

**EXPLANATORY MEMORANDUM TO**  
**THE ANIMALS AND ANIMAL PRODUCTS (EXAMINATION FOR RESIDUES AND**  
**THE MAXIMUM RESIDUE LIMITS) (AMENDMENT) REGULATIONS 2009**

**SI 2009 No. 1925**

1. This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty. This memorandum contains information for the Joint Committee on Statutory Instruments.

**2. Purpose of the Instrument**

2.1 This Statutory Instrument implements Directive 2008/97 of the European Parliament and of the Council. Directive 2008/79 amends Council Directive 96/22/EC, which prohibits the use in stockfarming of certain substances having a hormonal or thyrostatic action and beta-agonists.

**3. Matters of Special Interest to the JCSI**

3.1 This is the third amendment to the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 – “the Residues Regulations”. There is a case for consolidating this piece of legislation. However, an EU Regulation on establishing Maximum Residues Limits (MRLs) which impacts on the Residues Regulations has recently been published, and the Commission has indicated that it will shortly start a review of Council Directive 96/23 governing surveillance of residues in food, which is also implemented by these Regulations. The Government is therefore minded to await the outcome of the review before consolidating the text.

3.2 The UK’s intention was to implement Directive 2008/97 and the later EU Regulation on establishing MRLs for pharmacologically active substances in foodstuffs of animal origin (Council Regulation 470/2009) at the same time. However, the Commission issued an Article 226 letter threatening infraction proceedings if Directive 2008/79 is not implemented in a reasonable timescale. To avoid infraction the Government has decided to implement the Directive now.

**4. Legislative Context**

4.1 The amendment fulfils a European obligation. A transposition table is attached.

**5. Territorial Extent and Application**

5.1. The SI applies to Great Britain. Parallel legislation is being passed by the Northern Ireland authorities.

**6. European Convention on Human Rights.**

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

## **7. Policy Background**

7.1. The EU introduced a ban on the use of hormonal substances for growth promotion in food producing animals in 1988 owing to concerns about their safety in respect of consumer health. Council Directive 96/22/EC prohibits the use of hormonal and thyrostatic substances and beta-agonists that might be used to promote growth in farm animals. It does, however, allow the limited use of some hormonally-active substances for therapeutic and oestrus synchronisation purposes under strict veterinary supervision. An earlier amendment to Council Directive 96/22 (Council Directive 2003/74) phased out the use of oestradiol  $\beta$  17 and its ester-like derivatives except where it was needed for therapeutic purposes in the absence of viable alternative veterinary medicinal products. The Directive provided for a study to be carried out into alternatives, with a view to ending all uses of oestradiol  $\beta$  17 and its ester-like derivatives. The study showed that alternatives were available (prostaglandins), which has resulted in this Directive. The impact of this element of the Directive is very small, as the UK only had one product containing oestradiol, which was re-formulated to remove this hormone.

7.2. The Directive requires the Commission to gather further scientific information on another five hormonally-active substances, currently provisionally banned except for certain therapeutic and oestrus synchronisation uses, with a view to introducing further proposals. The list includes substances in some veterinary medicinal products authorised in the UK. A ban would, therefore, lead to the loss of other products, including the one mentioned above.

7.3. Unfortunately, Council Directive 96/22, whilst focused on food producing animals, extended the ban to all species which captured pet animals. This was because the Commission was concerned that products authorised for pet animals could be used in food animals. The Commission has now accepted that it would be uneconomic for producers to do this and Directive 2008/97 restricts the ban to food producing animals. The provision allowing some substances to be authorised for pet animals is deregulatory, and will be welcomed by the pharmaceutical industry, pet owners and veterinarians. It may have the effect of reducing barriers to trade, as third countries that authorise the substances concerned only for pet animals, will now be allowed to appear on the list of countries that are allowed to export food to the EU.

7.4. A further element was added to the proposal during Council negotiations. This is a further deregulatory measure that removes horses from the restrictions on authorising beta agonists to enable treatments for conditions such as navicular disease (affecting the pedal bone in the hoof) and laminitis (which affects the hoof).

