

2006 No. 263

FOOD

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

Made - - - - *12th June 2006*

Coming into operation - *14th July 2006*

The Department of Agriculture and Rural Development **(a)** and the Department of Health, Social Services and Public Safety **(b)**, are Departments designated **(c)** for the purposes of section 2 (2) of the European Communities Act 1972 **(d)** in relation to the common agricultural policy of the European Community and in relation to medicinal products.

Acting jointly as the Department concerned **(e)**, in exercise of the powers conferred by section 2 (2) of that Act, and those conferred by Articles 15(1)(a), (b) and (f), 15(3), 16(1) and (2), 25(1), (2)(a) and (3), 26(3), 30(9), 31(3), 32(1) and 47(2) of, and paragraph 7 of Schedule 1 to the Food Safety (Northern Ireland) Order 1991 **(f)**, having carried out the consultation, with such organisations as appear to them to be representative of interests likely to be substantially affected by the Regulations, as required by article 47 of the Order and Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down general principles and requirements of food law, establishing the European Food Safety Authority and Laying down procedures in matters of Food Safety **(g)**, hereby make the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Animals and Animal Products (Examination for Residues and Maximum Residues Limits) (Amendment) Regulations (Northern Ireland) 2006 and shall come into operation on 14 July 2006.

Interpretation

2.—(1) In these Regulations, “the principal Regulations” means the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations (Northern Ireland) 1998 **(h)**.

(a) Formerly the Department of Agriculture for Northern Ireland: see S.I. 1999/283 (N.I. 1), Article 3(4)
(b) Formerly the Department of Health and Social Services: see 1999/283 (N.I. 1), Article 3(6)
(c) S.I. 1972/1811 and S.I. 2000/2812
(d) 1972 c. 68
(e) S.R. 2000/78: see regulation 13(1)(d)(i), which allows the Department of Agriculture and Rural Development to join with the Department of Health and Social Services and Public Safety in making Regulations under the Food Safety (Northern Ireland) Order 1991 in relation to residues of veterinary products in food and food sources
(f) S.I. 1991/762 (N.I. 7) as amended by S.I. 1996/1633 (N.I. 12)
(g) O.J. No. L31, 1.2.2002, p.1
(h) S.R. 1998 No. 237

(2) The Interpretation Act (Northern Ireland) 1954 (a) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Amendment of the principal Regulations

3. The principal Regulations shall be amended in accordance with regulations 4 to 22.

4. In regulation 2—

(a) in paragraph (1)—

(i) at the appropriate places there shall be inserted the following definitions—

““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” there shall be substituted the following definition—

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

(iii) the definition of “the Marking Authorisations Regulations” shall be deleted;

(iv) for the definition of “unauthorised substance” there shall be substituted the following definition—

““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) the definition of “unlicensed product” shall be deleted; and

(b) after paragraph (3) there shall be inserted the following paragraph—

“(3A) Any reference to European Community legislation in these Regulations is to be construed, if it has been amended, as a reference to that legislation as amended at the making of the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations (Northern Ireland) 2006.”.

5. For regulation 3 there shall be substituted the following regulation—

“Prohibition on the sale of List A and List B substances

3.—(1) A person shall not sell, for administration to any animal, any—

(a) list A substance; or

(b) product 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), a person shall not 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.

(a) 1954 c. 33 (N.I.)

(b) O.J. No. L311, 28.11.2001, p.1

(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. ”.

6. For regulation 4 there shall be substituted the following regulation—

“Prohibition on possession of oestradiol 17 β or beta-agonists

4. A person, other than a veterinary surgeon, shall not possess on a farm—

- (a) any veterinary medicinal product containing oestradiol 17 β or its ester-like derivatives; or
- (b) a beta-agonist that is allowed to be used for induction purposes in the treatment of tocolysis.”.

