EUROPEAN COMMUNITIES (CONTROL OF VETERINARY MEDICINAL PRODUCTS

I, MICHAEL O'KENNEDY, Minister for Agriculture and Food, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purpose of giving further effect to Council Directive No. 81/851/EEC(1) of 28 September, 1981, and Council Directive No. 86/469/EEC(2) of 16 September, 1986, hereby make the following Regulations:
(1) O.J. No. L317, 6.11.1981, p.01.
(2) O.J. No. L275, 26.09.1986, p.36.

REG 1

1. (1) These Regulations may be cited as the European Communities (Control of Veterinary Medicinal Products and Their Residues) Regulations, 1990.
(2) These Regulations and the European Communities (Control of Oestrogenic, Androgenic, Gestagenic and Thyrostatic Substances) Regulations, 1988 (S.I. No. 218 of 1988), may be cited together as the and
Their Residues) Regulations, 1988 and 1990.
(3) These Regulations shall come into operation on the 13th day of July, 1990.

REG 2

2. (1) In these Regulations—
"authorised substance" means any substance in respect of which there is for the time being in force a product authorisation;
"the competent authority" means the National Drugs Advisory Board;
"the Council Directives" means—
(a) Council Directive No. 81/851/EEC of 28 September, 1981, in so far as it relates to substances,
(b) Council Directive No. 86/469/EEC of 16 September, 1986, in so far as it relates to substances, and
(c) any act of the European Communities, adopted pursuant to the Council Directives aforesaid, in so far as it relates to substances;
"the Minister" means the Minister for Agriculture and Food;
"the Principal Regulations" means the European Communities (Control of Oestrogenic, Androgenic, Gestagenic and Thyrostatic Substances) Regulations, 1988 (S.I. No. 218 of 1988);
"product authorisation" means an authorisation granted under the Regulations of 1986 to place on the market a veterinary medicinal product;
"prohibited substance" means a substance which is not an authorised substance;
"the Regulations of 1986" means the European Communities (Veterinary Medicinal Products) Regulations, 1986 (S.I. No. 22 of 1986);
"substance" means—

(a) a substance mentioned in Group III of Paragraph A (which group refers to inhibitors (antibiotics, sulphonamides and similar antimicrobial substances) and chloramphenicol) or in Group I of Paragraph B (which group refers to endo-parasitic and ectoparasitic substances, tranquillizers and beta-blockers, and other veterinary medicines) of Annex I to Council Directive 86/469/EEC of 16 September 1986, and
(b) any preparation, additive, premixture, feedingstuff or other thing consisting of or containing any such substance as aforesaid;
"veterinary medicines legislation" means—
(a) these Regulations,
(b) the Animal Remedies Act, 1956 (No. 41 of 1956), and regulations made thereunder,
(c) the Regulations of 1986,
(d) the Poisons (Control of Residues in Foods of Animal Origin) Regulations, 1985 (S.I. No. 257 of 1985), and
(e) the Poisons (Control of Residues in Foods of Animal Origin) (Amendment) Regulations, 1986 (S.I. No. 236 of 1986),
in so far as that Act and those Regulations relate to substances;
"veterinary medicinal product" has the meaning assigned to it by the Principal Regulations.
(2) A word or expression that is used in these Regulations and is also used in the Council Directives has, unless the contrary intention appears, the meaning in these Regulations that it has in the Council Directives.
(3) In these Regulations a reference to a Regulation shall be construed as a reference to a Regulation of these Regulations unless it is indicated that reference to some other provision is intended, and a reference in a provision to a paragraph or subparagraph shall be construed as a reference to a paragraph or subparagraph of that provision, unless it is indicated that reference to some other provision is intended.

REG 3

3. (1) The Principal Regulations shall be construed and have effect as if—
(a) except in Regulations 2, 11, 12, 13 (3) (b), 21 (2) (c) and 22, references to authorised substances (within the meaning of the Principal Regulations) included references to authorised substances,
(b) except in Regulation 2, references to prohibited substances (within the meaning of the Principal Regulations) included references to prohibited substances,
(c) references to substances (within the meaning of the Principal Regulations) included references to substances,
(d) references to hormone legislation included references to veterinary medicines legislation, and
(e) references to the Council Directives (within the meaning of the Principal Regulations) included references to the Council

Directives.
(2) Regulation 13 (2) of the Principal Regulations shall not apply—
(a) to the possession or control of an authorised substance by a person for the purposes of administration by him or under his direction to animals of any particular kind under his care if—
(i) the product authorisation concerned permits the use of the substance in animals of that kind,
(ii) the product authorisation permits the use of the substance by that person, and
(iii) the veterinary medicines legislation has been complied with in respect of the substance,
or
(b) to the possession or control of a substance, or anything to which Regulation 8 of the Principal Regulations applies, by a person who is the holder of a licence under Regulation 5 or 7 relating to that substance or, as the case may be, to the substance to the manufacture or administration of which that thing relates.
(3) Regulation 32 (6) of the Principal Regulations is hereby amended as respect offences committed after the commencement of these Regulations by the substitution of "two years" for "one year".

