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STATUTORY INSTRUMENTS

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**2013 No. 804**

**FOOD**

**The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2013**

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|-------------------------------|---------|------------------------|
| <i>Made</i>                   | - - - - | <i>4th April 2013</i>  |
| <i>Laid before Parliament</i> |         | <i>10th April 2013</i> |
| <i>Coming into force</i>      | - -     | <i>6th May 2013</i>    |

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972<sup>(1)</sup> (“the 1972 Act”) in relation to measures in the veterinary and phytosanitary fields for the protection of public health<sup>(2)</sup> and in relation to the common agricultural policy of the European Union<sup>(3)</sup>.

The Secretary of State has carried out the consultation required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council 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<sup>(4)</sup>.

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Secretary of State that it is expedient for any reference in these Regulations to the Annexes to 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<sup>(5)</sup>, to Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products<sup>(6)</sup> and to Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin<sup>(7)</sup> to be construed as a reference to those Annexes as amended from time to time.

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A of Schedule 2<sup>(8)</sup> to, the 1972 Act, and by sections 16(1)(a), (b) and (f) and (3), 17(1) and (2), 26(1) and 48(1) of, and paragraph 7 of Schedule 1 to, the Food Safety Act 1990<sup>(9)</sup> and now vested in the Secretary of State<sup>(10)</sup>.

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(1) 1972 c. 68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c.7).

(2) S.I. 1999/2027.

(3) S.I. 1972/1811.

(4) OJ No L 31, 1.2.2002, p.1, as last amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14).

(5) OJ No L 125, 23.5.1996, p.3, as last amended by Directive 2008/97/EC (OJ No L 318, 28.11.2008, p.9).

(6) OJ No L 125, 23.5.1996, p.10, as last amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14).

(7) OJ No L 15, 20.1.2010, p.1, as last amended by Commission Implementing Regulation (EU) No 1191/2012 (OJ No L 340, 13.12.2012, p.35).

(8) Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c.51) and amended by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c.7).

(9) 1990 c. 16.

**Title and commencement**

1. These Regulations may be cited as the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2013 and come into force on 6th May 2013.

**Amendment of the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997**

2.—(1) The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997<sup>(11)</sup> are amended in accordance with this regulation.

(2) In regulation 2(1)—

(a) omit the definition of “Annex IV substance”;

(b) for the definition of “Council Directive 96/22” substitute—

““Council Directive 96/22” means 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, and repealing Directives [81/602/EEC](#), [88/146/EEC](#) and [88/299/ECC](#),”<sup>(12)</sup>;

(c) for the definition of “Council Directive 96/23” substitute—

““Council Directive 96/23” means Council Directive [96/23/EC](#) on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives [85/358/EEC](#) and [86/469/EEC](#) and Decisions [89/187/EEC](#) and [91/664/EEC](#),”<sup>(13)</sup>;

(d) omit the definition of “the Council Regulation”;

(e) in the definition of “maximum residue limit” for “Annex I or Annex III to the Council Regulation in the tissues or body fluids of an animal or in an animal product, the limit specified in the fourth column” substitute “Table 1 in the tissues or body fluids of an animal or in an animal product, the limit (if any) specified in the fourth column”;

(f) after the definition of “reference analysis certificate” insert—

““Regulation 470/2009” means Regulation [\(EC\) No 470/2009](#) of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing [Council Regulation \(EEC\) No 2377/90](#) and amending

(10) The powers, so far as they are exercisable in relation to England, were transferred by article 2(6) of the Transfer of Functions (Agriculture and Food) Order 1999 ([S.I. 1999/3141](#)) to the Minister of Agriculture, Fisheries and Food and the Secretary of State acting jointly, and by article 2(3) of the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002 ([S.I. 2002/794](#)) to the Secretary of State. In so far as they are exercisable in relation to Scotland, they were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 ([c. 46](#)) but the Secretary of State retains a concurrent power to exercise them under section 57(1) of that Act. In so far as they are exercisable in relation to Wales, they were transferred to the National Assembly for Wales by article 2(a) of and Schedule 1 to the National Assembly for Wales (Transfer of Functions) Order 1999 ([S.I. 1999/672](#)) and then transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 ([c. 32](#)). However the Ministers of the Crown responsible retained a concurrent power to exercise them under paragraph 5 of Schedule 3 to the Government of Wales Act 1998 ([c. 38](#)); that concurrent power became vested in the Secretary of State in consequence of section 40 of and Schedules 5 and 6 to the Food Standards Act 1999 ([c. 28](#)), but subject to any power of the Minister of Agriculture, Fisheries and Food, saved by regulation 13 of the Food Standards Act 1999 (Transitional and Consequential Provisions and Savings) (England and Wales) Regulations 2000 ([S.I. 2000/656](#)), to join in making regulations in relation to residues of veterinary products; that joint power was transferred to the Secretary of State by article 2(3) of the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002. Schedule 3 to the Government of Wales Act 1998 was repealed by the Government of Wales Act 2006 ([c. 32](#)); the concurrent power of Ministers of the Crown is now contained in paragraph 5 of Schedule 3 to that Act.

(11) [S.I. 1997/1729](#) relevant amending instruments are [S.I. 2006/755](#) and [2009/1925](#).

(12) OJ No L 125, 23.5.1996, p.3, as last amended by Directive [2008/97/EC](#) (OJ No L 318, 28.11.2008, p.9).