## **8. Consultation**

8.1. Owing to pressure from the Portuguese to adopt the proposal during their Presidency, a four week consultation was held in September 2007. This sought comments from over 200 organisations covering the veterinary profession, pharmaceutical and farming industries, consumer bodies and other interested stakeholders. No concerns were expressed, probably because the prospect of a complete ban on the use of oestradiol was signalled during the twelve week consultation exercise on Council Directive 2003/74.

8.2. The provision on beta-agonists for horses was added to the proposal towards the end of the consultation period. It was publicised in an Open Meeting for stakeholders to discuss the various changes to legislation being considered in the EU, which was held at the Veterinary Medicines Directorate in January 2008, and in papers on its website. No concerns were expressed.

## **9. Guidance**

9.1 The effect of the changes to Directive 96/22 are straightforward and relatively minor. They were fully explained in the VMD's consultation letter, but will be brought to the attention of stakeholders again in a letter and included on the VMD's website.

## **10. Impact**

10.1 There are no extra costs and therefore no impact on business, charities or voluntary bodies. There may be some benefits in relation to new medicines and improved welfare of animals. However, these are very difficult to quantify.

10.2 The impact on the public sector is nil.

10.3 An Impact Assessment is attached to this memorandum.

## **11. Regulating small businesses**

11.1 The legislation is deregulatory so there are no additional costs to small businesses.

## **12. Monitoring and Review**

12.1 There are no plans to review this Directive. Officials will monitor the situation regarding the gathering of further information on the other hormonally-active substances.

## **13. Contact**

### **Drafting Officer Details**

**Name:** Eric Crutcher

**Division:** Residues Surveillance Unit, Veterinary Medicines Directorate

**Telephone number:** 01932 338322

**E-mail address:** [e.crutcher@vmd.defra.gsi.gov.uk](mailto:e.crutcher@vmd.defra.gsi.gov.uk)

**Parliamentary scrutiny history relevant to the opinion of the Commission pursuant to article 251(2), third subparagraph, point (c) of the EC treaty, on the European Parliament's amendments to the Council's common position regarding the proposal for a directive of the European Parliament and of the council amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists amending the proposal of the Commission pursuant to article 250 (2) of the EC Treaty.**

**EXPLANATORY MEMORANDUM 6976/01 OF 30 APRIL 2001**

**SCRUTINY COMMITTEES' RECOMMENDATIONS**

Commons		Lords	
Politically important-Cleared	Date : 2 May 2001 Report ref : (22317) HC 28 – xiii (Session 2000 - 01) Paragraph 10	Cleared from scrutiny	Date: 8 May 2001

**SUPPLEMENTARY EXPLANATORY MEMORANDUM 6976/01 OF 16 APRIL 2002**

**SCRUTINY COMMITTEES' RECOMMENDATIONS**

Commons		Lords	
Politically important-Cleared	Date : 23 April 2002 Report ref : (22317) HC 152 – xxv and HC 152 – xxvi (Session 2001 – 02) Paragraph 8	Sifted to Sub-Committee D	Date: 23 April 2001
		Cleared by letter to Minister for Food, Farming and Waterways (Lord Whitty)	Date: 15 May 2002

**2<sup>nd</sup> SUPPLEMENTARY EXPLANATORY MEMORANDUM 6976/01 OF 8 NOVEMBER 2002**

**SCRUTINY COMMITTEES' RECOMMENDATIONS**

Commons		Lords	
Not legally or politically important - Cleared	Date : 20 November 2002	Sifted to Sub committee D	Date: 19 November 2002
		Cleared by Sub-	Date: 4 December

**COUNCIL DIRECTIVE 96/22/EC**

Legislation	Council Directive 96/22/EC
Adopted	29 April 1996
Official Journal	L 125 of 23 May 1996 (page 3)
Explanatory Memoranda	8988/93 part III of 3 November 1993 SEM 8988/93 of 8 March 1996

EXPLANATORY MEMORANDUM 8988/93 PART III

SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Legally and politically important- not for debate	Date : 19 January 1993 Report ref : (14869) HC 48 -iv (Session 1993-94) Paragraph 5	Cleared (List A)	Date : 11 March 1996