REG 4

4. (1) Subject to paragraph (2), a person shall not, except under and in accordance with a licence under Regulation 5, administer any substance to a farm animal, or cause or permit any such administration.
(2) Paragraph (1) shall not apply to the administration of an authorised substance to a farm animal of any particular kind where—
(a) the administration is carried out in accordance with the provisions of the product authorisation concerned, the Council Directives and the veterinary medicines legislation, and
(b) the product authorisation concerned authorises the administration of the substance to farm animals of that kind, and
(c) the product authorisation authorises the use of the substance by that person, and
(d) the veterinary medicines legislation has been complied with in respect of the substance.
(3) (a) A person who administers, or authorises, directs or permits the administration of, an authorised substance to a farm animal shall—
(i) act in conformity with the conditions of use of the substance (other than those relating to the animal that fall to be complied with after such administration), and
(ii) if the person is not the owner or the person in charge of the animal, inform the owner or person in charge of the animal—
(I) of the conditions of use of the substance relating to the animal that fall to be complied with after such administration, and
(II) that the animal may not be slaughtered for human consumption, or sold or exported if it is intended to be slaughtered for human

consumption, during the withdrawal period specified in the conditions of use.
(b) The owner or person in charge of an animal to which an authorised substance has been administered—
(i) shall comply with the conditions of use of the substance relating to the animal that fall to be complied with after such administration, and
(ii) shall not slaughter the animal for human consumption, or export or sell the animal if it is intended to slaughter it for human consumption, during the withdrawal period specified in the conditions of use.
(c) In proceedings for an offence under subparagraph (b), it shall be a defence for the accused person to show that the substance concerned was administered by, or by a person acting on the direction of, a veterinary surgeon and that the accused person was not informed pursuant to subparagraph (a) (ii) of the matter to which the offence relates.
(d) In this paragraph "conditions of use", in relation to a substance, means the information and directions that, pursuant to the relevant product authorisation are required to appear on containers and outer packages of, and package inserts for, the substance.

REG 5

5. (1) Tests and trials of veterinary medicinal products for the purposes of Article 5.10 of Council Directive No. 81/851/EEC of 28 September, 1981, shall not be performed other than under and in accordance with a licence (referred to subsequently in this Regulation as "a licence") under this Regulation and by persons authorised in that behalf by the licence.
(2) Subject to the subsequent provisions of this Regulation, on application to the Minister in that behalf by or on behalf of any person and on payment to the Minister of such fee as he may specify, the Minister may, after consultation with the competent authority, if he is satisfied that the person is qualified and competent to perform on veterinary medicinal products the tests and trials aforesaid, grant a licence to the person authorising the performance by the person, for the purposes of the said Council Directive, of the said tests and trials on the veterinary medicinal products specified in the licence.
(3) The Minister may, if he thinks it appropriate to do so for the purpose of ensuring compliance with these Regulations and the law of the State and having regard to the provisions of this Regulation, attach conditions to a licence at the time of the grant of the licence or subsequently and may amend or revoke a condition attached to a licence.
(4) The Minister shall refuse to grant a licence to a person and shall revoke a licence held by a person if the person has been convicted of or committed an offence in relation to substances under the hormone legislation or the veterinary medicines legislation or is

for other reasons (including conviction of another offence) not, in the opinion of the Minister, a fit and proper person to hold a licence.

REG 6

6. (1) This Regulation applies to the following provisions, namely—
(i) the Food Hygiene Regulations, 1950 (S.I. No. 205 of 1950),
(ii) the Agricultural Produce (Fresh Meat) Acts, 1930 to 1988, and regulations thereunder,
(iii) the Abattoirs Act, 1988 (No. 8 of 1988), and regulations thereunder,
(iv) the Slaughter of Cattle and Sheep Acts, 1934 to 1936,
(v) orders under the Agricultural and Fishery Products (Regulation of Export) Act, 1947 (No. 18 of 1947),
(vi) the European Communities (Fresh Meat) Regulations, 1987 (S.I. No. 284 of 1987),
(vii) the European Communities (Fresh Poultry Meat) Regulations, 1976 to 1988, and
(viii) the Pigs and Bacon Acts, 1935 to 1988, and regulations thereunder.
(2) A farm animal to which a prohibited substance or a prohibited substance (within the meaning of the Principal Regulations) has been administered and any meat or meat product derived from such an animal shall, for the purposes of the provisions to which this paragraph applies, be deemed to be unfit for human consumption.
(3) Meat or a meat product that contains an amount of an authorised substance or an authorised substance (within the meaning of the Principal Regulations) in excess of the maximum levels permitted by law or authorised by a decision of the European Communities shall, for the purposes of the provisions to which this Regulation applies, be deemed to be unfit for human consumption.

