

## **CONTROL OF ANIMAL REMEDIES AND THEIR RESIDUES REGULATIONS 1998**

I, Joe Walsh, 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 Forestry (Alteration of Name of Department and Title of Minister) Order, 1997 (S.I. No. 302 of 1997)), and, in relation to Regulation 30 of these Regulations, section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purpose of giving effect to Council Directive 96/22/EC of 29 April 1996 and Council Directive 96/23/EC of 29 April 1996, and further effect to Council Directive No. 81/851/EEC of 28 September 1981, and after consultation with the Animal Remedies Consultative Committee, hereby make the following Regulations:

1. (1) These Regulations may be cited as the Control of Animal Remedies and their Residues Regulations, 1998.

(2) These Regulations shall come into operation on the 28 day of December, 1998.

### **Interpretation**

2. (1) In these Regulations -

"the Act" means the Animal Remedies Act, 1993 (No. 23 of 1993);

"the Act of 1988" means the Abattoirs Act, 1988 (No. 8 of 1988);

"abattoir" means an abattoir to which the Act of 1988 applies;

"animal remedies authorisation" has the same meaning as it has in the Regulations of 1996;

"approved laboratory" means a laboratory designated as an approved laboratory in accordance with Regulation 15;

"authorised animal remedy" has the same meaning as it has in the Regulations of 1996;

"the Council Directives" means Council Directive 96/22/EC of 29 April 1996 and Council Directive 96/23/EC of 29 April 1996;

"eartag" means an approved eartag within the meaning of the Bovine Tuberculosis (Attestation of the State and General Provisions) Order,

1989 (S.I. No. 308 of 1989), or an eartag referred to in Regulation 4 of the Bovine Tuberculosis (Attestation of the State and General Provisions) Order, 1996 (S.I. No. 103 of 1996), or an eartag referred to in Article 3 of Council Regulation (EC) No

820/974 of 21 April 1997 establishing a system for the identification and registration of bovine animals and regarding the

labelling of beef and beef products;

4 O.J. No. L117 of 7.05.97, p.1

"functions" includes powers and duties and references to the performance of functions includes as respects powers and duties,

references to the exercise of powers and the carrying out of duties;

"identity card" means-

(a) an identity card within the meaning of the Bovine Tuberculosis (Attestation of the State and General Provisions) Order, 1989 (S.I. No. 308 of 1989), or the Brucellosis in Cattle (General Provisions) Order, 1991 (S.I. No. 114 of 1991), or

(b) an animal passport to which Council Regulation (EC) 820/97 of 21 April 1997 establishing a system for the identification and

registration of bovine animals and regarding the labelling of beef and beef products applies;

"manufacturer's licence" has the same meaning as it has in the Regulations of 1996;

"maximum residue limit" has the same meaning as it has in Council Regulation (EEC) No. 2377/905 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin; 5 O.J. No. L.224 of 18.08.90, p.1

"member state" means a member state of the European Communities;

"national reference laboratory" means a laboratory designated as a national reference laboratory in accordance with Regulation 15;

"official mark" means a mark in the form set out in the Schedule;

"prescription" has the same meaning as it has in the Regulations of 1996, and cognate words shall be construed accordingly;

"the Regulations of 1996" means the Animal Remedies Regulations, 1996 (S.I. No. 179 of 1996);

"registered veterinary surgeon" means a person registered in The Register of Veterinary Surgeons for Ireland;

"slaughter" in relation to an animal, means slaughter for the purposes of the production of meat or other food intended for human or animal consumption.

"slaughterhouse" means -

(a) (i) an establishment approved under Regulation 4 of the European Communities (Fresh Meat) Regulations, 1997 (S.I. No. 434 of 1997),

(ii) an establishment approved under Regulation 4 of the European Communities (Fresh Poultry Meat) Regulations, 1996 (S.I. No. 3 of 1996), or

(iii) an establishment approved under Regulation 4 of the European Communities (Rabbit Meat and Farmed Game Meat) Regulations, 1995 (S.I. No. 278 of 1995),

used for or in connection with the slaughter of animals, or

(b) an abattoir.

(2) A word or expression that is used in these Regulations and that is also used in the Council Directives has, unless the contrary intention appears, the same meaning in these Regulations as it has in the Council Directives.

(3) In these Regulations a reference to a Regulation or Schedule is a reference to a Regulation of or Schedule to these Regulations, unless it is indicated that a reference to some other provision is intended, and a reference to a paragraph or subparagraph is a reference to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that a reference to some other provision is intended.

### Restrictions on Manufacture etc. of Certain Animal Remedies

3. (1) It shall not be lawful for a person to manufacture, import, possess, sell or supply an animal remedy consisting of or containing a stilbene, stilbene derivative, salt or ester of a stilbene or stilbene derivative, or a thyrostatic substance.

(2) Subject to the provisions of this Regulation, it shall not be lawful for a person to manufacture, import, possess, sell or supply an animal remedy consisting of or containing -

(a) a beta-agonist, or

(b) a substance having an oestrogenic, androgenic or gestagenic action.

(3) A person may, in accordance with an animal remedies authorisation and a manufacturer's licence, manufacture, or import from a state other than a member state, an animal remedy consisting of or containing a substance to which paragraph (2) applies.

(4) A person may, in accordance with an animal remedies authorisation, possess, sell or supply, or import from a member state, an authorised animal remedy consisting of or containing a substance to which paragraph (2) applies.

(5) It shall not be lawful for a person to manufacture, import, sell, hire or otherwise supply or use, or have in his or her possession or under his or her control any plant, machinery, instrument, cartridge, container, utensil, label, package, package insert or other thing, made or adapted for use in connection with

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(a) the manufacture of a substance, to which paragraph (1) applies, or a prohibited animal remedy,

(b) the administration of a prohibited animal remedy to a farm or aquaculture animal, or

(c) the administration of a substance, to which paragraph (1) applies, to a farm or aquaculture animal.

(6) A person may, pursuant to a licence under Regulation 26 of the Regulations of 1996, import into the State an animal remedy within the meaning of that Regulation consisting of or containing a substance to which paragraph (2) applies.

(7) This Regulation shall not apply to a substance -

(a) that is intended to be used for and capable, of being used for, purposes other than agricultural or veterinary purposes.

(b) that is labelled as being intended for purposes other than agricultural or veterinary purposes, and

(c) in respect of which there is for the time being in force a product authorisation under the Medical Preparations (Licensing and Sale) Regulations, 1996 (S.I. No. 43 of 1996).

