateir ar gyfer categori newydd o sylweddau annymunol yn Atodlen 5 Rheoliadau Bwyd Anifeiliaid (Cymru) 2006 (fel y'i diwygiwyd). Bydd hyn yn trosi i ddeddfwriaeth genedlaethol

ddarpariaethau Atodiad Cyfarwyddeb 2009/8/EC, ac heb niweidio awdurdodiad y sylweddau hyn fel ychwanegion bwyd o dan Reoliad 1831/2003 y GE.

8. Ceir mesur cyfochrog ar gyfer cario-drosodd ar weddillion cocsidiostatau i fwyd ar gyfer bwyta gan bobol. Caiff y goddefiadau hyn eu cyflwyno gan Reoliad y GE, a fydd yn uniongyrchol berthnasol ym mhob un o'r Aelod Wladwriaethau ac ar ba rai y mae cydweithwyr Asiantaethau cyfrifol am ddeddfwriaeth halogyddion bwyd yn ymgynghori fel rhan o gydgrynhoad y ddeddfwriaeth honno.

### **Proses Ymgynghori**

9. Diweddarwyd rhanddeiliaid allweddol am gynnwys y Gyfarwyddeb drafft tra roedd o dan drafodaeth yn y Pwyllgor Sefydlog ym Mrwsel. Rydym yn awr yn ymgynghori'n ffurfiol ar Reoliadau Bwyd Anifeiliaid (Sylweddau Annymunol Penodedig) (Cymru) 2009 i drosi darpariaethau'r Gyfarwyddeb yn gyfraith yng Nghymru. (Bydd ymgynghoriadau cyfochrog ond ar wahân yn yr Alban, Lloegr a Gogledd Iwerddon) Mae'r materion ar ba rai yr hoffem gael sylwadau rhanddeiliaid wedi eu nodi yn y blwch yn union isod. Gofynnir yn arbennig am sylwadau gan fusnesau bach.

- 1. Sylwadau ar uchafswm lefelau a ganiateir a nodir yn yr Atodlen i'r Rheoliadau Bwyd Anifeiliaid (Sylweddau Annymunol Penodedig) (Cymru) 2009 drafft.**
- 2. Gwybodaeth ar fanteision posibl cyflwyno uchafswm lefelau a ganiateir ar gyfer gweddillion cocsidiostatau mewn bwydydd anifeiliaid rhywogaethau di-darged. Byddai'n gymorth pen gellid mesur y manteision hyn mewn arian lle bo hynny'n bosibl.**
- 3. Sylwadau ar y dybiaeth na fydd costau newydd yn gysylltiedig â chyflwyno'r uchafswm lefelau a ganiateir.**
- 4. Gallu labordai i ddadansoddi hyd at yr uchafswm lefelau a ganiateir i'w cyflwyno gan y Rheoliadau drafft.**
- 5. Sylwadau gan awdurdodau gorfodi, yn enwedig ar effaith bosibl yr uchafswm lefelau a ganiateir newydd ar eu gwaith, yn cynnwys unrhyw leihad posibl yn amllder samplo a dadansoddi. Byddai'n gymorth pe gellid ei fesur mewn arian lle bynnag y bo'n bosibl.**
- 6. Unrhyw sylwadau eraill all fod gan rhanddeiliaid ynglŷn â'r rheoliadau Bwyd Anifeiliaid (Sylweddau Annymunol Penodedig) (Cymru) 2009.**

10. Caiff pob sylw a dderbynnir eu crynhoi a'u cyhoeddi ar wefan yr Asiantaeth Safonau Bwyd fel rhan o'r gweithredu ôl-ymgynghori, oni bai bod rhanddeiliaid yn gofyn yn benodol bod eu sylwadau yn cael eu trin yn gyfrinachol. Gellir gwneud sylwadau drwy lythyr, ffacs, neu drwy e-bost.

### **Dogfennau Perthnasol Eraill**

11. Cyhoeddir y Gyfarwyddeb y bwriedir i'r Rheoliadau Drafft ei throsi ar wefan y Comisiwn yn <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:040:0019:0025:EN:PDF>

## Ymatebion

12. **Gofynnir am ymatebion ddim hwyrach na 16 Mehefin 2009.** A wnewch chi nodi yn eich ymateb p'un ai a ydych yn ymateb fel unigolyn preifat neu ar ran sefydliad neu gwmni (gan gynnwys manylion am unrhyw randdeiliaid a gynrychiolir gan eich sefydliad).

