STATUTORY INSTRUMENTS

1997 No. 1729

The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997

PART I

INTRODUCTORY

Title and commencement

1. These Regulations may be cited as the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 and shall come into force on 11th August 1997.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

"the Act" means the Food Safety Act 1990;

"analysis" includes any technique for establishing the composition of an official sample;

"analyst" means the person having the management or control of an approved laboratory;

"animal" includes aquaculture animals;

"animal product" includes meat, meat products, processed products derived from animals, milk, honey and eggs;

"Annex IV substance" means a substance specified in Annex IV to the Council Regulation;

"appropriate Minister" means, as respects England, the Minister of Agriculture, Fisheries and Food and, as respects Scotland or Wales, the Secretary of State;

"approved laboratory" means—

(a) a laboratory approved by the appropriate Minister for the purposes of Council Directive 96/23; or

(b) any laboratory under the direction or control of a public analyst appointed in accordance with section 27 of the Act;

"authorised officer" means any person (whether or not an officer of an enforcement authority) who is authorised in writing by that authority, either generally or specially, to act in matters arising under these Regulations;

"carcase" means—

(a) the whole body of a slaughtered animal (other than an uneviscerated bird) after bleeding and dressing; or

(b) the whole body of a slaughtered uneviscerated bird after bleeding;

"commercial operation", in relation to an animal or batch of animals, means any of the following, namely—

(a) selling, possessing for sale and offering, exposing or advertising for sale;

(b) consigning or delivering by way of sale;

(c) storing or transporting for the purpose of sale;

(d) slaughtering or deriving food from it for the purpose of sale or for purposes connected with sale; and

(e) importing and exporting;

"Council Directive 96/22" means Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and replacing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC(**1**);

"Council Directive 96/23" means Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC(**2**);

"the Council Regulation" means the Regulation specified in Schedule 1;

"enforcement authority", subject to regulation 22(8) means, for the purposes of regulations 12, 20, 21, 22 and 23(1)(b), the Ministers and, except for the purposes of regulations 12, 20, 21 and 23(1)(b), means the Ministers and—

(a) where enforcement is in relation to food or food sources, a food authority within its area; and

(b) where enforcement is other than in relation to food or food sources, a local authority within its area;

"examination" includes a physical examination of an animal or animal product or other article or substance and the taking, and any analysis of, an official sample;

"farm of origin", in relation to an official sample taken from any animal or animal product means—

(a) where the official sample was taken at a farm, that farm;

(b) where the official sample was taken at any other place, the last farm on which the animal from which the sample was taken or derived was kept before being taken to that place;

"hormonal substance" means any substance within either of the following categories—

(a) stilbenes and thyrostatic substances;

(b) substances with oestrogenic, androgenic or gestagenic action;

"local authority" means—

(a) in relation to England—

(i) as respects the City of London (including the Temples) the Common Council;

(ii) as respects the Inner Temple or the Middle Temple, the appropriate Treasurer;

(iii) as respects the Isles of Scilly, the Council of the Isles of Scilly;

(iv) as respects any part of England other than the City of London, the Inner Temple, the Middle Temple or the Isles of Scilly—

(aa) where there is, within the meaning of the Local Government Changes for England Regulations 1994(**3**), a unitary authority for the local government area, that authority;

(**1**) OJNo. L125, 23.5.96, p.3.
(**2**) OJ No. L125, 23.5.96, p.10.
(**3**) S.I.1994/867; to which there are amendments not relevant to these Regulations.

(bb) where there is no such unitary authority, the council of each London borough, district or non-metropolitan county as appropriate;

(b) in relation to Wales, the council of each county or county borough;

(c) in relation to Scotland, each council constituted under section 2 of the Local Government etc. (Scotland) Act 1994(**4**);

"marketing authorisation" means a marketing authorisation within the meaning of the Marketing Authorisations Regulations or a product licence granted under the Medicines Act 1968(**5**);

"the Marketing Authorisations Regulations" means the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**6**);

"maximum residue limit" means, in relation to a concentration of a substance specified in the first column of Annex I or Annex III to the Council Regulation in the tissues or body fluids of an animal or in an animal product, the limit specified in the fourth column opposite the reference to that substance and the applicable animal species specified in the third column, where the substance is contained in the part of the animal specified opposite it in the fifth column or in an animal product derived from that part of the animal;

"offal" means meat other than that of the carcase whether or not naturally connected to the carcase;