#### Amendment of Regulation 9 of Regulations of 1996

4. Regulation 9 of the Regulations of 1996 is hereby amended by the insertion of the following paragraphs:

"(8) The Competent Authority shall, in granting or renewing a veterinary product authorisation in respect of a veterinary medicinal product consisting of or containing a substance to which Regulation 3(2) of the Regulations of 1998, applies, comply with the provisions of the Council Directives within the meaning of those Regulations.

(9) The Competent Authority shall not grant or renew a veterinary product authorisation in respect of a veterinary medicinal product consisting of or containing a substance to which Regulation 3(1) of the Regulations referred to in paragraph (8) applies.

(10) Where the Competent Authority grants a veterinary product authorisation in respect of a veterinary medicinal product that may be administered to a farm or aquaculture animal it shall furnish the Community reference laboratories designated under Chapter 1 of Annex V of Council Regulation 96/23/EC of 29 April 1996 and the national reference laboratories designated under the plan submitted to the Commission by the Minister pursuant to Article 5 of that Directive with the routine analysis methods."

Amendment of Regulation 23 of Regulations of 1996

5. Regulation 23 of the Regulations of 1996 is hereby amended by the substitution in paragraph (8)(b) of the following clause for clause (vi):

"(vi) if in the opinion of the Competent Authority the person is not, for any other reason (including conviction of the person concerned for an offence or a failure by him or her to comply with a condition attached to an earlier manufacturer's licence or animal remedies authorisation), or having regard to the provisions of Article 25 of Council Directive 96/23/EC of 29 April 1996, a fit and proper person to hold a manufacturer's licence."

Prohibition on Administration of Stilbenes etc.

6. (1) It shall not be lawful for a person to administer or cause to be administered to a farm or aquaculture animal an animal remedy consisting of or containing a substance to which paragraph (1) of Regulation 3 applies.

(2) It shall not be lawful for a person to -

- (a) import, export, sell, supply or slaughter an animal to which an animal remedy referred to in paragraph (1) has been administered,
- (b) import, export, sell or supply any meat of, or other food derived from, an animal referred to in subparagraph (a), or any meat product prepared from or with any such meat,
- (c) subject meat or other food referred to in subparagraph (b) to any manufacturing process, or
- (d) be in possession of or have under his or her control an animal to which an animal remedy has been administered in contravention of paragraph (1), or meat, meat products or other food derived from such an animal.

Restrictions on Administration of Beta-abonists etc.

7. (1) Subject to Regulations 10, 11 and 12, it shall not be lawful for a person to administer or cause to be administered to a farm or aquaculture animal an animal remedy consisting of or containing a substance to which paragraph (2) of Regulation 3 applies.

(2) It shall not be lawful for a person to -

- (a) import, export, sell, supply or slaughter an animal to which an animal remedy referred to in paragraph (1) has been administered,
- (b) import, export, sell or supply any meat of, or other food derived from, an animal referred to in subparagraph (a), or any meat product prepared from or with any such meat,
- (c) subject meat or other food referred to in subparagraph (b) to any manufacturing process, or
- (d) be in possession of or have under his or her control an animal to which an animal remedy has been administered in contravention of paragraph (1), or meat, meat products or other food derived from such an animal.

Unlawful to Sell or Slaughter certain Animals etc.

8. (1) It shall not be lawful for a person to sell or slaughter a farm or aquaculture animal to which a prohibited animal remedy has been administered.

(2) It shall not be lawful for a person to sell or slaughter a farm or aquaculture animal where there is present in such animal a quantity of an animal remedy in excess of the maximum residue limit.

(3) It shall not be lawful for a person to sell meat, a meat product or other food of animal origin that contains an animal remedy consisting of or containing a substance to which Regulation 3(1) applies, or a quantity of an authorised animal remedy in excess of the maximum residue limit.

(4) It shall not be lawful for a person to sell meat, a meat product or other food of animal origin that contains a prohibited animal remedy.

#### Detention of Certain Animals at Slaughterhouses

9. (1) Where an authorised person has reasonable grounds for believing that a prohibited animal remedy or an animal remedy consisting of or containing a substance to which Regulation 3(1) applies has been administered to an animal presented for slaughter at a slaughterhouse he or she shall -

(a) direct that the animal be slaughtered separately from other animals at the slaughterhouse at such time as he may specify, and

(b) (i) issue a direction under Regulation 16 in respect of the meat, offal and carcase of the animal concerned, or

(ii) detain the meat offal and car case of the animal concerned under Regulation 11 of the Abattoirs Act, 1988 (Veterinary Examination) Regulations, 1992 (S.I. No. 89 of 1992) for such period as he deems appropriate.

(2) Where an authorised person has reasonable grounds for believing that an authorised animal remedy has been administered to an animal presented for slaughter at a slaughterhouse and that the withdrawal period in respect thereof has not expired he or she shall give a direction under Regulation 16 to the owner or occupier of the slaughterhouse concerned -

(a) prohibiting the movement of the animal from the slaughterhouse, and

(b) prohibiting the sale or slaughter of the animal, until such time as he is satisfied that the quantity of the authorised animal remedy concerned present in the animal no longer exceeds the maximum residue limit.

(3) A prohibition in a direction given under paragraph (2) shall remain in force for a period of not less than 28 days.

(4) Where having regard to the provisions of Article 24(2) of Council Directive 96/23/EC of 29 April 1996 it would not be practicable for an authorised person to give a direction in accordance with paragraph (2) he may direct that the animal concerned be slaughtered before the expiration of the period specified in paragraph (3) and give a direction under Regulation 16 to the owner or occupier of the slaughterhouse concerned prohibiting the movement or sale of all meat, meat products or other food derived from such animal until such time as he is satisfied that it does not contain a quantity of an authorised animal remedy in

excess of the maximum residue limit.

(5) An authorised person shall declare to be unfit for human consumption all meat, meat products or other food derived from an animal in which, at the time of its slaughter, there is present a quantity of an authorised animal remedy in excess of the maximum residue limit.

(6) An authorised person shall declare to be unfit for human consumption all meat, neat products or other food of animal origin containing a quantity of an authorised animal remedy in excess of the maximum residue limit.

(7) In this Regulation, "authorised person" means an authorised officer who is a registered veterinary surgeon, an authorised officer under the Act of 1988 who is a veterinary surgeon, or a veterinary inspector appointed under Part IV of that Act.

#### Administration of certain Animal Remedies for Therapeutic Purposes

10. (1) A registered veterinary surgeon may, for therapeutic purposes, administer to a farm animal an authorised animal remedy consisting of or containing oestradiol 17B, testosterone, progesterone, or derivatives thereof that readily yield the parent compound on hydrolysis after absorption at the site of application:

Provided that -

(a) (i) where it is intended to administer the authorised animal remedy for the purpose of treating ovarian dysfunction in the farm animal concerned, it is administered by vaginal spiral, or

(ii) in all other cases, it is administered by injection, and

(b) the animal remedy concerned is administered in accordance with the animal remedies authorisation in respect thereof.