13. Diolch i chi ar ran yr Asiantaeth Safonau Bwyd am gyfranogi yn yr ymgynghoriad cyhoeddus hwn.

Yn gywir,



**Mike Pender**  
**Asiantaeth Safonau Bwyd Cymru**

## Amgaeedig

**Atodiad A: Gwybodaeth Ymgynghori Safonol**

**Atodiad B: Aseiad Effaith**

**Atodiad C: Rhestr o Bartïon â Diddordeb**

**Atodiad D: Rheoliadau Bwyd Anifeiliaid (Sylweddau Annymunol Penodedig) (Cymru) 2009 drafft**

## GWYBODAETH YMGYNGHORI SAFONOL

### Ymholiadau

1. Os oes gennych unrhyw ymholiadau yn ymwneud â'r ymgynghoriad arbennig hwn cysylltwch â'r person a enwir ar dudalen 1, a fydd yn gallu ymateb i'ch cwestiynau.

### **Cyhoeddi Data Personol a Chyfrinachedd Ymatebion**

2. Yn unol ag egwyddor yr Asiantaeth Safonau Bwyd o fod yn agored, bydd ein Canolfan Wybodaeth yn Aviation House yn cadw copi o'r ymgynghoriad wedi'i gwblhau. Bydd yr ymatebion ar gael i'r cyhoedd ar gais. Bydd yr Asiantaeth hefyd yn cyhoeddi crynodeb o'r ymatebion, a all gynnwys data personol megis manylion eich enw llawn a'ch cyfeiriad cyswllt. Os nad ydych yn dymuno i'w wybodaeth hon gael ei ryddhau a wnewch chi lenwi a dychwelyd y ffurflen Cyhoeddi Data Personol sydd i'w gweld ar wefan yr Asiantaeth yn

<http://www.food.gov.uk/multimedia/pdfs/dataprotection.pdf> A fyddech cystal â nodi nad yw dychwelyd y ffurflen hon yn golygu y byddwn yn ymdrin â'ch ymateb i'r ymgynghoriad yn gyfrinachol, dim ond eich data personol.

3. Yn unol â darpariaethau Deddf Rhyddid Gwybodaeth 2000 a Rheoliadau Gwybodaeth Amgylcheddol 2004, gall pob gwybodaeth a gynhwysir yn eich ymateb gael ei gyhoeddi neu ei ddatgelu. Os byddwch yn ystyried na ddylai rhyw ran o'r wybodaeth a ddarperir yn eich ymateb gael ei ddatgelu, dylech nodi'r wybodaeth berthnasol, gofyn iddi beidio cael ei datgelu ac esbonio pa ddrwg yr ystyriwch chi fyddai'n deillio o ganlyniad i'w datgelu. Bydd y penderfyniad terfynol ar p'un ai a ddylai gwybodaeth gael ei dal yn ôl yn nwylo'r Asiantaeth Safonau Bwyd. Fodd bynnag byddwn yn ystyried eich safbwynt wrth wneud y penderfyniad hwn.

4. Ni chaiff unrhyw ymwadiad cyfrinachedd awtomatig a grëir gan eich system TG ei ystyried fel cais o'r fath oni bai eich bod yn cynnwys cais yn benodol, gydag esboniad, ym mhrif destun eich ymateb.

### **Gwybodaeth Bellach**

5. Mae rhestr partïon sydd â diddordeb, y caiff y llythyr hwn ei anfon atynt, i'w gweld yn Atodiad C. Mae croeso i chi drosglwyddo'r ddogfen hon i bartïon â diddordeb eraill, neu anfonwch eu manylion cyswllt allwn atom a byddwn yn trefnu i anfon copi iddynt yn uniongyrchol.