"official sample" means a sample taken by an authorised officer for analysis for the purpose of these Regulations which bears a reference to the type, the amount or quantity concerned and the method of collection and, in the case of an animal or animal product, the species and, where appropriate, particulars identifying the sex and origin of the animal;

"owner" includes, in relation to any animal, batch of animals or premises, the person in charge of such animal, batch of animals or premises, and in relation to any animal product the person in possession of such product;

"possession" in relation to any farm animal or aquaculture animal does not include possession under official control;

"primary analysis" means an analysis of an official sample carried out by an approved laboratory;

"primary analysis certificate" means an analyst's certificate specifying the finding of a primary analysis;

"prohibited substance" means any beta-agonist or hormonal substance administered to an animal contrary to the prohibition in regulation 5;

"reference analysis" means an analysis carried out by an approved laboratory to check the finding of a primary analysis;

"reference analysis certificate" means an analyst's certificate specifying the finding of a reference analysis;

"sale" includes possess for sale, and offer, expose or advertise for sale, and "sale" and "sold" shall be construed accordingly;

"unauthorised substance" includes Annex IV substances, prohibited substances and unlicensed substances;

(**4**) 1994 c. 39.
(**5**) 1968 c. 67.
(**6**) S.I. 1994/3142.

"unlicensed product" means a veterinary medicinal product, other than one which is or contains a beta-agonist or hormonal substance, in respect of which there is, in the United Kingdom, neither—

(a) any current marketing authorisation authorising its sale or supply for administration to an animal or batch of animals; nor

(b) any current animal test certificate, within the meaning of section 32 of the Medicines Act 1968, authorising its administration to an animal or batch of animals;

"unlicensed substance" means a substance, other than a hormonal substance, beta-agonist or Annex IV substance which, if transmitted to an animal product, would be likely to be harmful to human health and which has been administered or is intended for administration in the United Kingdom to an animal or batch of animals or, which has been administered to an animal in a member State of the European Community other than the United Kingdom and at the time of administration neither that substance, nor any product containing it, was authorised for use in that animal in that State;

"veterinary surgeon" means a person registered in the register of veterinary surgeons or in the supplementary veterinary register;

"withdrawal period", in relation to a veterinary medicinal product administered to an animal or batch of animals, means the period, specified in a current veterinary medicinal product licence or marketing authorisation relating to the product or (in the absence of any such specification) specified in a prescription given by a veterinary surgeon in respect of the administration of the product, which is required to elapse from the cessation of the medication of the animal or batch of animals with the product to the slaughter of the animal or batch of animals for human consumption or to the taking of animal products derived from the animal or batch of animals for human consumption.

(2) For the purpose of ascertaining whether the maximum residue limit has been exceeded for the purposes of these Regulations, the presence of the drug or drug metabolite (or combination thereof) specified in the second column of Annex I or III to the Council Regulation opposite the reference to each substance specified in the first column of those Annexes shall be taken to indicate the presence of that substance in that part of an animal or batch of animals, or in any animal product derived from that part of an animal or batch of animals, specified in the fifth column of such Annex I or III, opposite the reference to that substance and the maximum residue limit specified in the fourth column of such Annex I or III opposite the reference to that substance shall then apply in respect of the presence in such part of an animal or batch of animals, or in any animal product derived from such part of an animal or batch of animals, of any such drug or drug metabolite (or combination thereof) as if it were that substance.

(3) Other expressions used in these Regulations and in Council Directive 96/22, Council Directive 96/23 or the Council Regulation have, in so far as the context admits, the same meaning as they bear in those Directives or that Regulation, as appropriate.

(4) Any reference in these Regulations to a numbered regulation or Schedule shall, unless the context otherwise requires, be construed as a reference to the regulation or Schedule so numbered in these Regulations.

PART II

PROHIBITIONS AND EXCEPTIONS

Prohibition of the sale of stilbenes, thyrostatic substances or beta-agonists

3.—(1) No person shall sell, for administration to an animal, any—

(a) stilbene or thyrostatic substance; or

(b) product which contains a stilbene or thyrostatic substance.

(2) Subject to paragraph (3) below, no person shall sell any beta-agonist, or any product which contains a beta-agonist, for administration to an animal which is, or any animal product of which is, intended for human consumption.

(3) The prohibition in paragraph (2) above shall not apply to the sale of a product which is, or which contains, a beta-agonist if that product complies with the requirements of sub-paragraphs (a) and (b) of regulation 25(1) and is for administration in accordance with regulation 27.