7. For regulation 5 there shall be substituted the following regulation—

“Prohibition of administration of beta-agonists or hormonal substances

5.—(1) Subject to paragraph (2), a person shall not administer or knowingly cause or permit to be administered to any animal any—

- (a) substance listed in Annexes II or III of Council Directive 96/22; or
- (b) product which contains a substance listed in either of those Annexes.

(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 that product is administered in accordance with regulation 26;
- (b) containing allyl trenbolone or beta-agonists, if that product is administered in accordance with regulation 27;
- (c) having oestrogenic action (but not containing oestradiol 17 β or its ester-like derivatives), androgenic action or gestagenic action if that product is administered in accordance with regulation 28; or
- (d) containing oestradiol 17 β or its ester-like derivatives, if that product is administered 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. ”.

8. In regulation 6—

- (a) paragraph (1) shall be deleted;
- (b) in paragraph (2) the words “or unlicensed product” shall be deleted; and
- (c) in paragraph (3) there shall be substituted for the words “4 or 5 of the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994” the words “regulation 8(3) of or paragraphs 1, 2 and 5 of Schedule 4 to the Veterinary Medicines Regulations 2005 (a).”

9. In regulations 8 and 25, there shall be substituted for the words “beta-agonist or hormonal substance”, in each place where they occur, the words “substance listed in Annex II or Annex III of Council Directive 96/22”.

10. For regulation 9 there shall be substituted the following regulation—

“Prohibition on the sale of animals

(a) S.I. 2005/2745

9.—(1) Subject to paragraph (2), a person shall not 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 Annexes II or III of Council Directive 96/22 has been administered;
- (d) to which a list A substance, oestradiol 17 β , or a substance listed in Annex III of Council Directive 96/22 has been administered;
- (e) which contains a substance specified in Annex I or III to the Council Regulation at a concentration exceeding the relevant 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 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.”.

11. In regulation 15, for paragraph (3) substitute—

“(3) For the purposes of this regulation and regulations 16 and 17, “relevant person” shall mean—

- (a) the owner of the premises where the sample was taken; or
- (b) in the event that the person in sub-paragraph (a) is not also the owner of the animal, batch of animals, animal product or other article or substance from which the sample was taken, the owner thereof,

whichever one of them that the authorised officer considers appropriate.”.

12. For regulation 18 there shall be substituted the following regulation—

“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).”.

13. For regulation 20 there shall be substituted the following regulation—

“Animal inspections

20.—(1) Where an authorised officer considers it reasonable to do so, he may, by giving notice in writing, require the detention of an animal or a batch of animals in the place where it is, or its removal to such other place as is specified in the notice and detain it there, to enable it to be inspected to ascertain—

- (a) whether the animal or any animal in the batch contains any unauthorised substance or a residue of any other substance which he reasonably suspects may result in any animal product derived from it containing an unauthorised substance or a substance listed in Annex I or III to the Council Regulation which is at a concentration exceeding its maximum residue limit; or
- (b) whether or not any withdrawal period has expired.

(2) Where detention alone is required, the notice shall not be served on the owner of the premises where the animal or batch of animals is located.

(3) Where removal and detention elsewhere is required the notice shall be served on—

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

- (a) the owner of the premises where the animal or batch of animals is located; or
- (b) in the event that the person in sub-paragraph (a) is not also the owner of the animal or, batch of animals, the owner thereof,

whichever one of them that the authorised officer considers appropriate.”.

14. In regulation 23—

- (a) in sub-paragraph (a) of paragraph (1), for “32 (1), (2)” there shall be substituted “32 (2)”; and
- (b) in paragraphs (2) and (4), the reference “6 (1) or” shall be deleted.

15. For regulation 24 there shall be substituted the following regulation—

“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 or beta-agonist, 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.”.

16. For regulation 26 there shall be substituted the following regulation—

“Exception to prohibition on administration for testosterone and progesterone

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

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

17. For regulation 27 there shall be substituted the following regulation—

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

27.—(1) Subject to paragraphs (2) and (3), administration shall be in accordance with this regulation 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) shall apply to a veterinary medicinal product which is, or which contains, allyl trenbolone only if it is authorised for oral administration, it is administered in accordance with the manufacturer’s instructions and it is administered to non-production animals.