6. Cysylltwch â ni am fersiynau amgen o'r dogfennau ymgynghori mewn Braille, neu mewn ieithoedd eraill neu ar dâp sain.

7. Mae'r Cod Ymarfer yn datgan y dylai Asesiad Effaith gael ei gyhoeddi fel arfer ar y cyd ag ymgynghoriad ffurfiol. Mae'r Asesiad Effaith ar gyfer yr ymgynghoriad hwn yn Atodiad B ac mae'n ymwneud â'r rheoliadau cyfatebol a baratoir yn Lloegr.

Mae Aseiad Effaith Rheoleiddiol yn cael ei baratoi ar gyfer Cymru ar hyn o bryd. At ddiben yr ymarferiad hwn byddem yn croesawu eich sylwadau ar unrhyw oblygiadau cost a all godi o'r cynnig hwn fel y mae'n ymwneud â Chymru.

8. Am fanylion ynglŷn â'r broses ymgynghori (nid am gynnwys yr ymgynghoriad arbennig hwn) a wnewch chi gysylltu â: Food Standards Agency Consultation Co-ordinator, Room 2C, Aviation House, 125 Kingsway, London, WC2B 6NH. Ffôn: 0207 276 8630.

### **Sylwadau ar y Broses Ymgynghori Ei Hun**

9. Mae gennym ddiddordeb yn eich barn am yr ymgynghoriad hwn a byddem felly yn croesawu eich adborth cyffredinol ynglŷn â'r pecyn ymgynghori a'r broses ymgynghori yn gyffredinol. Os hoffech ein cynorthwyo i wella ansawdd ymgynghoriadau yn y dyfodol mae croeso i chi rannu eich syniadau gyda ni drwy lenwi'r Holiadur Adborth Ymgynghori yn

<http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc>

10. **Os hoffech gael eich cynnwys yn ymgynghoriadau'r Asiantaeth Safonau Bwyd yn y dyfodol ar bynciau eraill, dywedwch wrthym pa feysydd y gallech fod â diddordeb penodol ynddynt drwy ddefnyddio'r Holiadur Adborth Ymgynghori. Gellir defnyddio'r Holiadur hefyd i'n diweddarau ni am eich manylion cyswllt.**

## Summary: Intervention & Options

<b>Department /Agency: Food Standards Agency</b>	<b>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</b>	
<b>Stage:</b>	<b>Version: 1</b>	<b>Date:</b>
<b>Related Publications: Consultation Letter</b>		

**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:

\* 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

<b>COSTS</b>	<b>ANNUAL COSTS</b>		Description and scale of <b>key monetised costs</b> by 'main affected groups' Quantified monetary information on the potential costs will be sought as part of the public consultation.
	<b>One-off</b> (Transition)	<b>Yrs</b>	
	£		
	<b>Average Annual Cost</b> (excluding one-off)		
	£		<b>Total Cost (PV)</b> £
Other <b>key non-monetised costs</b> 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			

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>		Description and scale of <b>key monetised benefits</b> by 'main affected groups' Quantified monetary information on the potential benefits will be sought as part of the public consultation.
	<b>One-off</b>	<b>Yrs</b>	
	£		
	<b>Average Annual Benefit</b> (excluding one-off)		
	£		<b>Total Benefit (PV)</b> £
Other <b>key non-monetised benefits</b> 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	<b>Net Benefit Range</b> (NPV) £		<b>NET BENEFIT</b> (NPV Best estimate) £	
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
<b>Impact on Admin Burdens Baseline</b> (2005 Prices)				(Increase - Decrease)	
Increase of	£	Decrease of	£	<b>Net Impact</b>	£

## 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 coccidiostats 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

## Annexes

### 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.

## Interested Parties List

Cate	Barrow	ADAS Wales
Mary	James	National Farmers Union Cymru
Alan	Horine	Guild of Welsh Lamb & Beef Suppliers
Non	Rhys	Federation of Small Businesses, Wales
Barrie	Jones	Royal Welsh Agricultural Society
Julie	Barratt	Chartered Institute of Environmental Health Wales
Elinor	Plow	Welsh Food Alliance
Wynfford	James	Welsh Assembly government
Christianne	Glossop	Welsh Assembly government
Gwyn	Howells	Hybu Cig Cymru - Meat Promotion Wales
Heather	McCalman	Grassland Development Centre, IGER
Trevor	Johnson	Minton Treharne Davies Ltd
V	Taylor	Country land & Business Association
Gareth	Walters	Trading Standards Institute (Wales)
Moss	Jones	Farm Assured Welsh Livestock
Jane	Shepherd	Welsh Local Government Association
Nick	Fenwick	Farmers' Union of Wales