(4) If sold, any stilbene, thyrostatic substance or beta-agonist or any product which contains a stilbene, thyrostatic substance or beta-agonist, which is capable of being used for administration to animals shall be presumed, until the contrary is proven, to have been sold for administration to an animal and in the case of the sale of a beta-agonist or a product which contains a beta-agonist, that animal or an animal product derived therefrom shall, if that animal or animal product, as appropriate, is commonly used for human consumption, be presumed to be intended for human consumption.

Prohibition of possession of beta-agonists or hormonal substances

4.—(1) No person shall be in possession of any beta-agonist or hormonal substance unless—

(a) subject to paragraph (3) below, it is, or is contained in, a product which complies with the requirements of regulation 25 and is for the purposes of administration in accordance with regulation 26, 27 or 28; or

(b) that person is the holder of a manufacturer's or wholesale dealer's licence granted under section 8 of the Medicines Act 1968(**7**) and is in possession of it for the purposes of a marketing authorisation relating to a product which is to contain that beta-agonist or hormonal substance.

(2) No person shall be in possession of any product which contains a beta-agonist or hormonal substance unless—

(a) that person is the holder of a marketing authorisation which authorises the placing on the market of that product;

(b) that person is the holder of a manufacturer's or wholesale dealer's licence granted under section 8 of the Medicines Act 1968 and is in possession of it for the purpose of the marketing authorisation relating to it; or

(c) subject to paragraph (3) below, it complies with the requirements of regulation 25 and is for the purposes of administration in accordance with regulation 26, 27 or 28.

(3) No person, other than a veterinary surgeon, shall, on a farm, be in possession of a beta-agonist, or any product containing a beta-agonist which, if administered to an animal, could be for induction purposes in the treatment of tocolysis.

Prohibition of administration to animals of beta-agonists or hormonal substances

5.—(1) Subject to paragraph (2) below, no person shall administer or knowingly cause or permit to be administered to an animal any—

(a) beta-agonist or hormonal substance; or

(b) product which contains a beta-agonist or hormonal substance.

(2) The prohibition in paragraph (1) above shall not apply to the administration of a product which is, or which contains, a beta-agonist or a hormonal substance if that product complies with

(**7**) 1968 c. 67.

the requirements of regulation 25 and is administered in accordance with regulation 26, 27 or 28, as appropriate.

Prohibition of administration to animals of unlicensed substances or products

6.—(1) If any person contravenes the prohibition in Article 14 of the Council Regulation on the administration to food-producing animals of veterinary medicinal products containing pharmaco logically active substances which are not mentioned in Annexes I, II or III of the Council Regulation he shall be guilty of an offence.

(2) Subject to paragraph (3) below, no person shall administer or knowingly cause or permit to be administered to an animal any unlicensed substance or unlicensed product.

(3) Nothing in paragraph (2) above shall prohibit the administration of any veterinary medicinal product in accordance with an exemption specified in regulation 4 or 5 of the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994(**8**).

Prohibition of administration to animals of Annex IV substances

7. If any person contravenes the prohibition in Article 5 of the Council Regulation on the administration of Annex IV substances to food-producing animals he shall be guilty of an offence.

Prohibition of possession or slaughter of animals and of processing

8.—(1) No person shall slaughter or otherwise be in possession on a farm of an animal intended for use for human consumption to which there has been administered, which contains, or in which the presence has been established of, any beta-agonist or hormonal substance.

(2) No person shall process the meat of an animal intended for human consumption where that animal contains or the presence in has been established of, or to which there has been administered, any beta-agonist or hormonal substance.

(3) Any animal slaughtered or in the possession of a person on a farm which is commonly slaughtered or possessed for use for human consumption shall be presumed, until the contrary is proven, to have been slaughtered or possessed for such use and an animal commonly used for human consumption from which meat is processed shall be presumed, until the contrary is proven, to be an animal for such use.

Prohibition of the sale of animals

9.—(1) No person shall sell, or supply for slaughter, for human consumption any animal—

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

(b) which contains an authorised substance in any of its tissues at a concentration exceeding the relevant maximum residue limit; or

(c) if the withdrawal period in relation to the product administered to that animal has not expired.

(2) Subject to paragraph (3) below, no person shall sell an animal not intended for human consumption which contains, or in which the presence is established of, any beta-agonist or hormonal substance.

(3) Nothing in paragraph (2) above shall prohibit the sale of any—

(**8**) S.I. 1994/2987; relevant amending instrument is S.I. 1994/3142.