(2) A registered veterinary surgeon or, pursuant to a prescription, a person other than a registered veterinary surgeon, may, for therapeutic purposes, administer to an equid or companion animal an authorised animal remedy consisting of or containing allyl trenbolone, provided that it is administered orally and in accordance with the animal remedies authorisation in respect thereof.

(3) A farm animal (other than a bovine animal to whose ear an eartag has been affixed) to which an authorised animal remedy has been administered in accordance with this Regulation shall be marked by the owner or person in charge of the farm animal at the time the animal remedy is administered in such manner as will enable it to be readily identified.

(4) In this Regulation, "prescription" means a prescription issued by a registered veterinary surgeon in accordance with and in the form prescribed by Regulation 45 (other than paragraph (2)(c)(ii) thereof) of the Regulations of 1995.

#### Administration of Beta-agonists

11. (1) A registered veterinary surgeon may, for the purpose of inducing tocolysis, administer to a cow in calf an authorised animal

remedy consisting of or containing a beta-agonist, provided that the animal remedy concerned is administered by injection and in accordance with the animal remedies authorisation in respect thereof.

(2) A registered veterinary surgeon or, pursuant to a prescription (within the meaning of Regulation 10), a person other than a registered veterinary surgeon, may, for the purpose of tocolysis or to treat a respiratory problem, administer, to equidae raised for purposes other than meat production or a companion animal, an authorised animal remedy consisting of or containing a beta-agonist, provided that the animal remedy concerned is administered in accordance with the animal remedies authorisation in respect thereof.

(3) A farm animal (other than a bovine animal to whose ear an eartag has been axed) to which an authorised animal remedy has been administered in accordance with this Regulation shall be marked by the owner or person in charge of the farm animal at the time the animal remedy is administered in such manner as will enable it to be readily identified.

(4) In this Regulation, "companion animal" has the same meaning as it has in Regulation 32 of the Regulations of 1996 (inserted by paragraph (f) of Regulation 32 of these Regulations).

#### Administration of certain Animal Remedies for Zootechnical Purposes

12. (1) A registered veterinary surgeon may, for zootechnical purposes, administer to a farm animal an authorised animal remedy consisting of or containing a substance having an oestrogenic, androgenic or gestagenic action:

Provided that-

(a) the farm animal concerned is deemed, for the purposes of Regulation 44 of the Regulations of 1996, to be under the care of the registered veterinary surgeon who administers the authorised animal remedy,

(b) the registered veterinary surgeon is deemed, for the purposes of the said Regulation 44 to have been consulted in a professional capacity regarding the care of the farm animal concerned, and

(c) the animal remedy concerned is administered in accordance with the animal remedies authorisation in respect thereof.

(2) A registered veterinary surgeon or, pursuant to a prescription, a person other than a registered veterinary surgeon, may, in accordance with an animal remedies authorisation, administer an authorised animal remedy consisting of or containing a substance having an oestrogenic, androgenic or gestagenic action to a farm animal for the purposes of synchronising oestrus and preparing donors and recipients for the implantation of embryos.

(3) A registered veterinary surgeon or, pursuant to a prescription, a person other than a registered veterinary surgeon, may, in accordance with an animal remedies authorisation, administer an authorised animal remedy consisting of or containing a substance having an androgenic action to an aquaculture animal of not more than 3 months in age for the purposes of sex inversion.

(4) A farm animal (other than a farm animal to whose ear an eartag has been affixed) to which an authorised animal remedy has been administered in accordance with this Regulation shall be marked by the owner or person in charge of the farm animal at the time the animal remedy is administered in such manner as will enable the

farm animal to be readily identified.

(5) In this Regulation, "prescription" means a prescription issued by a registered veterinary surgeon in accordance with Regulation 45 (other than paragraph (2)(c)(ii), (iii) and (iv) thereof of the Regulations of 1996.

#### Register of Animal Remedies administered

13. (1) A registered veterinary surgeon to whom Regulation 10, 11 or 12 applies shall cause to be established and maintained a register of all authorised animal remedies administered under those Regulations by him or her or pursuant to a prescription issued by him or her.

(2) A registered veterinary surgeon shall, at the time of administering or prescribing an animal remedy, as the case may be, pursuant to Regulation 10, 11 or 12, enter in the register maintained under this Regulation the following particulars, that is to say:

- (a) the nature of the treatment given to the farm animal concerned,
- (b) the animal remedy administered,
- (c) the date of the treatment, and
- (d) the identity of the farm animal concerned.

(3) Where a person other than a registered veterinary surgeon administers, pursuant to Regulation 10, 11 or 12, an authorised animal remedy to a farm animal he shall on that day inform the registered veterinary surgeon who issued the prescription in respect of the farm animal concerned of the fact and the registered veterinary surgeon shall thereupon enter in the register maintained under this Regulation the particulars specified in paragraph

(4) Where a person other than a registered veterinary surgeon administers, pursuant to Regulation 10, 11 or 12, an authorised animal remedy to a farm animal the registered veterinary surgeon shall, in addition to entering the particulars specified in paragraph (2), in the register maintained under this Regulation, enter therein the date of issue by him or her of the relevant prescription.

(5) An entry in a register maintained under this Regulation shall be kept for a period of 5 years and shall be made available for inspection by an authorised officer on a request being made in that behalf by him or her.

(6) It shall not be lawful for a person to contravene a provision of this Regulation.

#### Prohibition on administration of Authorised Animal Remedy

14. Notwithstanding Regulations 10, 11 and 12, it shall not be lawful for a person to administer or cause to be administered an authorised animal remedy, to which any of those Regulations apply, to -

- (a) a farm animal intended for fattening,
- (b) a castrate farm animal other than an equid, or
- (c) a reproductive farm animal during the fattening period at the end of its breeding life.

#### Laboratories



15. (1) The Minister may, for the purposes of these Regulations and the Council Directives, designate, by instrument in writing, a laboratory as an approved laboratory, and the persons for the time being employed or engaged in the analysis of specimens at a laboratory so designated may perform the functions of an approved laboratory specified in these Regulations and the Council Directives.

(2) The Minister shall, in accordance with Article 14 of Council Directive 96/23/EC of 29 April 1996, designate, in the plan submitted by him or her under Article 5 of that Directive, a laboratory as a national reference laboratory, and the persons for the time being employed or engaged in the analysis of specimens at a laboratory so designated may perform the functions of a national reference laboratory specified in these Regulations and the Council Directives.