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

- (a) member of the equidae family;
- (b) pet; or
- (c) calving cow, by injection by a veterinary surgeon, to induce tocolysis during labour.”.

18. For regulation 28 there shall be substituted the following regulation—

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

28. Administration shall be in accordance with this regulation if—

- (a) in the case of farm animals other than production animals—
 - (i) it is carried out on a clearly identified animal for the purpose of zootechnical treatment;
 - (ii) it is carried out, 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 in any other case, by a veterinary surgeon; and
 - (iii) the veterinary surgeon responsible for the treatment issues a prescription for the products to be administered, whether he supplies them or not; and
- (b) in the case of aquaculture animals it is—
 - (i) of products with androgenic action;
 - (ii) for sex inversion purposes; and
 - (iii) carried out on fish aged three months or less.”.

19. After regulation 28 there shall be inserted the following regulation—

“Exception to prohibition on administration for oestradiol 17β

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

- (a) oestrus induction in cattle, horses, sheep or goats and it is carried out no later than 14th October 2006; or
- (b) the treatment of cattle for foetus maceration, mummification or pyometra.”.

20. In regulation 32—

- (a) paragraph (1) shall be deleted;
- (b) in paragraph (3) there shall be substituted for the words “The persons referred to in paragraph (1)(b) and sub-paragraphs (a) and (b) of paragraph (2) of regulation 4” the words “Persons holding a manufacturing or wholesale dealer’s authorisation granted under the Veterinary Medicines Regulation 2005, for purposes relating to a marketing authorisation for a product to which regulation 4 applies,”; and
- (c) in paragraphs (4) and (5) the reference “(1),” shall be deleted.

21. Regulation 33 shall be deleted.

22. In Schedule 2 —

- (a) at the top of Column 1 there shall be inserted, “The Medicines (Stilbenes and Thyrostatic) Regulations (Northern Ireland) 1982”; and
- (b) at the top of column 2 there shall be inserted, “S.R. 1982 No.279”.

Sealed with the Official Seal of the Department of Agriculture and Rural Development on 12 June 2006.

(L.S.)

David Small
A senior officer of the
Department of Agriculture and Rural Development

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 12 June 2006.

(L.S.)

Andrew McCormick
A senior officer of the
Department of Health, Social Services and Public Safety

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 (Northern Ireland) 1998 (S.R. 1998 No. 237) 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 Directive 81/602/EEC, Directive 88/146/EEC and Directive 88/299/EEC (OJ No. L125, 23.5.1996, p. 3).

Regulation 3 amends the Animal and Animal Products (Examination of Residues and Maximum Residue Limits) Regulations (Northern Ireland) 1998 as follows:-

- (a) regulations (4)(a)(i), (5)-(7), (9)-(10) and (15)-(19) 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.
- (b) regulations (4)(a)(ii)-(iv) and (b), (8)(c), (14)(a) and (20)(b) update references to Community and domestic legislation by amending regulations 2,6,23 and 32.
- (c) regulations (8)(a) and (b), (14)(b), (20)(a) and (c) and (21) remove provisions duplicated in the Veterinary Medicines Regulations 2005 (S.I. 2005/2745) by amending regulations 6, 23 and 32 and revoking regulation 33.
- (d) regulation (11) clarifies upon whom an authorised officer may serve a notice specifying the results of a sample analysed by amending regulation 15.
- (e) regulation (12) 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 18.

© Crown Copyright 2006

Published and printed in the UK by The Stationery Office Limited under the authority and superintendence of Carol Tullo, Controller of Her Majesty's Stationery Office being the Government Printer for Northern Ireland and the Officer appointed to print the Acts of the Northern Ireland Assembly

Dd. N2726. C2. 6/06. Gp. 130. 14567.

£3.00