(a) high-value horse which contains, or in which there is present, a beta-agonist or hormonal substance which is, or was contained in, a product which complies with regulation 25 and was administered in accordance with regulation 26 or 27;

(b) animal, other than a high-value horse, for breeding purposes which contains, or in which there is present, a beta-agonist or hormonal substance which is, or was contained in, a product which complies with regulation 25 and was administered in accordance with regulation 26, 27 or 28.

Prohibition of the sale of animal products

10.—(1) No person shall sell for human consumption any animal product derived from an animal the sale or supply for slaughter of which is prohibited under regulation 9.

(2) No person shall sell for human consumption any animal product which contains—

(i) an unauthorised substance; or

(ii) an authorised substance at a concentration exceeding the relevant maximum residue limit.

Prohibition of disposal of slaughtered animal or batch of animals

11. Where an animal or batch of animals has been slaughtered under regulation 22, no person shall dispose of the carcase or offal of that animal or of any animal of that batch of animals, or any part of such carcase or offal, for human or animal consumption.

Exception to prohibition on slaughter

12.—(1) Notwithstanding the prohibition on slaughter of an animal or batch of animals by notice given in accordance with regulation 22(4), that animal or batch of animals may be slaughtered before the withdrawal of such notice if the owner of that animal or batch of animals complies with the following paragraphs of this regulation.

(2) Notice of the proposed date and place of slaughter shall be given to an authorised officer before that date.

(3) The animal or batch of animals, marked, or caused to be marked, by an authorised officer under regulation 21(2)(c), shall be accompanied to the place of slaughter by a certificate issued by an authorised officer identifying the animal or batch of animals and the farm of origin.

(4) After slaughter any animal product derived from the animal or from an animal of that batch of animals shall be retained in such place and manner as an authorised officer may specify, while it is subjected to such examination as an authorised officer may reasonably consider necessary.

(5) Where the examination (the result of which shall be given by an authorised officer to the owner by notice in writing) confirms that any animal product referred to in paragraph (4) above contains an authorised substance at a concentration exceeding the relevant maximum residue limit, the animal product shall be disposed of for a purpose other than human consumption.

PART III

SAMPLING AND ANALYSIS

Procurement of samples

13. An authorised officer may—

(a) take a sample of any article or substance which is found by him on or in any premises which he is authorised to enter and which he has reason to believe may be required as evidence in proceedings under any of the provisions of these Regulations; and

(b) take a sample from any animal, whether or not intended for human consumption, which is found by him on or in any such premises.

Primary analysis of official samples

14.—(1) An official sample shall be submitted for analysis at an approved laboratory and dealt with in accordance with paragraph (2) or (3) below.

(2) Except where the official sample is of a kind described in paragraph (3) below, part of that sample shall be subjected to a primary analysis, the remainder being retained for any reference analysis.

(3) Where the official sample contains the remains of any solid implant or injection site, the analyst shall prepare an extract of such implant or injection site and subject part of that extract to a primary analysis, the remainder of the extract being retained for any reference analysis.

Results of primary analysis

15.—(1) Where the primary analysis shows that an official sample, or in the case of such a sample containing the remains of a solid implant or injection site, such remains of solid implant or injection site, contains—

(a) an unauthorised substance;

(b) a substance which an analyst reasonably suspects may be an unauthorised substance;

(c) in the case of a sample taken from an animal or batch of animals, its excrement or body fluids or from its tissues, an authorised substance at a concentration which is notified to the analyst by an authorised officer as one which causes him reasonably to suspect that an animal product derived from that animal or batch of animals may contain an authorised substance at a concentration exceeding the relevant maximum residue limit; or

(d) in the case of a sample taken from any animal product, an authorised substance at a concentration exceeding the relevant maximum residue limit,

the analyst shall give a primary analysis certificate to an authorised officer who shall then give this to the relevant person.

(2) Where the primary analysis does not show anything requiring a primary analysis certificate to be given under paragraph (1) above, the analyst shall notify an authorised officer of that fact and the authorised officer shall then notify the relevant person.

(3) For the purposes of this regulation and regulations 16 and 17 "relevant person" means the owner of the animal, batch of animals, animal product or other article or substance from which the sample was taken or the owner of the premises where the sample was taken.