#### Restriction of Movement of Certain Animals

16. (1) Where -

(a) an authorised officer has reasonable grounds for believing that in relation to a farm animal, meat, meat product, other food of animal origin or an animal remedy there has been a contravention of the Act, or these Regulations.

(b) an authorised officer receives a notification in writing from an approved laboratory or a national reference laboratory, as the case may be, that a specimen taken from a farm animal, meat, meat product or other food of animal origin was found, on analysis at the laboratory concerned -

(i) to contain a prohibited animal remedy or a substance to which paragraph (1) of Regulation 3 applies, or

(ii) to contain a residue of an authorised animal remedy in excess of the maximum residue limit in respect thereof,

(c) a prohibited animal remedy or a substance to which paragraph (1) of Regulation 3 applies is found on land or premises, or

(d) any plant, machinery, instrument, cartridge, container, utensil, label, package, insert or other thing to which paragraph (5) of Regulation 3 applies is found on land or premises,

the authorised officer may give a direction, in accordance with paragraph (2), to -

(i) the owner or occupier of -

(I) the land or premises on which the authorised officer concerned has reasonable grounds for believing that the contravention referred to in paragraph (a) has taken place,

(II) the land or premises on which the specimen referred to in paragraph (b) was taken, or

(III) the land or premises to which paragraph (c) or (d) applies, as may be appropriate, or

(ii) the owner or person in charge or control of -

(I) the farm animal, meat, meat product or other food of animal origin to which paragraph (a) or (b) applies, or

(II) any farm animal, meat, meat product or other food of animal origin found on land or premises to which paragraph (c) or (d) applies,

as may be appropriate.

(2) A direction under paragraph (1) shall be in writing and may, subject to paragraph (5) -

- (a) prohibit the movement of-
- (i) all farm animals, meat, meat products, or other food of animal origin, or
  - (ii) such farm animal, meat, meat product or other food of animal origin as is specified in the direction, from such land or premises or any part thereof as is specified in the direction,
- (b) prohibit the movement of all farm animals, meat, meat products or other food of animal origin into such land or premises,
- (c) prohibit the sale or slaughter of such farm animals as may be specified in the direction, or
- (d) require the owner or occupier of such land or premises or the person in charge of or in control of the farm animal, meat, meat product or food concerned to comply with such other restrictions relating to the movement of farm animals, meat, meat products or food of animal origin as may be specified in the direction for such period as may be specified in the direction.
- (3) An authorised officer may by direction in writing amend or revoke a direction given by him or her under this Regulation, including a direction under this paragraph.
- (4) A direction under this Regulation shall remain in force until it is revoked.
- (5) An authorised officer may, on the application in writing of the owner of a farm animal to which a direction under this Regulation applies, and on the taking from such farm animal by an authorised officer and analysis at an approved laboratory of such specimens (if any) as the authorised officer considers appropriate, issue a permit allowing the movement of the farm animal concerned into or out of the land or premises or part thereof to which the direction relates, or the sale or slaughter of such farm animal.
- (6) The costs of the taking and analysis of a specimen pursuant to paragraph (5) shall be borne by the owner of the farm animal concerned and shall be recoverable by the Minister in any court of competent jurisdiction as a simple contract debt.

#### Testing of Animals where Illegal Treatment established

17. (1) Where an authorised officer receives a notification in writing from an approved laboratory or a national reference laboratory, as the case may be, that on analysis at that laboratory concerned, a specimen taken by him or her from a farm animal was found to contain a prohibited animal remedy or a substance to which Regulation 3(1) applies, an authorised officer shall, in accordance with Article 17 of Council Directive 96/23/EC of 29 April 1996, take specimens from a statistically representative sample of the batch of animals to which the said farm animal belongs.
- (2) Where, in relation to not less than half of the specimens taken under paragraph (1), an authorised officer receives a notification in writing from an approved laboratory or a national reference laboratory, as the case may be, that the specimens concerned were found, on analysis at the laboratory concerned, to contain a prohibited animal remedy or a substance to which Regulation 3(1) applies -
- (a) a direction served under Regulation 16 in respect of those farm animals or in respect of the land or premises at which they are

kept shall remain in force for a period of not less than 12 months, and

(b) specimens shall be taken by an authorised officer from all farm animals in the batch referred to in paragraph (1) other than those farm animals from which specimens have been taken under that paragraph.

(3) The costs of the taking and analysis of a specimen under this Regulation shall be borne by the owner or person in charge of the farm animal concerned and shall be recoverable by the Minister in any court of competent jurisdiction as a simple contract debt.

(4) Paragraph (2)(b) shall not apply where the owner or person in charge of the farm animal concerned consents to their destruction in accordance with Regulation 22.

#### Surrender of Identity Cards

18. (1) Any person having in his or her possession, or under his or her control -

(a) an identity card issued in respect of an animal on land or premises to which a direction under Regulation 16 applies, or

(b) an identity card issued in respect of an animal to which a direction under the said Regulation applies,

shall surrender the identity card concerned to an authorised officer.

(2) The owner or occupier of land or premises to which a direction under Regulation 16 applies shall make a declaration in writing in the form specified in the direction of the number and species of animals on the land or premises concerned.

(3) The owner or person in charge or control of an animal to whom a direction under Regulation 16 is addressed shall make a declaration in writing in the form specified in the direction of all land or premises of which he is the owner or occupier and the number and species of animals on such land or premises.

(4) Where the owner or person in charge of an animal referred to in paragraph (1) or the owner or occupier of land on which such animal is for the time being kept does not have in his or her possession or under his or her control the identity card in respect of the animal concerned then, he or she shall inform an authorised officer of the place at which, and the name and address of the person from whom, it may be obtained.

(5) It shall not be lawful for a person to whom a provision of this Regulation applies to fail to comply with that provision.

#### Marking of Animals

19. (1) Where an authorised officer receives a notification in writing from an approved laboratory or a national reference laboratory, as the case may be, that a specimen taken from a farm animal by an authorised officer was found, on analysis at the laboratory concerned, to contain a prohibited animal remedy or a substance to which Regulation 3(1) applies, the official mark in indelible form, shall be affixed to the farm animal, from which the specimen was taken, in such manner as an authorised officer considers appropriate.