SUPPLEMENTARY EXPLANATORY MEMORANDUM 8988/93 PART III

SCRUTINY COMMITTEES' RECOMMENDATIONS

Commons		Lords	
Politically important- not for debate	Date : 13 March 1996 Report ref : (14869) HC 51-xiii (Session 1995-96) Paragraph 5	Cleared (List A)	Date : 11 March 1996

**EXPLANATORY MEMORANDUM 10060/00 OF 3 AUGUST 2000**

**SCRUTINY COMMITTEES' RECOMMENDATIONS**

Commons		Lords	
Politically important-not cleared – further information requested	Date : 15 November 2000 Report ref : (21460) HC 23 - xxix (Session 1999 - 2000) Paragraph 8	Referred to Sub-Committee (List B)	Date: 3 October 2000 Sub-Committee D
		Cleared by letter to the Minister (List F)	Date: 14 December 2000

**SUPPLEMENTARY EXPLANATORY MEMORANDUM 10060/00 OF 20 JANUARY 2001**

**SCRUTINY COMMITTEES' RECOMMENDATIONS**

Commons		Lords	
Politically important-not cleared; further information requested	Date : 7 February 2001 Report ref : (21460) HC 28 - v (Session 2000 - 2001) Paragraph 6	Referred to Sub-Committee (List B)	Date: 23 January 2001 Sub-Committee D
Notes: Supplementary Explanatory Memorandum cleared on 2 May with Explanatory Memorandum 6976/01		Cleared without report (List C)	Date: 21 February 2001

### UK transposition table for Directive 2008/97

Showing amendments to the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997, made by the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2009

This table shows the amendments to the above regulations that are being made in order to transpose Directive 2008/97 (which amends Directive 96/22)

Article	Objective	Notes	Proposed implementation in the 1997 regulations <sup>1</sup>	Cross Reference to Amending Regulation
Art 1(2)	Replaces Art 2 in Dir 96/22 with new text prohibiting the placing on the market of substances listed on the <u>new Annex II</u> to Dir 96/22 but only for food producing animals, not all animals as was previously the case.  <u>Policy effect:</u> bans the remaining (therapeutic) uses of oestradiol 17b.	Previous Art 2 prohibited placing on market of List A substances for <u>all</u> species, but only prohibited List B substances for food producing animals (except for the exceptions set out in Articles 4(2) and 5a: Art 4(2) = MS power to authorise therapeutic uses of vet meds containing beta-agonists to horses, pets and cows. [nb reference to “pets” is deleted in new Reg – see below] Art 5a = MS power to authorise therapeutic use of oestrogen substances in farm animals [5a is deleted in new Reg – see below])	See reg 3 for the prohibitions. <b>Revise reg 3 so that the prohibition on Annex II substances now applies to food producing animals only. This is done by deleting reg 3(1) and 3(2), and amending reg 3(3) and reg 3(5).</b>	Regs 2(4)(a)-(b)
Art 1(3)	Deletes words “and pets” from Art 4(2)(i). <u>Policy effect:</u> removes the existing restrictions on using beta agonists on	Reference to “pets” in this context is in reg 27(3)(b)	Remove reference to pets by <b>deleting reg 27(3)(b)</b> .	Reg 2(9)(b)-(c)

<sup>1</sup> “the 1997 regulations” means the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 (S.I. 1729 of 1997)

Article	Objective	Notes	Proposed implementation in the 1997 regulations <sup>1</sup>	Cross Reference to Amending Regulation
Art 1(4)	<p>pets.</p> <p>Deletes Art 5a.  <u>Policy effect:</u> has the effect of banning what were some remaining therapeutic uses of oestradiol 17b and its ester-like derivatives in substances used on farm animals.</p>	<p>The transposition of each element of Art 5a are dealt with below:</p>		
		<p>Art 5a(1) and (2) are transposed in reg 28A.</p>	<p><b>1) Delete reg 28A.</b></p> <p><b>2) Also delete reg 5(2)(d)</b> (because this permitted use of oestradiol 17b or its ester-like derivatives if administered in accordance with reg 28A – but this is now redundant since reg 28A itself is being deleted)</p>	<p>1) Reg 2(10) and 2(3)(c)</p> <p>2) Reg 2(6)</p>
		<p>Art 5a(3) is transposed in reg 32 and reg 4.</p> <p>Reg 32 refers to recordkeeping requirements for “hormonal substances and beta-agonists” and does not expressly refer to oestradiol 17b.</p> <p>Reg 4 transposes the final sentence of Art 5a, which prohibits <u>holding</u> on a farm any products containing oestradiol 17b.</p>	<p>Reg 32 itself does not need amending as it does not refer to “oestradiol 17b and its ester-like derivatives”. But reg 32 does refer to reg 4 – which includes at 4(b) a reference to “oestradiol 17b and its ester-like derivatives”. Regulation 4(b) allowed only vets (but not farmers) to possess certain substances on farms. But because oestradiol 17b is now a prohibited substance on List A of Directive 96/22, the reference to it in reg 4(a) should be removed. Consequently, the reference to oestradiol 17b in the heading to reg 4 should also be deleted. This has</p>	<p>Reg 2(5)</p>



