STATUTORY INSTRUMENTS

2006 No. 755

FOOD

The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2006

Made - - - -	10th March *2006*
Laid before Parliament	16th March *2006*
Coming into force - -	*6th April 2006*

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(**a**) in relation to the common agricultural policy of the European Economic Community and in relation to medicinal products(**b**).

She makes the following Regulations in exercise of the powers conferred by section 2(2) of that Act, and those conferred by sections 6(4), 16(1)(a), (b) and (f), 16(3), 17(1) and (2), 26(1), (2)(a) and (3), 30(9), 31(1) and 48(1) of and paragraph 7 of Schedule 1 to the Food Safety Act 1990(**c**) and now vested in her(**d**).

In accordance with 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(**e**), she has consulted those she considers likely to be affected by these Regulations.

Title and commencement

1. These Regulations may be cited as the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2006 and come into force on 6th April 2006.

(a) 1972 c. 68.
(b) S.I. 1972/1811.
(**c**) 1990 c. 16.
(d) 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) but the Ministers of the Crown responsible retain 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.
(**e**) OJ No. L31, 1.2.2002, p. 1.

Amendments

2.—(1) The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997(**a**) shall be amended in accordance with this regulation.

(2) In regulation 2—

(a) in paragraph (1)—

(i) insert at the appropriate places—

""list A substance" means a substance named in List A of Annex II to Council Directive 96/22;"; and

""list B substance" means a substance named in List B of Annex II to Council Directive 96/22;";

(ii) for the definition of "marketing authorisation", substitute—

""marketing authorisation" has the same meaning as it bears in article 5 of Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products;"(**b**);

(iii) delete the definition of "the Marketing Authorisations Regulations";

(iv) for the definition of "unauthorised substance", substitute—

""unauthorised substance" means an Annex IV substance, a prohibited substance and any other substance or product the administration of which to animals is prohibited by or under European Community legislation;"; and

(v) delete the definition of "unlicensed product"; and

(b) after paragraph (3) insert—

"(3A) Any reference in these Regulations to a Community instrument is a reference to that instrument as amended on the date the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2006(**c**) are made.".

(3) For regulation 3, substitute—

"**Prohibition on the sale of list A and list B substances**

3.—(1) No person shall sell, for administration to any animal, any product which is, or which contains, a list A substance.

(2) Any product sold which is, or which contains, a list A substance shall be presumed, unless the contrary is proven, to have been sold for administration to an animal.

(3) Subject to paragraph (4), no person shall sell for administration to any animal any product which is, or which contains, a list B substance, if the animal or any product of that animal is intended for human consumption.

(4) Paragraph (3) shall not apply to the sale of a product that complies with the requirements of regulation 25 and which is for administration in accordance with regulations 27 or 28A.

(5) Any product sold which is, or which contains, a list B substance shall be presumed, unless the contrary is proven, to have been sold for administration to an animal which is, or any product of which is, intended for human consumption.".

(4) For regulation 4, substitute—

(**a**) S.I. 1997/1729 as amended by S.I. 2001/3590, S.I. 2004/147, S.I. 2005/2626, S.I. 2005/3254 (W. 247) and S.S.I. 2005/616.
(**b**) OJ No. L311, 28.11.2001, p. 1.
(**c**) S.I. 2006/****.

"**Prohibition on possession of oestradiol 17β or beta-agonists**

4. No person, other than a veterinary surgeon, shall possess on a farm any veterinary medicinal product containing—

(a) oestradiol 17β or its ester-like derivatives; or

(b) a beta-agonist which is authorised to be used for induction purposes in the treatment of tocolysis.".

(5) For regulation 5, substitute—

"**Prohibition on administration of beta-agonists or hormonal substances**

5.—(1) Subject to paragraph (2), no person shall administer or knowingly cause or permit to be administered to any animal any product which is, or which contains, a substance listed in Annex II or III to Council Directive 96/22.

(2) The prohibition in paragraph (1) shall not apply to the administration of a compliant veterinary medicinal product —

(a) containing testosterone, progesterone or a derivative of these substances which readily yields the parent compound on hydrolysis after absorption at the site of application, if the administration is in accordance with regulation 26;

(b) containing allyl trenbolone or a beta-agonist, if the administration is in accordance with regulation 27;

(c) having oestrogenic action (but not containing oestradiol 17β or its ester-like derivatives), androgenic action or gestagenic action, if the administration is in accordance with regulation 28; or

(d) containing oestradiol 17β or its ester-like derivatives, if the administration is in accordance with regulation 28A.