(2) Where -

(a) an authorised officer has reasonable grounds for believing that

- there is present in a farm animal a residue of an authorised animal remedy exceeding the maximum residue limit,
- (b) a specimen taken from a farm animal by an authorised officer is shown, on analysis at an approved laboratory, to contain a residue of an authorised animal remedy exceeding the maximum residue limit,
- (c) an authorised officer has reasonable grounds for believing that a prohibited animal remedy or a substance to which Regulation 3(1) applies has been administered to a farm animal, the official mark (other than in indelible form) shall be affixed to the farm animal concerned in such manner as an authorised officer considers appropriate.
- (3) It shall not be lawful for a person, other than a person specified hereunder, to have in his or her possession or under his or her control a farm animal to which a mark has been affixed pursuant to this Regulation, that is to say:
- (a) a person to whom a direction under Regulation 16 is addressed,
- (b) an authorised officer, or
- (c) a person authorised in that behalf by an authorised officer.
- (4) It shall not be lawful for a person to remove, or attempt to remove, or obscure other than in accordance with the instructions of an authorised officer, the official mark affixed under this Regulation.
- (5) It shall not be lawful for a person to move an animal to which the official mark is affixed from the land or premises at which it was affixed other than for the purpose of destroying such animal in accordance with Regulation 22.
- (6) It shall not be lawful for a person to sell or slaughter an animal to which the official mark is affixed.

#### Register of Persons trading in Farm Animals

20. (1) The Minister shall, as soon as may be after the coming into operation of these Regulations, cause to be established and maintained a register of all persons owning or having under their control farm animals for the purpose of sale or supply.
- (2) Any person who owns or proposes to own or has or proposes to have under his or her control a farm animal for the purpose of sale or supply may, in accordance with this Regulation, apply to the Minister to be registered in the register maintained under this Regulation.
- (3) An application under this Regulation shall be in writing and shall include the following particulars, that is to say:
- (a) the applicant's name and the address at which he or she ordinarily resides.
- (b) the species of farm animal in respect of which the applicant seeks to be registered.
- (c) the nature of the business carried on or proposed to be carried on by the applicant.
- (d) the address at which the applicant keeps or proposes to keep farm animals to which the application concerned relates, and
- (e) the herd number or other identifying number allocated to the applicant in respect of the farm animals for which he or she seeks to be registered.
- (4) An application under this Regulation shall, having regard to the

provisions of Article 9A.1 of Council Directive 96/23/EC of 29 April 1996, be accompanied by such undertaking as the Minister deems appropriate.

(5) On receipt of an application for registration under and in accordance with this Regulation the Minister shall, subject to paragraph (6), cause to be entered in the register maintained by him or her under this Regulation, the particulars required to be included in the application by virtue of paragraph (3).

(6) The Minister may refuse to register, or may remove from a register, the name of a person where -

(a) the application concerned or undertaking under paragraph (4) fails to comply with the provisions of this Regulation, or

(b) in the opinion of the Minister, the application concerned or undertaking under paragraph (4) contains a statement that is false or misleading in any material respect.

(7) It shall not be lawful for a person to own or have in his charge or under his control a farm animal for the purpose of sale or supply if he is not registered in the register maintained under this Regulation in relation to the species to which the farm animal concerned belongs.

(8) Before refusing an application for registration in the register maintained under this Regulation the Minister shall by notice in writing served on the applicant concerned inform the applicant concerned of his or her intention to refuse such application and of the reasons for such refusal and shall consider any representations made by the applicant within 21 days of receipt of the notice by the applicant.

(9) Registration of a person under this Regulation shall cease on the happening of one or more of the following events, that is to say:

(a) notice in writing being served on the Minister by or on behalf of a person to whom an entry in the register relates stating that such person has ceased to sell or supply farm animals to which the entry relates,

(b) the payment pursuant to Council Regulation (EEC) 2079/926 of 30th July 1992 of a pension to a person to whom registration relates,

6 O.J. No. L215 of 30.07.92, p.91

(c) a person being notified in writing by the Minister of the Minister's belief that the person has ceased to sell or supply farm animals to which an entry in the register maintained under this Regulation relates,

or

(d) the disqualification of the person under section 24 of the Act from keeping, dealing in or having charge or control of directly or indirectly, an animal or class of animal to which an entry in the register maintained under this Regulation relates.

(10) A notification under subparagraph (c) of paragraph (9) shall include a statement that the person to whom it is addressed may make representations to the Minister within 21 days of receipt by him or her of the notification.

(11) Where a person registered in the register dies the Minister shall on the application of the personal representative of such person enter in the register the name of the personal representative in lieu of that person.

(12) A person who on or before the 1st day of January, 2000 applies to be registered under this Regulation shall, until such time as the Minister grants or refuses the application concerned, be entitled to sell or supply farm animals of the species to which the application relates.

#### Unlawful Possession of Animal Remedy

21. (1) Subject to the provisions of this Regulation, it shall not be lawful for a person to have in his or her possession or under his or her control an animal remedy consisting of or containing a substance specified in Part II of the Second Schedule to the Regulations of 1996 (other than an animal remedy to which paragraph 5 thereof or Regulation 14(3) or (4) of those Regulations applies).

(2) A person may, pursuant to a prescription, have in his or her possession or under his or her control an authorised animal remedy to which paragraph (1) applies, that is labelled in accordance with the Regulations of 1996.

(3) A registered veterinary surgeon may, for any lawful purpose, have in his or her possession or under his or her control an authorised animal remedy to which paragraph (1) applies.

(4) A member of the Garda Síochána, an authorised officer or an officer of Customs and Excise may have in his or her possession or under his or her control an authorised animal remedy to which paragraph (1) applies, for the purposes of carrying out his or her functions under the Act or these Regulations.

#### Destruction of Animal where Illegal Treatment established

22. (1) Where the official mark has been applied to a farm animal pursuant to Regulation 19(1) or where an authorised officer receives a notification in writing from an approved laboratory or a national reference laboratory, as the case may be, that a specimen taken from a farm animal was found, on analysis at the laboratory concerned, to contain a prohibited animal remedy or a substance to which Regulation 3 (1) applies, the Minister shall destroy or cause to be destroyed the farm animal concerned and its carcass in such manner as he or she deems appropriate.

(2) Notwithstanding the provisions of Regulations 6 and 7, a person may have in his or her possession or under his or her control an animal or carcass of an animal to which either of those Regulations apply for the purpose of complying with paragraph (1).

(3) The cost of destroying a farm animal or its carcass under this Regulation shall, subject to paragraph (4), be borne by the owner of such animal and may be recoverable in any court of competent jurisdiction as a simple contract debt.

(4) Where the owner and person in charge of an animal destroyed under this Regulation are not the same person both the owner and the person in charge of the animal shall be jointly and severally liable for the costs of the destruction of the animal and its carcass.

#### Lawful to sell etc. Animal where Withdrawal Period has elapsed

23. (1) It shall be lawful for a person to export or sell a farm animal to which an animal remedy has been administered in accordance

with Regulation 10, 11 or 12 provided that the withdrawal period in respect thereof pursuant to Council Regulation (EEC) No. 2377/90 of 26 June 1990 has elapsed. there has been compliance with Regulation 42(2) of the Regulations of 1996; and the Animal Remedies Record is available for inspection on request by an authorised officer.