REG 7

7. (1) Notwithstanding Regulation 3 of the Principal Regulations, a person may manufacture, import in to the State or sell a prohibited substance under and in accordance with a licence under this Regulation (referred to subsequently in this Regulation as "a licence").
(2) Subject to the subsequent provisions of this Regulation, on application to the Minister in that behalf by or on behalf of any person and on payment to the Minister of such fee as he may specify, the Minister may grant a licence to the person authorising the manufacture, importation or sale by the person of such quantity as may be specified in the licence of a prohibited substance so specified.
(3) The Minister may, if he thinks it appropriate to do so for the purpose of ensuring compliance with these Regulations and the law of the State and having regard to the provisions of this

Regulation, attach conditions to a licence at the time of the grant of the licence or subsequently and may amend or revoke a condition attached to a licence.
(4) The Minister shall not grant a licence authorising the manufacture of a prohibited substance unless he is satisfied that—
(a) all of the substance is intended to, and will, be administered to animals in the course of a test or trial authorised by a licence under Regulation 5, or
(b) all of the substance is intended to, and will, be exported from the State, or
(c) all of the substance is intended to, and will, be supplied to the competent authority for the purpose of an application for a product authorisation.
(5) The Minister shall not grant a licence authorising the importation of a prohibited substance unless he is satisfied that all of the substance is intended to, and will, be administered to animals in the course of a test or trial referred to in paragraph (4) or will be supplied to the competent authority for the purpose of an application for a product authorisation.
(6) The Minister shall refuse to grant a licence to a person or shall revoke a licence held by a person if—
(a) the person has been convicted of or committed an offence in relation to substances under the hormone legislation or the veterinary medicines legislation or is for other reasons (including conviction of any other offence) not, in the opinion of the Minister, a fit and proper person to hold a licence,
(b) the manufacture, importation or sale (as may be appropriate having regard to the particular class of licence applied for or held) of the substance concerned—
(i) is contrary to the law of the State, or
(ii) in the opinion of the Minister, prejudices or would prejudice public or animal health or the trade in the exportation of animals or animal products from the State,
(c) in the opinion of the Minister, the substance concerned is being or would be sold or used in the State otherwise than for a purpose specified in paragraph (4) or (5) of this Regulation, or
(d) in the case of a licence authorising the manufacture of a substance, in the opinion of the Minister, the premises are not, or the equipment, machinery or plant used or to be used is not, suitable for the purpose of such manufacture.

REG 8

8. (1) An application for a licence under these Regulations shall be made on such form as the Minister may specify.
(2) A person applying for a licence under these Regulations shall furnish the Minister with such information as he may reasonably require for the purposes of his functions under these Regulations.
(3) The Minister may refuse to grant a licence under these Regulations if, in relation to the application therefor, information

required by him has not been furnished to him or information that is, in the opinion of the Minister, false or misleading in a material particular has been furnished to him.
(4) (a) Where the Minister proposes to refuse to grant or to revoke a licence under these Regulations or to attach a condition to, or amend or revoke a condition attached to, such a licence, he shall notify in writing the person who made the application for or, as the case may be, holds the licence of his proposal and the reasons for it.
(b) A person who has been notified of a proposal under subparagraph (a) may, within 21 days of the receipt of the notification, makes representations in writing to the Minister and the Minister shall—
(i) before deciding the matter, take into consideration any representation duly made to him under this paragraph in relation to the proposal, and
(ii) notify the person in writing of his decision and the reasons therefor.
(c) A notification under subparagraph (a) shall include a statement that the person concerned may make representations to the Minister within 21 days of the receipt by him of the notification.