(3) In paragraph (2), "compliant veterinary medicinal product" means a veterinary medicinal product which complies with the requirements of regulation 25. ".

(6) In regulation 6—

(a) delete paragraph (1);

(b) in paragraph (2), delete "or unlicensed product"; and

(c) in paragraph (3), for "regulation 4 or 5 of the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994", substitute "regulation 8(3) of or paragraphs 1, 2 and 5 of Schedule 4 to the Veterinary Medicines Regulations 2005(**a**)".

(7) In regulations 8 and 25, for each reference to "beta-agonist or hormonal substance", substitute "substance listed in Annex II or Annex III to Council Directive 96/22".

(8) For regulation 9, substitute—

"**Prohibition on the sale of animals**

9.—(1) Subject to paragraph (2), no person shall sell or supply, for slaughter for human consumption, any animal—

(a) which contains or to which there has been administered an unauthorised substance;

(b) to which there has been administered a substance in contravention of regulation 5;

(c) that is an aquaculture animal to which a substance listed in Annex II or III of Council Directive 96/22 has been administered;

(d) to which a list A substance, oestradiol 17β, or a substance listed in Annex III of Council Directive 96/22 has been administered;

(**a**) S.I. No. 2005/2745.

(e) which contains a substance specified in Annex I or III to the Council Regulation at a concentration exceeding the maximum residue limit; or

(f) to which a medicinal product has been administered if the withdrawal period for that product has not expired.

(2) Nothing in paragraph (1)(f) shall prohibit the sale before the end of the withdrawal period of any high-value horse to which has been administered allyl trenbolone or a beta-agonist in accordance with regulation 5, provided that the type and date of treatment was entered on the horse's passport by the veterinary surgeon directly responsible for the treatment.".

(9) In regulation 15, for paragraph (3) substitute—

"(3) For the purposes of this regulation and regulations 16 and 17, "relevant person" means the owner of the premises where the sample was taken or, where another person is the owner of the animal, animal product or other article or substance from which the sample was taken, whichever one of them the authorised officer considers appropriate.".

(10) For regulation 18, substitute—

"**Methods of analysis**

18. The analysis of an official sample shall be carried out in accordance with methods authorised by Commission Decision 2002/657 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results(**a**).".

(11) For regulation 20, substitute—

"**Animal inspections**

20.—(1) An authorised officer may, by giving written notice, require—

(a) the detention of an animal or a batch of animals in the place where the animal or the batch is located; or

(b) the removal to, and the detention at, another place of an animal or batch of animals,

in order to carry out an inspection.

(2) An inspection under paragraph (1) shall be undertaken to ascertain whether—

(a) any animal contains any unauthorised substance or a residue of any other substance which the authorised officer reasonably suspects may result in any animal product derived from the animal containing an unauthorised substance or a substance listed in Annex I or III to the Council Regulation at a concentration exceeding the maximum residue limit; or

(b) any withdrawal period has expired.

(3) Where detention alone is required, the notice shall be served on the owner of the premises where the animal or batch of animals is located.

(4) Where removal and detention elsewhere is required the notice is to be served on the owner of the premises where the animal or batch animals is located unless another person is the owner of the animal or batch of animals, in which case the authorised officer shall serve the notice on whichever one of them he considers appropriate.".

(12) In regulation 23—

(a) in sub-paragraph (a) of paragraph (1), for "32(1), (2)" substitute "32(2)";

(b) in paragraphs (2) and (5), delete "6(1) or"; and

(c) in paragraph (2), for "level 5 on the standard scale", substitute "the statutory maximum".

(**a**) OJ No. L221, 17.8.2002, p. 8.

(13) For regulation 24, substitute—

"Defences and exceptions

24.—(1) In any proceedings for an offence alleging a contravention of regulation 4 it shall be a defence for the person charged to prove that the veterinary medicinal product to which the allegation relates is intended for purposes other than administration to an animal.

(2) In any proceedings for an offence alleging a contravention of regulation 8 it shall be a defence for the person charged to prove that the substance listed in Annex II or Annex III of Council Directive 96/22 contained or present in the animal or which has been administered to the animal was administered in accordance with regulation 5.".

(14) For regulation 26, substitute—

"Exception to prohibition on administration for testosterone and progesterone

26.—(1) Subject to paragraph (2), administration is in accordance with this regulation if it is carried out by a veterinary surgeon for a therapeutic purpose on a farm animal by injection.