(2) It shall be lawful for a person to export or sell meat, a meat product or other food derived from a farm animal to which an animal remedy has been administered in accordance with Regulation 10, 11 or 12, or to process such meat, meat product or other food provided that the withdrawal period in respect of the animal remedy concerned set out in Council Regulation (EEC) No. 2377/90 of 26 June 1990 had elapsed at the time the farm animal concerned was slaughtered and there had in respect of that farm animal been compliance with Regulation 42(2) of the Regulations of 1996, and the Animal Remedies Record in respect of that farm animal is available for inspection on request by an authorised officer.

(3) It shall be lawful for a person to slaughter an animal to which an animal remedy has been administered in accordance with Regulation 10, 11 or 12 provided that the withdrawal period in respect thereof set out in Council Regulation (EEC) No. 2377/90 of 26 June 1990 has elapsed and there has been compliance with Regulation 42(2) of the Regulations of 1996, and the Animal Remedies Record is available for inspection on request by an authorised officer.

(4) Notwithstanding paragraph (1) or (2), it shall be lawful for a person to import, export or sell a high-value horse, in particular, a racehorse, competition horse, circus horse or horse intended for stud purposes or for exhibition purposes, including a registered equid, to which an animal remedy consisting of or containing -  
(a) allyl trenbolone has been administered in accordance with Regulation 10, or  
(b) a beta-agonist has been administered in accordance with Regulation 11, before the end of the withdrawal period in respect thereof provided that the certificate or passport in respect of the animal concerned specifies the nature, method and date of administration of the animal remedy concerned.

#### Register of Certain Substances etc

24. (1) A person who engages in -

(a) the manufacture of a substance to which Regulation 3(7) applies, or

(b) the importation, purchase or sale of such substance, shall cause to be established and maintained a register containing the particulars specified in paragraph (2).

(2) A person to whom paragraph (1) applies shall enter in chronological order the following particulars in the register established and maintained by him or her under this Regulation, that is to say:

(a) the quantities of each substance referred to in paragraph (1) manufactured, imported, purchased or otherwise acquired by him or her;

(b) the quantities of each such substance sold for or used in the manufacture of pharmaceutical or veterinary medicinal products; and

(c) the name of the person to whom such quantities were sold or

from whom they were purchased or otherwise acquired and the address at which he or she ordinarily resides.

(3) A person to whom this Regulation applies shall furnish the Minister with such particulars required to be entered in a register under this Regulation as the Minister may from time to time direct in such form as he or she may direct.

(4) It shall not be lawful for a person to contravene a provision of this Regulation.

#### Detection by Processors of Illegal Treatment

25. (1) The owner or person in charge of an approved establishment shall, not later than -

(a) the 31st day of October in the year 1999, and

(b) the 31st day of October in each year thereafter,

prepare and submit to the Minister a plan for the detection, in the year immediately following the year in which the plan is prepared and submitted, of substances, veterinary drugs and contaminants specified in Annex 1 to Council Directive 96/23/EC of 26 April 1996 in -

(i) farm animals presented for slaughter, and

(ii) meat, meat products or other food derived from such animals, at the approved establishment concerned, and the plan shall, if approved by the Minister, be carried out by the owner or person in charge of the approved establishment in accordance with its terms.

(2) The owner or person in charge of an approved milk processing plant shall, not later than-

(a) the 31st day of October in the year 1999, and

(b) the 31st day of October in each year thereafter,

prepare and submit to the Minister a plan for the detection, in the year immediately following the year in which the plan is prepared and submitted, of substances, veterinary drugs and contaminants specified in the Annex referred to in paragraph (1) in milk presented for processing at the approved milk processing plant concerned, and the plan shall, if approved by the Minister, be carried out by the owner or person in charge of the approved milk processing plant in accordance with its terms.

(3) Without prejudice to the generality of paragraphs (1) and (2), the Minister may direct that a plan prepared and submitted under this Regulation shall contain such provisions and comply with such requirements as are specified in the direction, including provisions and requirements relating to -

(a) the form of the plan,

(b) the taking of specimens at an approved establishment or an approved milk processing plant, as may be appropriate.

(c) the manner in which the analysis of specimens is to be carried out,

(d) the frequency with which testing for illegal treatment is to be conducted,

(e) the number, species and age of animals to be tested for illegal treatment,

(f) the foods of animal origin to be tested for illegal treatment, and

(g) measures to be taken by the owner or person in charge of the approved establishment or approved milk processing plant concerned



where illegal treatment is detected.

(4) A plan prepared and submitted under this Regulation shall comply with a direction given under paragraph (3).

(5) The Minister may approve a plan prepared and submitted under this Regulation.

(6) The Minister may within a period of 60 days of the submission of a plan to him or her under this Regulation require, by notice in writing, that the plan concerned be modified in such manner as he directs.

(7) Where the Minister requires that a plan submitted under paragraph (1) or (2) be modified the owner or person in charge of the approved establishment or approved milk processing plant concerned shall modify the plan in accordance with directions of the Minister and shall within a period of 30 days of receipt by him or her of a notice under paragraph (6) submit the plan as so modified to the Minister for approval by him or her.

(8) Where the Minister fails, within a period of 60 days of the submission of a plan to him or her under paragraph (1) or (2), to

-

(a) approve,

(b) refuse approval of, or

(c) require under paragraph (7) the modification of, the plan concerned it shall, for the purposes of this Regulation, be deemed to have been approved by him or her.

(9) The owner or person in charge of an approved establishment or approved milk processing plant shall, not later than the 31st day of March in each year, prepare and submit to the Minister a report, on the implementation in the immediately preceding year, of a plan approved by the Minister under this Regulation.

(10) Without prejudice to the generality of paragraph (9), a report submitted under that paragraph shall in respect of the year to which the report relates include the following, that is to say:

(a) in the case of an approved establishment, the number and species of animals slaughtered at the approved establishment concerned,

(b) the name of the person responsible for ensuring the implementation of the plan at the approved establishment or the approved milk processing plant concerned,

(c) in the case of an approved establishment, the number and species of animals from which specimens were taken and analysed under the plan,

(d) in the case of an approved milk processing plant, particulars of the specimens analysed under the plan;

(e) in the case of an approved establishment, the number and species of animals from which specimens taken were found on analysis to contain -

(i) a prohibited animal remedy or a substance to which Regulation 3(1) applies, or

(ii) a residue of an authorised substance in excess of the maximum residue limit.

