

**SI No. 827 of 2004.**

**Control of Animal Remedies and their Residues (Amendment) Regulations 2004.**

I, Mary Coughlan, Minister for Agriculture and Food, in exercise of the powers conferred on me by section 8 of the Animal Remedies Act, 1993 (No. 23 of 1993) (as adapted by the Agriculture, Food and Rural Development (Alteration of Name of Department and Title of Minister) Order 2002 (S.I. No. 306 of 2002), for the purpose of giving further effect to Council Directive 96/22/EC of 29 April 1996, as amended by Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003, and Directive 2001/82 of the European Parliament and of the Council, as amended, and after consultation with the Animal Remedies Consultative Committee, hereby make the following Regulations:

1. (a) These Regulations may be cited as the Control of Animal Remedies and their Residues (Amendment) Regulations 2004.  
(b) These Regulations shall come into force on 1 January 2005.
2. The Control of Animal Remedies and their Residues Regulations 1998 (S.I. 507 of 1998) are amended -
  - (a) In Regulation 10(1), by deleting “oestradiol 17 $\beta$ ,”,
  - (b) In Regulation 12(1), by inserting after “oestrogenic” the following:  
“(other than oestradiol 17 $\beta$  and its ester-like derivatives),”
  - (c) In Regulation 12(2), by inserting after “oestrogenic” the following:  
“(other than oestradiol 17 $\beta$  and its ester-like derivatives),”
  - (d) By inserting after Regulation 12 the following:

“Administration of Oestradiol and its ester-like derivatives.

**12(A)** (1) Notwithstanding Regulation 12(1), a registered veterinary surgeon may, in accordance with an animal remedies authorisation, administer an authorised animal remedy containing oestradiol 17 $\beta$  or its ester-like derivatives only for:

- (a) treatment of foetus maceration or mummification in bovine animals,
- (b) treatment of pyometra in bovine animals, or
- (c) the purpose of oestrus induction in bovines, ovines, equidae and caprines in the period up to, but no later than 14 October 2006.

(2) It shall not be lawful for a person, other than a veterinary surgeon, or a person licensed in accordance with Regulation 23 or 30 of the Animal Remedies Regulations 1996 (S.I. No. 179 of 1996), at the premises referred to in the relevant license, to possess an authorised animal remedy covered by this Regulation.

(3) A person who fails to comply with this Regulation is guilty of an offence.”,

(e) In Regulation 13(1) by substituting for “Regulation 10, 11 or 12” the following:

“Regulation 10, 11, 12 or 12A”,

(f) In Regulation 13(2), by substituting for “Regulation 10, 11 or 12” the following:

“Regulation 10, 11, 12 or 12A”,

(g) In Regulation 13(2), by inserting after subparagraph (d) the following:

“and

(e) the date of expiry of the withdrawal period referred to in Regulation 42 of the Animal Remedies Regulations 1996 (S.I. No 179 of 1996).”,

(h) In Regulation 14, by substituting for “Regulations 10, 11 or 12” the following:  
“Regulations 10, 11, 12 or 12A”,

(i) In Regulation 23(1), by substituting for “Regulation 10, 11 or 12” the following:  
“Regulation 10, 11, 12 or 12A”,

(j) In Regulation 23(2), by substituting for “Regulation 10, 11 or 12” the following:  
“Regulation 10, 11, 12 or 12A”,

(k) In Regulation 23(3), by substituting for “Regulation 10, 11 or 12” the following:  
“Regulation 10, 11, 12 or 12A”.

3. The Animal Remedies Regulations 1996 (S.I. No. 507 of 1996) are amended –

(a) By substituting for Regulation 13(1)(a) the following:

“Regulation 13(1)(a)

veterinary surgeon only in respect of an animal remedy which may be administered:

A. in the case of an animal remedy referred to in Regulation 10(1), 11(1), 12(1), or 12A of the Control of Animal Remedies and their Residues Regulations 1998, as amended, by a registered veterinary surgeon only and the product label shall bear the following statement in addition to the designated route of sale or supply – “Administration by Veterinary Surgeon only”:

B. in all other cases only:

- (i) by a registered veterinary surgeon, or
- (ii) under the direct supervision of a registered veterinary surgeon where such registered veterinary surgeon is present at the time of administration and is in a position to render assistance if required.”.

(b) In the First Schedule, Part IV, by inserting in paragraph 1, after “VSO”, the following:

“In the case of an animal remedy referred to in Regulation 13(1)(a)A of these Regulations, the following statement shall appear on the label in addition: “Administration by Veterinary Surgeon Only” ”.

**GIVEN** under my Official Seal

15 December 2004

L.S.

SIGNED

Mary Coughlan,

Minister for Agriculture and Food.

Explanatory Note

*(This note is not part of the instrument and does not purport to be a legal interpretation)*

These Regulations give effect to Directive 2003/74 of the European Parliament and of the Council by restricting further the availability and administration of animal remedies containing oestradiol 17 $\beta$  and its esther-like derivatives. Such animal remedies may only be administered by a registered veterinary surgeon for the three specific purposes specified at Section 2(d) of these Regulations.