(2) Paragraph (1) does not apply to the treatment of ovarian dysfunction, in which case administration is accordance with this regulation if it is carried out by a veterinary surgeon using a product in the form of vaginal spirals.".

(15) For regulation 27, substitute—

"Exception to prohibition on administration for allyl trenbolone and beta-agonists

27.—(1) Subject to paragraphs (2) and (3), administration is in accordance with this paragraph if it is carried out for a therapeutic purpose and it is carried out by a veterinary surgeon or under his direct responsibility.

(2) Paragraph (1) only applies to a veterinary medicinal product which is, or which contains, allyl trenbolone if it is authorised for oral administration, it is administered in accordance with the manufacturer's instructions and it is administered to an animal which is not a production animal.

(3) Paragraph (1) only applies to a veterinary medicinal product which is, or which contains, a beta-agonist if it is administered to—

(a) a member of the *equidae* Family;

(b) a pet; or

(c) a calving cow, by injection by a veterinary surgeon, to induce tocolysis during labour.".

(16) For regulation 28, substitute—

"Exception to prohibition on administration for products having oestrogenic, androgenic or gestagenic action

28.—(1) Administration is in accordance with this regulation if, in the case of farm animals other than production animals—

(a) the administration is carried out for the purpose of zootechnical treatment;

(b) the administration is carried out—

(i) in the case of the synchronisation of oestrus or the preparation of donors or recipients for the implantation of embryos by, or under the direct responsibility of a veterinary surgeon, and

(ii) in any other case, by a veterinary surgeon; and

(c) the veterinary surgeon responsible for the treatment issues a prescription for the products to be administered, whether he supplies them or not.

(2) Administration is in accordance with this regulation if, in the case of fish aged three months or less, the administration is of products with an androgenic action for sex inversion purposes.".

(17) After regulation 28, insert—

"Exception to prohibition on administration for oestradiol 17β

28A. Administration is in accordance with this regulation if it is carried out by a veterinary surgeon—

(a) no later than 14th October 2006 for oestrus induction in cattle, horses, sheep or goats; or

(b) for treating cattle for foetus maceration, mummification or pyometra.".

(18) In regulation 32—

(a) delete paragraph (1);

(b) in paragraph (3), for "The persons referred to in paragraph (1)(b) and sub-paragraphs (a) and (b) of paragraph (2) of regulation 4", substitute "Persons holding a manufacturing or wholesale dealer's authorisation granted under the Veterinary Medicines Regulations 2005, for purposes relating to a marketing authorisation for a product to which regulation 4 applies,"; and

(c) in paragraphs (4) and (5), delete "(1),".

(19) Delete regulation 33.

(20) In regulation 34, in paragraph (4)—

(a) for "(a)(ii)", substitute "(b)(ii)"; and

(b) for "these Regulations", substitute "section 32 of the Act as applied by this regulation".

Ben Bradshaw
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

Date 10th March 2006

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend provisions of the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 (S.I. 1997/1729) that give effect 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, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ No. L125, 23.5.1996, p. 3).

Regulation 2 amends the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 as follows:

Paragraphs (2)(a)(i), (3)-(5), (7)-(8) and (13)-(17) transpose Directive 2003/74/EC (OJ No. L262, 14.10.2003, p. 17) by amending regulations 2-5, 8-9, 24-28 and inserting a new regulation, 28A.

Paragraphs (2)(a)(ii)-(iv) and (b), (6)(c), (12)(a) and (18)(b) update references to Community and domestic legislation by amending regulations 2, 6, 23 and 32.

Paragraphs (6)(a) and (b), (12)(b), (18)(a) and (c) and (19) remove provisions duplicated in the Veterinary Medicines Regulations 2005 (S.I. 2005/2745) by amending regulations 6, 23 and 32 and revoking regulation 33.

Paragraph (9) clarifies upon whom an authorised officer may serve a notice specifying the result of a sample analysed by amending regulation 15.

Paragraph (10) transposes Commission Decision 2002/657 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (OJ No. L221, 17.8.2002, p. 8) by amending regulation 20.

Paragraph (12)(c) applies the statutory maximum as the penalty for summary offences by amending regulation 23.

Paragraph (20) corrects drafting errors in regulation 34.

A Regulatory Impact Assessment has been prepared and a copy has been placed in the library of each House of Parliament together with a Transposition Note setting out how the main elements of Directive 2003/74/EC and Decision 2002/657 are transposed in these Regulations. Copies may be obtained from the Veterinary Medicines Directorate, Woodham Lane, Addlestone, Surrey, KT15 3LS.

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