(f) particulars in relation to food of animal origin from which specimens taken were found on analysis to contain -

(i) a prohibited animal remedy or a substance to which Regulation 3(1) applies, or

(ii) a residue of an authorised substance in excess of the maximum

residue limit,

(g) the name of the person from whom each animal to which subparagraph (e) applies, or food of animal origin to which subparagraph (f) applies, was purchased, and the address at which he or she ordinarily resides,

(h) in the case of an approved establishment, the name of the person from whom each animal (from which a food of animal origin to which subparagraph (f) applies, was obtained) was purchased, and the address at which he or she ordinarily resides, and

(i) particulars of measures taken in respect of each animal to which subparagraph (e) applies, or food of animal origin to which subparagraph (f) applies.

(11) The Minister may by direction in writing, -

(a) require the owner or person in charge of a slaughterhouse to take such measures for the detection of substances, veterinary drugs and contaminants specified in the Annex referred to in paragraph (1), in farm animals presented for slaughter at the slaughterhouse concerned, as are specified in the direction.

(b) require the owner or person in charge of an approved milk processing plant to take such measures for the detection of substances, veterinary drugs and contaminants specified in the Annex referred to in paragraph (1), in milk presented for processing at the approved milk processing plant concerned.

(12) Where, in the carrying out of a plan under this Regulation, or the taking of measures pursuant to a direction under paragraph (11), a specimen taken from an animal or food of animal origin is found, an analysis, to contain a substance to which Regulation 3(1) applies, a prohibited animal remedy or an amount of an authorised animal remedy in excess of the maximum residue limit, the owner or person in charge of the approved establishment, approved milk processing plant or abattoir, as the case may be, at which such specimen was taken shall immediately inform the Minister or an authorised officer of that finding and of the name and address of the person who presented the animal concerned for slaughter, or food of animal origin concerned for processing, at such approved establishment, approved milk processing plant or abattoir.

(13) It shall not be lawful for a person to contravene paragraph (1), (2), (7), (9), (10) or (12).

(14) In this Regulation -

"approved establishment" means a slaughterhouse other than an abattoir;

"approved, milk processing plant" means an approved milk treatment establishment, an approved milk processing establishment or an approved milk processing establishment with limited production capacity, registered under Regulation 12 of the European Communities (Hygienic Production and Placing on the Market of Raw Milk, Heat-Treated Milk and Milk-Based Products) Regulations, 1996 (S.I. No. 9 of 1996).

Evidence by certificate in proceedings for an offence

26. (1) In proceedings for an offence consisting of a contravention of these Regulations, a certificate purporting to be signed by a

person employed at an approved laboratory or a national reference laboratory, as the case may be, stating the capacity in which that person is so employed and stating any one or more of the following, namely -

(a) that the person received a specimen submitted to the approved laboratory or the national reference laboratory, as the case may be,  
(b) that, for such period as is specified in the certificate, the person had in his or her custody a specimen so submitted,  
(c) that the person gave to such other person as is specified in the certificate a specimen so submitted, or  
(d) that the person carried out any procedure for the purpose of detecting the presence, in a specimen so submitted, of an animal remedy, or that the specimen concerned contained such animal remedy or such amount thereof as is specified in the certificate, shall, unless the contrary is proved, be evidence of the matters stated in the certificate.

(2) In proceedings for an offence under these Regulations the court may, if it considers that the interests of justice so require, direct that oral evidence of the matters stated in a certificate under this Regulation be given, and the court may for the purpose of receiving oral evidence adjourn the proceedings to a later date.

#### Forgery of Documents

27. (1) It shall not be lawful for a person to forge or utter knowing it to be forged -

(a) a register purporting to be established and maintained under these Regulations or a document purporting to be an extract therefrom (hereafter in this Regulation referred to as "a forged register"), or  
(b) a direction, permit or other document purporting to be issued, granted or given under these Regulations (hereafter in this Regulation referred to as "a forged document").

(2) It shall not be lawful for a person to alter with intent to defraud or deceive, or to utter knowing it to be so altered -

(a) a register established and maintained under these Regulations or an extract therefrom (hereafter in this Regulation referred to as "an altered register"), or

(b) a direction, permit or other document issued, granted or given under these Regulations (hereafter in this Regulation referred to as "an altered document"),

(3) It shall not be lawful for a person to have, without lawful authority, in his or her possession a forged register, forged document, altered register or altered document.

(4) It shall not be lawful for a person to aid or abet the contravention of a provision of this Regulation.

#### Aiding or Abetting Obstruction of Authorised Officers

28. It shall not be lawful for a person to aid or abet a contravention of section 16 of the Act.

#### Service of Documents

29. (1) A direction or other document under these Regulations shall, subject to paragraph (2) be addressed to the person concerned by name, and may be served on or given to the person in one of the following ways:

- (a) by delivering it to the person,
- (b) by leaving it at the address at which the person ordinarily resides or, in a case in which an address for service has been furnished, at that address,

#### Evidential Burden

30. In proceedings for an offence consisting of a contravention of Regulation 3(2), 7, or 8(1) or (4), it shall not be necessary to negative by evidence the existence of an animal remedies authorisation, a manufacturer's licence, a licence under Regulation 26 of the Regulations of 1996 or a product authorisation under the Medical Preparations (Licensing and Sale) Regulations, 1996 (S.I. No. 43 of 1996), and accordingly the onus of proving the grant or issue of such authorisation or licence shall be on the defendant.

#### 31 Persons not entitled to Community Aid

31. (1) Where the owner or person for the time being in charge of a slaughterhouse is convicted of an offence consisting of a contravention of Regulation 25(9), (10)(e), (f), (g) or (h), or (12), 27 or 28, or section 16 of the Act, none of the following, that is to say:

- (a) the owner,
- (b) a company in which he or she has a controlling interest, or
- (c) in circumstances where the owner is a company, a related company,

shall be entitled to receive Community aid -

- (i) for a period of 12 months commencing on the date of such conviction, or
- (ii) that but for the making of this Regulation would be payable in respect of the whole or part of such period.

(2) In this Regulation -

"company" has the same meaning as it has in section 155 of the Companies Act, 1963 (No. 33 of 1963);

"holding company" means a holding company within the meaning of the said section 155;

"related company" in relation to a company, means the holding company or a subsidiary of that company, or a company that is a subsidiary of the first-mentioned company's holding company;

"subsidiary" means a subsidiary within the meaning of the said section 155;

(3) In this Regulation, a person has a controlling interest in a company if circumstances exist whereby, were that person a company, the first-mentioned company would be that company's subsidiary.