Article	Objective	Notes	Proposed implementation in the 1997 regulations <sup>1</sup>	Cross Reference to Amending Regulation
Art 1(5)	Deletes references to Art 5a in articles 3, 6, 7, 8, 11 and 14a. <u>Policy effect</u> (see above).		been done by substituting a new reg 4.	
Art 3	Deletes references to Art 5a in articles 3, 6, 7, 8, 11 and 14a. <u>Policy effect</u> (see above).	The transposition of the deletion of Art 5a within articles 3, 6, 7, 8, 11 and 14a are dealt with in turn below:  <u>Art 3(b)</u> – prohibition on holding on a farm animals on a farm that contain Annex II and III substances, AND on placing them on the market or slaughter for human consumption unless the animals come within the exceptions set out in Arts 4, 5 [or 5a].  Transposed in: 1) reg 8, regarding possession and slaughter of animals intended for human consumption, and 2) reg 9, regarding sale of animals intended for human consumption,.	Re Art 3(b): The deletion of the reference to Art 5a within Art 3(b):  1) does not require any changes to reg 8, as these prohibit possession on a farm and slaughter of animals to which any substance on the Annexes to the Directive have been administered - and oestradiol 17b is on Annex II;  2) <u>does</u> require amendment to reg 9 to remove the reference to oestradiol 17b.	1) not applicable  2) Reg 2(7)
Art 6		<u>Art 6(1)</u> – administration of hormonal products <sup>2</sup> and beta-	Re Art 6(1): The deletion of the reference to Art 5a within Art 6(1) does	

<sup>2</sup> “hormonal products” is not defined in the Directive

Article	Objective	Notes	Proposed implementation in the 1997 regulations <sup>1</sup>	Cross Reference to Amending Regulation
		<p>agonists to farm animals within the exceptions set out in Arts 4, 5 [or 5a] must comply with Dir 2001/82 (the Vet Meds Community Code). Transposed in reg 5(2)(b).</p> <p>[Possibly the inclusion of “Art 5a” within Art 6 in the 1997 directive is an error, because Art 6(1) covers administration of hormonal products and beta-agonists, whereas the Art 5a exception covers administration of oestradiol 17b or its ester-like derivatives.]</p>	<p>not require changes to reg 5(2)(b) as the conditions on such administration are set out in reg 27.</p>	
	<p>Art 7</p>	<p><u>Art 7(1)</u> – Allows placing on market of animals and meat from them, where Annex II or III substances were used on them pursuant to the exceptions set out in Arts 4, 5 [or 5a], if conditions in Art 4, 5 [or 5a] and withdrawal periods were complied with.</p> <p>Transposed in</p> <ol style="list-style-type: none"> <li>1) reg 9(1)(d) re sale of animals,</li> <li>2) reg 10(1) re sale of products from animals cited in Reg 9.</li> </ol>	<p>Re Art 7(1)</p> <ol style="list-style-type: none"> <li>1) The deletion of the reference to Art 5a within Art 7(1) requires a revision of Reg 9(1)(d), which prohibits sale of animals “to which a List A substance, oestradiol 17b, or an Annex III substance has been administered”. Because oestradiol 17b is now within List A, the reference to oestradiol 17b should be deleted. So <b>in Reg 9(1)(d), delete the words “oestradiol 17b”</b>.</li> <li>2) Reg 10: no changes needed, since the change has been made in reg 9.</li> </ol>	<ol style="list-style-type: none"> <li>1) Reg 2(7)</li> <li>2) not applicable</li> </ol>