(13) OJ No L 125, 23.5.1996, p.10, as last amended by Regulation [\(EC\) No 596/2009](#) (OJ No L 188, 18.7.2009, p.14).

Directive [2001/82/EC](#) of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council<sup>(14)</sup>;

“Regulation 37/2010” means Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin;”;

(g) after the definition of “sale” insert—

““Table 1” means Table 1 of the Annex to Regulation 37/2010, and “Table 1 substance” means a substance specified in the first column of Table 1;

“Table 2 substance” means a substance specified in Table 2 of the Annex to Regulation 37/2010;”;

(h) in the definition of “unauthorised substance”<sup>(15)</sup> for “an Annex IV substance” substitute “a Table 2 substance”; and

(i) in the definition of “unlicensed substance” for “Annex IV substance” substitute “Table 2 substance”.

(3) For regulation 2(2) substitute—

“(2) For the purpose of ascertaining whether the maximum residue limit has been exceeded for the purposes of these Regulations—

(a) the presence of the drug or drug metabolite (or combination thereof) specified in the second column (marker residue) of Table 1 opposite the corresponding entry in the first column (pharmacologically active substance) of that Table shall be taken to indicate the presence of that substance in that part of an animal or batch of animals, or in any animal product derived from that part of an animal or batch of animals, specified in the corresponding entry in the fifth column (target tissues) of that Table; and

(b) the maximum residue limit (if any) specified in the fourth column of that Table in the entry corresponding to that substance shall apply in respect of the presence in such part of an animal or batch of animals, or in any animal product derived from such part of an animal or batch of animals, of any such drug or drug metabolite (or combination thereof) as if it were that substance.”.

(4) In regulation 2(3) for “the Council Regulation” substitute “Regulation 470/2009”.

(5) Omit regulation 2(3A)<sup>(16)</sup>.

(6) After regulation 2(3A) insert—

“(3B) Any reference in these Regulations to an Annex to Council Directive 96/22, Council Directive 96/23 or Regulation 37/2010 is a reference to that Annex as amended from time to time.”.

(7) For regulation 7 substitute—

#### **“Prohibition of administration of Table 2 substances**

7. It is an offence to contravene Article 14(6) of Regulation 470/2009 (prohibition on administration of substances to food-producing animals in certain circumstances).”.

(8) For regulation 9(1)(e)<sup>(17)</sup>, substitute—

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<sup>(14)</sup> OJ No L 152, 16.6.2009, p.11.

<sup>(15)</sup> The definition of “unauthorised substance” was substituted by [S.I. 2006/755](#).

<sup>(16)</sup> Regulation 2(3A) was inserted by [S.I. 2006/755](#); a relevant amendment was made by [S.I. 2009/1925](#).

<sup>(17)</sup> Regulation 9 was substituted by [S.I. 2006/755](#).

- “(e) which contains a Table 1 substance at a concentration exceeding the maximum residue limit; or”.
- (9) In regulation 15(1), for the words “the analyst shall” to “the relevant person” substitute “the analyst shall record that information in a primary analysis certificate and provide a copy of that certificate to an authorised officer who shall then give that copy to the relevant person”.
- (10) For regulation 16(2) substitute—
- “(2) The analyst shall record the results of the reference analysis in a reference analysis certificate and provide a copy of that certificate to an authorised officer who shall then give this copy to the relevant person.”.
- (11) In regulation 20(2)(a)(18) for “a substance listed in Annex I or III to the Council Regulation” substitute “a Table 1 substance”.
- (12) In regulation 22(3) for “an Annex IV substance” substitute “a Table 2 substance”.
- (13) In regulation 34(6) for “Articles 5 and 14 of the Council Regulation” substitute “Articles 14(6) and 16 of Regulation 470/2009”.
- (14) After regulation 36 insert —

#### **“Review**

- 37.—**(1) The Secretary of State must from time to time—
- carry out a review of these Regulations;
  - set out the conclusions of the review in a report; and
  - publish the report.
- (2) In carrying out the review the Secretary of State must, so far as is reasonable, have regards to how Council Directive 96/22 and Council Directive 96/23 (which are implemented by these Regulations) are implemented in other member States.
- (3) The report must in particular—
- set out the objectives intended to be achieved by these Regulations;
  - assess the extent to which the objectives have been achieved;
  - assess whether the objectives remain appropriate and, if so, the extent to which they could be achieved in a less burdensome way.
- (4) The first report under this regulation must be published before the end of the period of five years beginning with 6th May 2013.
- (5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.”.

4th April 2013

*Richard Benyon*  
Parliamentary Under Secretary  
Department for Environment, Food and Rural  
Affairs

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## EXPLANATORY NOTE

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

These Regulations amend the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 (S.I. 1997/1729) (“the principal Regulations”) that provided for the enforcement of [Council Regulation \(EEC\) No 2377/90](#) laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ No L 224, 18.8.1990, p.1).

That Council Regulation has now been replaced, and these Regulations make supplementary provision to provide for the enforcement of its successor, Regulation [\(EC\) No 470/2009](#) laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (OJ No L 152, 16.6.2009, p.11).

In addition, these Regulations provide for the enforcement of Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ No L 15, 20.1.2010, p.1).

Regulation 2 amends the principal Regulations so that the references to EU legislation are up to date. Provision is also made for the review of the principal Regulations (regulation 2(14)).

A full Impact Assessment has not been prepared in respect of these Regulations as no impact on the private, voluntary or public sectors is foreseen.