REG 9

9. (1) An authorised officer, on production of the officer's authorisation, if so required by any person affected, may, for the purposes of Regulations 5 and 7 and the Council Directives do all or any of the following things, namely:
(a) at all times enter—
(i) any premises or place where he reasonably believes that tests or trials referred to in Regulation 5 are being carried on, or
(ii) any premises or place where it is proposed to manufacture prohibited substances or where he reasonably believes that such manufacture is being carried on, or
(iii) any premises or place where he reasonably believes that a prohibited substance is kept,
and there carry out or have carried out such inspections, examinations, tests and checks of the premises or place and any equipment, machinery or plant in or at the premises or place as he reasonably considers to be necessary or expedient,
(b) require any person on the premises or at the place to give to him such information and to produce to him such records and other documents within the power or procurement of the person as he reasonably considers to be necessary or expedient,
(c) examine and take copies of, or copies of extracts from, any such records or documents aforesaid,
(d) take, without payment, such samples of any substance found on the premises or at the place as he may reasonably require and carry out or have carried out on the samples such examinations, tests, checks, and analyses as he reasonably considers necessary or

expedient, and
(e) take such specimens (including blood, urine, faeces, tissue or remains of implants) from any animals, meat or meat products found on the premises or at the place and may, for that purpose, perform any procedure (including surgery) as he reasonably considers necessary or expedient on such animals, meat or meat products.
(2) A person who obstructs or impedes an authorised officer in the exercise of a power or, without reasonable excuse, does not comply with a requirement, under this Regulation or who, in purported compliance with such a requirement, gives information to an authorised officer that he knows to be false or misleading in a material respect shall be guilty of an offence.
(3) In this Regulation "authorised officer" has the meaning assigned to it by the Principal Regulations.

REG 10

10. (1) In a prosecution for an offence under these Regulations or the Principal Regulations in relation to a substance that is a veterinary medicinal product but is not an authorised substance or an authorised substance within the meaning of those Regulations, the substance shall be deemed to be an authorised substance or an authorised substance within the meaning of the Principal Regulations, as the case may be if it is shown that—
(a) particulars of the product had been furnished to the Secretary of the Department of Agriculture and Food pursuant to the Animal Remedies (Registration of Manufacturers, Importers and Wholesalers) Regulations, 1980 (S.I. No. 115 of 1980), before the date of the commission of the alleged offence,
(b) the substance is of a kind that was first placed on the market in the State before the 1st day of January, 1987,
(c) in case the substance and the time of the commission of the alleged offence were such that an application for the grant of a product authorisation in relation to the substance was required, pursuant to Article 5 (3) of the Regulations of 1986, to have been made before that time, such an application had been made, and had not been refused, before that time, and
(d) the date of the commission of the alleged offence was a date earlier than the date specified in the second column of the Schedule to the Regulations of 1986 opposite the mention in the first column of that Schedule of the class of veterinary medicinal products to which the substance belongs.
(2) In a prosecution for an offence under these Regulations or the Principal Regulations in relation to a substance or a substance within the meaning of the Principal Regulations that is also an additive, premixture or feedingstuff within the meaning, in each case, of the European Communities (Additives in Feedingstuffs) Regulations, 1989 (S.I. No. 49 of 1989), it shall be a defence for the person charged with the offence to show—
(a) in case the substance is such an additive, that it is an

additive specified in the First or Second Schedule to those Regulations or that it is a medicinal additive manufactured or imported in pursuance of an additive licence under those Regulations, and

(b) in case the substance is such a premixture or feedingstuff, that it contains an additive that complies with subparagraph (a), and that the said European Communities (Additives in Feedingstuffs) Regulations, 1989, were complied with in relation to the additive.

REG 11

11. (1) A person who contravenes a provision of these Regulations or a condition of a licence under these Regulations shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1,000 or to imprisonment for a term not exceeding two years or to both.

(2) Proceedings for an offence under these Regulations may be brought and prosecuted by or on behalf of the Minister.

(3) Where an offence under these Regulations or the Principal Regulations has been committed by a body corporate and is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of a person, being a director, manager, secretary or other officer of that body corporate, or a person who was purporting to act in any such capacity, that person shall be guilty of an offence and shall be liable to be proceeded against and punished as if he had been guilty of the first-mentioned offence.

(4) Notwithstanding section 10 (4) of the Petty Sessions (Ireland) Act, 1851, proceedings for an offence under these Regulations may be instituted at any time within two years of the date of the commission of the offence.

REG 12

12. (1) Fees paid to the Minister under these Regulations shall be paid into, or disposed of for the benefit of, the Central Fund in accordance with the directions of the Minister for Finance.

(2) The Public Offices Fees Act, 1879, shall not apply in respect of any fees paid under these Regulations.

GIVEN under my Official Seal this 6th day of July, 1990.

MICHAEL O'KENNEDY,
Minister for Agriculture and Food.