#### 32 Miscellaneous amendments to Regulations of 1996

32. The Regulations of 1996 are hereby amended by -

- (a) in Regulation 2(1) -
  - (i) the substitution in the definition of "the Council Directives" of "1981" for "1987" in each place where it occurs, and
  - (ii) the insertion of the following definition:  
"the Regulations of 1998" means the Control of Animal Remedies and their Residues Regulations, 1998;
- (b) the substitution in Regulation 10(3) of "First Schedule" for "Second Schedule",
- (c) the substitution in Regulation 14(3)(c) of "Regulation 13(6)" for "Regulation 13(7)",
- (d) in Regulation 26 -
  - (i) the substitution of "animal remedy" for "prohibited animal remedy" in each place where it occurs, and
  - (ii) the insertion of the following paragraph:  
"(7) In this Regulation, 'animal remedy' means an animal remedy that, but for the granting of a licence under this Regulation, would be a prohibited animal remedy.",
- (e) the substitution in Regulation 31 (7) of "3 years" for "one year",
- (f) the substitution of the following Regulation for Regulation 32:  
"32 (1) The Minister shall, as soon as may be after the coming into operation of these Regulations, cause to be established and maintained a register of all persons carrying on the business of selling companion animal medicines.  
(2) Any person who proposes to carry on the business of selling companion animal medicines may, in accordance with this Regulation, apply to the Minister to be registered in the register maintained under this Regulation.  
(3) A person who immediately prior to the commencement of the Regulations of 1998 was lawfully carrying on the business of selling companion animal medicines shall, within 12 months of such commencement, apply, in accordance with this Regulation, to be registered in the register maintained under this Regulation.  
(4) A person to whom paragraph (3) applies may, pending the determination of an application under that paragraph by him or her, continue to carry on the business of selling companion animal medicines.  
(5) An application under this Regulation shall be in writing and shall include the following particulars, that is to say:
  - (a) the applicant's name and the address at which he or she ordinarily resides.
  - (b) the nature of the business carried on or proposed to be carried on by the applicant, and
  - (c) the address at which the applicant carries on or proposes to carry on the sale of companion animal medicines.
- (6) On receipt of an application for registration under and in accordance with this Regulation the Minister shall, subject to paragraph (7), cause to be entered in the register maintained by him or her under this Regulation, the particulars required to be included in the application by virtue of paragraph (5).
- (7) The Minister may refuse to register, or remove from a register, the name of a person where -
  - (a) the application concerned fails to comply with the provisions of this Regulation, or
  - (b) in the opinion of the Minister, the application concerned

contains a statement that is false or misleading in any material respect.

(8) It shall not be lawful for a person to sell a companion animal medicine if he or she is not registered in the register maintained under this Regulation.

(9) Before refusing an application for registration in the register maintained under this Regulation the Minister shall, by notice in writing served on the applicant concerned, inform the applicant concerned of his or her intention to refuse such application and of the reasons for such refusal and shall consider any representations made by the applicant within 21 days of receipt of the notice by the applicant.

(10) Registration of a person under this Regulation shall cease on the happening of one or more of the following events, that is to say:

(a) notice in writing being served on the Minister by or on behalf of a person to whom an entry in the register relates stating that such person has ceased to carry on the business of selling companion animal medicines, or

(b) a person being notified in writing by the Minister of the Minister's belief that the person has ceased to carry on such business.

(11) A notification under subparagraph (b) of paragraph (10) shall include a statement that the person to whom it is addressed may make representations to the Minister within 21 days of receipt by him or her of the notification.

(12) Where a person registered in the register dies the Minister shall on the application of the personal representative of such person enter in the register the name of the personal representative in lieu of that person.

(13) A person who before the commencement of the Regulations of 1998 applied for a companion animal medicine seller's licence shall be deemed to have applied under this Regulation to be registered in the register maintained under this Regulation.

(14) This Regulation shall not apply to -

(a) a registered veterinary surgeon,

(b) a pharmacist,

(c) the holder of an Animal Remedies Merchant's Licence.

(d) the holder of an Animal Remedies Wholesaler's Licence,

(e) a person who may, pursuant to these Regulations or the Regulations of 1998, manufacture companion animal medicines.

(15) In this Regulation

'companion animal' means domestic dogs, cats, rabbits (other than rabbits kept for human consumption), small rodents, cage birds, homing pigeons, terrarium animals and aquarium fish;

'companion animal medicine' means an animal remedy which has been designated by the Competent Authority as a companion animal medicine."

(g) the substitution in Part I of the Second Schedule of "Council Directive 96/22/EC of 29 April 1996" for "Council Directive 81/602/EEC of the 31 July 1981", and

(h) the insertion of the following Regulation:

"56A. It shall not be lawful for a person to contravene Regulation 3(2), 4, 6, 10(7) or (9), 14, 15, 18(2), (3), (4) or (7), 21, 23(4), (5) or (6), 26(1), 28, 29, 30(1) or (8), 31(1) or (8), 33,

34(2), 35, 36, 38, 39, 40(3), (5), (6) or (8), 41(1), (2) or (6);  
42, 43(3), (4), (5), (6), (7) or (8), 45(2), (4), (5), (6), (7),  
(8) or (10), 46(2), 50(2)(b), 53, 56 or 59."

#### Revocation and Saver

33. (1) The following regulations are hereby revoked, that is to say:

(a) the Regulations of 1988, and  
(b) the European Communities (Control of Veterinary Medicinal Products and Their Residues) Regulations, 1990 (S.I. No. 171 of 1990.).

(2) A notice served under Regulation 19 of the Regulations of 1988 that was in force immediately prior to the commencement of this Regulation shall after the commencement of this Regulation, continue to be in force and operate as if it were a direction under Regulation 16.

(3) In this Regulation, "the Regulations of 1988" means the European Communities (Control of Oestrogenic, Androaenic, Gestagenic and Thyrostatic Substances) Regulations, 1988 (S.I. No. 218 of 1988.).

#### SCHEDULE

##### Official Mark

GIVEN under my Official Seal, this 21st day of December, 1998.

Joe Walsh, TD

Minister for Agriculture and Food.

#### EXPLANATORY NOTE

These Regulations implement in the State the provisions of Council Directive 96/22/EC of 29 April, 1996 concerning the prohibition in stockfarming of certain substances having hormonal or thyrostatic action and of beta agonists and Council Directive 96/23/EC of 29 April, 1996 on measures to monitor certain substances and residues thereof in live animals and animal products. The Regulations also provide for the registration of persons engaged in trade in farm animals and for measures to be taken by processors to assure consumers that animals and meat are free of illegal residues.

The Regulations also amend the Animal Remedies Regulations, 1996 by, inter alia, extending the period of validity of an animal remedies merchant's licence to three years and by replacing the companion animal seller's licence with a once off registration.