**2009 No. (W. )**

**AGRICULTURE, WALES**

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

**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

**1.** These Regulations make further amendments to the Feeding Stuffs (Wales) Regulations 2006 (S.I. 2006/116 (W.14) as already amended by S.I. 2006/617 (W.69), S.I. 2006/2928 (W.263), S.I. 2006/3256 (W.296), S.I. 2007/3171 (W.277), S.I. 2008/1806 (W.174) and S.I. 2009/106 (W.20)) (“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 Food Standards Agency, 11<sup>th</sup> Floor, Southgate House, Wood Street, Cardiff CF10 1EW.

**2009 No. (W. )**

**AGRICULTURE, WALES**

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

<i>Made</i>	2009
<i>Laid before the National Assembly for Wales</i>	2009
<i>Coming into force</i>	2009

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 66(1), 74A and 84 of the Agriculture Act 1970(1).

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(2) 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. The title of these Regulations is the Feed (Specified Undesirable Substances) (Wales) Regulations 2009 and they come into force on [ ] 2009.

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- (1) 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). Section 74A was inserted by the European Communities Act 1972 (1972 c. 68), Schedule 4, paragraph 6.
- (2) 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).

**Amendments to the Feeding Stuffs (Wales) Regulations 2006**

2. At the end of Schedule 5 (prescribed limits for undesirable substances) to the Feeding Stuffs (Wales) Regulations 2006<sup>(1)</sup> add the entries set out in the Schedule to these Regulations.

Signed under authority of the Minister for Health and Social Services, one of the Welsh Ministers

Date

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(1) S.I. 2005/3281, as amended by S.I. 2006/116 (W.14) as amended by S.I. 2006/617 (W.69), S.I. 2006/2928 (W.263), S.I. 2006/3256 (W.296), S.I. 2007/3171 (W.277), S.I. 2008/1806 (W.174) and S.I. 2009/106 (W.20).

## SCHEDULE

Regulation 2

### Entries to comprise Chapter E of Schedule 5 to the Feeding Stuffs (Wales) Regulations 2006

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

Decoquinat	Feed materials	0.4
	Compound feeding stuffs for:	
	— laying birds and chickens reared for laying (> 16 weeks old)	0.4
	— chickens for fattening for the period before slaughter in which the use of decoquinat is prohibited	0.4
	— other animal species	1.2 <sup>(1)</sup>
Premixtures for use in feed in which the use of decoquinat is not authorised		
Halofuginone hydrobromide	Feed materials	0.03
	Compound feeding stuffs for:	
	— laying birds and chickens reared for laying (> 16 weeks old) and turkeys (> 12 weeks old)	0.03
	— chickens for fattening and turkeys (< 12 weeks old) for the period before slaughter in which the use of halofuginone hydrobromide is prohibited	0.03
	— other animal species other than chickens reared for laying (< 16 weeks old)	0.09
Premixtures for use in feed in which the use of halofuginone hydrobromide is not authorised	(1)	
Nicarbazin	Feed materials	0.5
	Compound feeding stuffs for:	
	— equine species, laying birds and chickens reared for laying (> 16 weeks old)	0.5
	— chickens for fattening for the period before slaughter in which the use of nicarbazin (in combination with narasin) is prohibited	0.5
	— other animal species	1.5 <sup>(1)</sup>
Premixtures for use in feed in which the use of nicarbazin (in combination with narasin) is not authorised		
Diclazuril	Feed materials	0.01
	Compound feeding stuffs for:	
	— laying birds, chickens reared for laying (> 16 weeks old) and turkeys for fattening (> 12 weeks old)	0.01
	— rabbits for fattening and breeding for the period before slaughter in which the use of diclazuril is prohibited	0.01
	— other animal species other than chickens reared for laying (< 16 weeks old), chickens for fattening and turkeys for fattening (< 12 weeks old)	0.03
Premixtures for use in feed in which the use of diclazuril is not authorised	(1)	

<sup>(1)</sup> 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.