Article	Objective	Notes	Proposed implementation in the 1997 regulations <sup>1</sup>	Cross Reference to Amending Regulation
	Art 8	<u>Art 8(2)(d)</u> – MS shall ensure that the random checks to detect unauthorised substances (as set out in Art 11 of Dir 96/233) are carried out without notice to ascertain any failure to observe the restrictions on the use of certain substances laid down in Arts 4, 5 [and 5a]. Transposed in Reg 13 and Part II generally.	Art 8(2)(d): The deletion of the reference to Art 5a within Art 8(2)(d) does not require changes to reg 13 or Part III of the regs.	
	Art 11	<u>Art 11(2)(a)(ii)</u> – MS to prohibit import from 3rd countries of meat from animals on which Annex II List B or Annex III substances were used, unless the products comply with restrictions in Arts 4, 5 [5a] and 7 and withdrawal periods were observed. Transposed in regs 23 and 24 of the Products of Animal Origin (Third Country Imports) (England) Regulations 2006 (SI 2841/2006) and in directly applicable Community legislation.	The deletion of the reference to Art 5a within Art 11(2)(a)(ii) does not require any changes to these regs or to the Products of Animal Origin (Third Country Imports) (England) Regulations 2006.	
	Art 14a	<u>Art 14a</u> – allows the same exceptions as set out in Arts 4(1) and 5 where animals treated	The deletion of the reference to Art 5a within Art 14a requires deletion of Reg 28A (see above).	Reg 2(10)

<sup>3</sup> Title is “on measures to monitor certain substances and residues thereof in live animals and animal products”.

Article	Objective	Notes	Proposed implementation in the 1997 regulations <sup>1</sup>	Cross Reference to Amending Regulation
		<p>with oestradiol 17b or its ester-like derivatives, notwithstanding Arts 3 [and 5a], where that was done before 14 Oct 2004.</p> <p>Transposed in reg 28A. This transitional exemption is not being renewed – see recital 10 to Dir 2008/97.</p>		
Art 1(6)	<p>Replaces Art 11(1) with new text that replaces reference to “animals of all species” with reference to food-producing animals in relation to lists of countries prepared by the EC.  <u>Policy effect:</u> puts pet animals outside the scope of the restrictions on using certain hormonal substances (stilbenes, stilbene derivatives and their salts and esters, and thyrostatic substances).</p>	<p>Art 11(1) says that where a 3rd country allows stilbenes, stilbene derivatives, their salts and esters or thyrostatic substances to be administered to animals, that country cannot appear on EC lists showing countries from which MSs can import meat or animals.</p> <p>Concerns duties of the Commission.</p>	No transposition is needed.	
Art 1(7)	Replaces Art 11a with new text	Concerns duties of the Commission.	No transposition is needed.	
Art 1(8)	Inserts new Art 11b	Concerns duties of the Commission.	No transposition is needed.	
Art 1(9)	Replaces Annex II with a new Annex II	New version of Annex II moves “oestradiol 17b and its ester-like derivatives” to List A of Annex II.	No transposition is needed, since the regulations continue to refer to List A, List B and Annex II.	

Article	Objective	Notes	Proposed implementation in the 1997 regulations <sup>1</sup>	Cross Reference to Amending Regulation
Art 2(1) and (2)	MS must provide a transposition table and communicate it to Commission		This table, when finalised, will be the transposition table.	
			<p>Amendments made for reasons of domestic law:</p> <p>1) definition of Council Regulation 2377/90 is revised, to update the reference and to make it consistent with reg 2(3A).</p> <p>2) reg 2(3A) is updated to refer to these 2009 amending regulations rather than the former 2006 ones.</p> <p>3) and 4) insert operative words into the text where previously they appeared only in the heading.</p>	<p>1) Reg 2(2)</p> <p>2) Reg 2(3)</p> <p>3) Reg 2(8)</p> <p>4) Reg 2(9)(a)</p>