Reference analysis

16.—(1) The finding specified in the primary analysis certificate shall be referred by an authorised officer to an approved laboratory for a reference analysis together with the remainder of the official sample retained by the analyst in accordance with regulation 14(2) or 14(3), as appropriate, if—

(a) the finding shows that the official sample, whether or not an extract of any solid implant or injection site, contains a substance which is specified under the heading 'Group A' in Annex 1 to Council Directive 96/23; or

(b) an authorised officer in any event so decides.

(2) The analyst shall give a reference analysis certificate to an authorised officer who shall then give this to the relevant person.

(3) The relevant person may, on the basis of a contradictory analysis and by notice in writing served on an authorised officer, challenge the finding specified in a primary analysis certificate in relation to an official sample at any time before that sample, or part thereof, is referred for a reference analysis.

(4) Where, in accordance with paragraph (3) above, the relevant person challenges the finding specified in a primary analysis certificate he shall be liable for the costs of any reference analysis which confirms the finding specified in that certificate.

Notification to analyst

17.—(1) An authorised officer who submits to an approved laboratory a sample for primary analysis shall inform the analyst of that approved laboratory of the name and address of the relevant person.

(2) An authorised officer who refers to an approved laboratory a finding specified in a primary analysis shall inform the analyst of that approved laboratory of the name and address of the relevant person.

Methods of analysis

18. The analysis of an official sample shall be carried out—

(a) in relation to a primary analysis, in accordance with methods authorised by Commission Decision 93/256/EEC(**9**), and

(b) in relation to a reference analysis, in accordance with methods authorised by Commission Decision 93/257/EEC(**10**).

Certificates of analysis

19.—(1) Any certificate given by an analyst under these Regulations—

(a) shall be signed by the analyst; and

(b) shall specify the name of the authorised officer who submitted the sample for analysis and the name and address of the enforcement authority of which he is an officer.

(2) In any proceedings under these Regulations, the production by one of the parties—

(a) of a document purporting to be a certificate given by an analyst under paragraph (1) above; or

(b) of a document supplied to him by the other party as being a copy of such a certificate,

shall be sufficient evidence of the facts stated in it unless, in a case falling within sub-paragraph (a) above, the other party requires the analyst to be called as a witness.

Inspection of an animal or batch of animals

20. An authorised officer may, by notice in writing reasonably given to the owner of an animal or batch of animals, require him to detain the animal or batch of animals at the place where it then is, or to remove it to such other place as is specified in the notice and detain it there, to enable the animal or batch of animals to be inspected by an authorised officer for the purpose of ascertaining whether

(**9**) OJ No. L118, 14.5.93, p.64.
(**10**) OJ No. L118, 14.5.93, p.75.

there is present in it an unauthorised substance or a residue of an authorised substance which an authorised officer reasonably suspects may result in any animal product derived from that animal or batch of animals containing an authorised substance at a concentration exceeding the relevant maximum residue limit or whether or not any withdrawal period has expired.

Examination of an animal or batch of animals

21.—(1) If it appears to an authorised officer, as a result of an inspection carried out for the purposes referred to in regulation 20, that any animal or batch of animals may contain an unauthorised substance or a residue of an authorised substance which he reasonably suspects may result in any animal product derived from that animal or batch of animals containing an authorised substance at a concentration exceeding the relevant maximum residue limit or that the withdrawal period in relation to any animal has not expired, an authorised officer shall have the powers specified in paragraph (2) below in relation to such an animal or batch of animals.

(2) An authorised officer may—

(a) give notice in writing to the owner of the animal or batch of animals that, until the notice is withdrawn by a further notice in writing—

(i) no commercial operations are to be carried out with respect to the animal or batch of animals;

(ii) the animal or batch of animals is not to be moved from the place where it then is or is not to be so moved except to a place specified in the notice; and

(iii) no animal, other than one within sub-paragraph (ii) above, shall be moved from the farm of origin except as specified in the notice;

(b) subject the animal or batch of animals to such examinations for the presence of substances or residues as the authorised officer may reasonably consider to be necessary;

(c) paint, stamp, clip, tag or otherwise mark, or cause to be marked, the animal or batch of animals in order to identify it for the purposes of these Regulations.

Notice on completion of examination

22.—(1) On completion of an examination specified in regulation 21(2)(b), an authorised officer shall give notice in writing to the owner of the animal or batch of animals in accordance with the following paragraphs of this regulation.

(2) Where such an examination shows that an animal or batch of animals does not contain any unauthorised substance or the residue of any authorised substance at a concentration likely to result in any animal product derived from that animal or batch of animals having a concentration of the substance exceeding the relevant maximum residue limit or where an authorised officer considers that such an examination is unnecessary the notice shall so declare and shall withdraw any notice served on the owner of the animal or batch of animals under regulation 21(2)(a) in so far as it relates to that animal or batch of animals.

(3) Where the examination shows that an animal or batch of animals contains a prohibited substance, an unlicensed substance or an Annex IV substance the notice shall so declare, shall specify the result of the examination and shall require the owner of the animal or batch of animals to slaughter the animal or batch of animals, or to cause it to be slaughtered, within such a period and in accordance with such requirements as may be specified in the notice.

(4) Where the examination shows that an animal or batch of animals contains a concentration of an authorised substance which an authorised officer reasonably suspects may result in any animal product derived from that animal or batch of animals having a concentration of that substance exceeding the relevant maximum residue limit, the notice shall so declare, shall specify the result

of the examination and shall, subject to regulation 12, prohibit the slaughter of that animal or batch of animals for human consumption.

(5) A notice given in accordance with paragraph (4) above prohibiting the slaughter of any animal or batch of animals may at any time be withdrawn by a further notice in writing given by an authorised officer to the owner of the animal or batch of animals and a notice given in accordance with paragraph (4) above shall be so withdrawn as soon as an authorised officer is satisfied that the animal or batch of animals does not contain a concentration of an authorised substance which may result in any animal product derived from the animal or batch of animals having a concentration of that substance exceeding the relevant maximum residue limit.

(6) If any person on whom a notice has been served under paragraph (3) above fails to comply with the requirements of the notice relating to the slaughter of an animal or batch of animals, an authorised officer may, without prejudice to any proceedings arising out of such default, slaughter, or cause to be slaughtered, that animal or batch of animals.

(7) The enforcement authority may make a charge of an amount equal to the amount of expenses reasonably incurred by the authorised officer in the exercise of the powers conferred on him under—

(a) regulation 21(2), if paragraph (3) or (4) above applies; or

(b) paragraph (6) above.

(8) The charge referred to in paragraph (7) above shall be payable by the person in default and shall be recoverable by the enforcement authority which shall be the appropriate Minister determined according to where exercise of the powers in regulation 21(2) or paragraph (6) above, as appropriate, takes place.

PART IV

OFFENCES AND PENALTIES

Offences, penalties and enforcement

23.—(1) A person shall be guilty of an offence if he—

(a) contravenes regulation 3, 4, 5, 6(2), 8, 9, 10, 11, 32(1), (2), (3), (4) or (5) or any provision of a notice given to him under these Regulations; or

(b) without the consent in writing of an authorised officer, defaces, obliterates or removes any marking made under regulation 21(2)(c) or attempts to do so.

(2) A person guilty of an offence under paragraph (1) above or regulation 6(1) or 7 is liable on summary conviction to a fine not exceeding level 5 on the standard scale or on conviction on indictment to a fine.

(3) Each enforcement authority shall enforce these Regulations and shall give such assistance and information to each other enforcement authority as that other enforcement authority reasonably requires for the purpose of its duties under these Regulations.

(4) Where an offence under these Regulations is committed in Scotland by a Scottish partnership 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 partner, he as well as the partnership shall be guilty of the offence and be liable to be proceeded against and punished accordingly.

(5) No prosecution for an offence under paragraph (1) above or regulation 6(1) or 7 shall be begun after the expiry of—

(a) three years from the commission of the offence; or

(b) one year from its discovery by the prosecutor,

whichever is the earlier.

Defences and exceptions

24.—(1) In any proceedings for an offence alleging a contravention of paragraph (1) or (2) of regulation 4 it shall be a defence for the person charged to prove that the beta-agonist or hormonal substance, or product containing the beta-agonist or hormonal substance, the possession of which is alleged is intended for purposes other than administration to an animal.

(2) In any proceedings for an offence alleging a contravention of regulation 8(1) it shall be a defence for the person charged to prove that the beta-agonist or hormonal substance, as appropriate, contained or present in the animal, or which has been administered to the animal was, or was contained in, a product which complies with the requirements of regulation 25 and was administered in accordance with regulation 26, 27 or 28.

25.—(1) A product which is, or which contains, a beta-agonist or hormonal substance complies with the requirements of this regulation if—

(a) a marketing authorisation has been issued in relation to it;

(b) in the case of a product which is, or which contains, a beta-agonist, it has a withdrawal period of less than 28 days after the end of treatment; and

(c) in the case of a product which is, or which contains, a hormonal substance, it is not a product which falls within paragraph (2) below.

(2) A product falls within this paragraph if it—

(a) acts as a deposit;

(b) has a withdrawal period of more than 15 days after the end of treatment; or

(c) was authorised before 1st January 1995, has no known conditions of use and for which no reagents or equipment exists for use in the analytical techniques for detecting the presence of residues in excess of the prescribed limits.

26.—(1) Administration is in accordance with this regulation if—

(a) it is of a veterinary medicinal product containing oestradiol 17β, testosterone or progesterone or a derivative of any of these substances which readily yields the parent compound or hydrolysis after absorption at the site of application; and

(b) it is carried out for a therapeutic purpose on a clearly identified farm animal by a veterinary surgeon, who makes an appropriate record of the treatment, by injection or for the treatment (other than by implant) of ovarian dysfunction in the form of vaginal spirals.

(2) For the purposes of paragraph (1)(b) above and regulation 28(c) “appropriate record”means the entry in a register of the following details—

(a) type of treatment;

(b) the type of products authorised or prescribed;

(c) the date of treatment;

(d) the identity of the animals treated; and

(e) any applicable withdrawal period.

27. Administration is in accordance with this regulation if carried out—

(a) for a therapeutic purpose, on an animal other than a production animal by, or under the direct responsibility of, a veterinary surgeon and is of a veterinary medicinal product containing—

(i) allyl trenbolone which is administered orally and in accordance with manufacturers' instructions; or

(ii) beta-agonists which are administered in accordance with manufacturers' instructions to equidae or to a pet; or

(b) by a veterinary surgeon of a veterinary medicinal product containing beta-agonists which is administered in the form of an injection for the purpose of inducing tocolysis in a cow when calving.

28. Administration is in accordance with this regulation if—

(a) it is of a veterinary medicinal product having an oestrogenic, androgenic or gestagenic action for the purpose of zootechnical treatment of a clearly identified animal other than a production animal;

(b) it is carried out, in the case of the synchronisation of oestrus or the preparation of donors or recipients for the implantation of embryos by, or under the direct responsibility of a veterinary surgeon, and in any other case, by a veterinary surgeon;

(c) the veterinary surgeon who carries out, or who is responsible for, the administration makes an appropriate record of the treatment and makes out a non-renewable prescription specifying the treatment in question and the quantity of the product required; and

(d) in the case of the treatment of aquaculture animals for the purpose of sex inversion, it is of a veterinary medicinal product having an androgenous action and carried out on fish aged 3 months or less.

29. In any proceedings for an offence under regulation 10 it shall be a defence for the person charged to prove—

(a) that the animal product in respect of which the offence is alleged to have been committed was intended for export to a country which has legislation analogous to these Regulations and that the animal product complies with that legislation; and

(b) in the case of intended export to an EEA State, that the legislation complies with the provisions of Council Directive 96/22 and Council Directive 96/23.

PART V

MISCELLANEOUS

Responsibilities of processors

30. The owner of an establishment of initial processing of animal products shall, in respect of each animal or animal product brought into that establishment, ensure that—

(a) it does not contain—

(i) a residue level which exceeds the maximum permitted limit;

(ii) any unauthorised substance or product; and

(b) any appropriate withdrawal period has been observed.

31. It is hereby declared that a person shall not be entitled to rely on the defence provided by section 21(1), (5) and (6) of the Act, as applied by regulation 34, in any proceedings alleging a contravention of regulation 8 or 10 if he has contravened regulation 30.

Keeping and retention of records

32.—(1) A person engaged by way of business in the rearing, production or treatment of animals intended for human consumption, or in a business in the course of which any commercial operation is carried out with respect to animals intended for human consumption, shall keep a record of particulars relating to the administration of any veterinary medicinal product to such animals or batch of animals which record shall be made as soon as practicable after administration and shall include the following information—

(a) date of administration;

(b) identity and quantity of the veterinary medicinal product;

(c) name and address of the supplier of the veterinary medicinal product;

(d) identification of the animal or batch of animals to which the veterinary medicinal product was administered.

(2) The owner of an establishment of initial processing of animal products shall keep such records as are sufficient, either alone or in combination with records or information held by some other person, to enable the animals from which those animal products were derived, and the farm of origin or departure of those animals, to be identified.

(3) The persons referred to in paragraph (1)(b) and sub-paragraphs (a) and (b) of paragraph (2) of regulation 4 shall, in relation to hormonal substances and beta-agonists, keep a record in chronological order of—

(a) quantities produced;

(b) quantities purchased or otherwise acquired and from whom each quantity was purchased or acquired;

(c) quantities sold and to whom each quantity was sold; and

(d) quantities used in the production of pharmaceutical or veterinary medicinal products.

(4) Any person required to keep a record by paragraph (1), (2) or (3) above shall keep that record in a permanent and legible form and shall retain that record for a period of three years from the end of the calendar year to which such record relates save in the case of a prescription intended to show that withdrawal periods have been observed which shall be retained for a period of five years from the date of the commencement of the withdrawal period to which it relates.

(5) Subject to paragraph (6) below if an authorised officer directs a person to produce for inspection a record which paragraph (1), (2) or (3) above requires him to keep, he shall comply with the direction.

(6) No direction may be given under paragraph (5) above after the end of the period mentioned in paragraph (4) above.

(7) The requirement in paragraph (4) above to keep records in a legible form is not to be taken to prevent their being kept by means of computer.

(8) Where a record is so kept, the duty under paragraph (5) above to produce it for inspection, is a duty to produce it in a form in which it can be taken away.

Suspension or revocation of manufacturers' licences

33. The powers of suspension or revocation of a manufacturer's licence given by section 28 of the Medicines Act 1968(**11**) shall additionally be exercisable by the licensing authority within the meaning of section 6 of that Act in accordance with Article 25 of Council Directive 96/23 in circumstances where the holder of the licence is in possession of, uses or manufactures, unauthorised substances or products, and the relevant provisions of Schedule 2 to that Act shall apply accordingly.

(**11**) 1968 c. 67.

Application and modification of provisions of the Food Safety Act 1990

34.—(1) The following provisions of the Act shall apply for the purposes of these Regulations and, unless the context otherwise requires, any reference in them to that Act shall be construed for the purposes of these Regulations as a reference to these Regulations—

(a) section 2 (extended meaning of "sale" etc.);

(b) section 3 (presumption that food is intended for human consumption);

(c) section 20 (offences due to fault of another person);

(d) section 21(1), (5) and (6) (defence of due diligence);

(e) section 22 (defence of publication in the course of business);

(f) section 33 (obstruction etc. of officers);

(g) section 35(1) to (3) (punishment of offences) in so far as it relates to offences under section 33(1) and (2); and

(h) section 36 (offences by bodies corporate).

(2) Section 9 of the Act (inspection and seizure of suspected food) shall, subject to paragraph (3) below, apply for the purposes of these Regulations as if an animal product which it is an offence to sell under these Regulations were food which failed to comply with food safety requirements.

(3) Section 9 of the Act shall apply with the following modifications—

(a) for the words "food authority" in each place where they occur there shall be substituted the words "enforcement authority"; and

(b) the reference in sub-section (5)(a) to sections 7 and 8 of the Act shall be construed as a reference to these Regulations.

(4) Section 29 of the Act (procurement of samples) shall apply subject to the modification that for the words "section 32 below" in sub-section (a)(ii) there shall be substituted the words "these Regulations".

(5) Section 30 of the Act (analysis etc. of samples) shall apply subject to the modification that after the words "section 29 above" there shall be inserted the words ", other than an official sample,".

(6) Section 32 of the Act (powers of entry) shall apply with the omission of the word "food"in sub-section (5) and the references to "regulations" in sub-section (1) shall, for the purposes of these Regulations, be construed as including a reference to Articles 5 and 14 of the Council Regulation.

(7) Section 44 of the Act (protection of officers acting in good faith) shall apply subject to the modification that for the words "food authority" in each place where they occur there shall be substituted the words "enforcement authority".

Amendments

35.—(1) In the Food Safety (Sampling and Qualifications) Regulations 1990(**12**) in Schedule 1 (provisions to which these regulations do not apply) the title of the Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations 1991 in the left hand column and their reference in the right hand column shall be deleted and at the end of that Schedule there shall be added in the left hand column the title of these Regulations and against it in the right hand column their reference.

(2) In the Meat (Hygiene, Inspection and Examination for Residues) (Charges) Regulations 1995(**13**) in paragraph (1) of regulation 2 (interpretation) for the definition of "the Residues Regulations" there shall be substituted the following—

(**12**) S.I. 1990/2463; to which there are amendments not relevant to these Regulations.
(**13**) S.I. 1995/361; relevant amending instrument is S.I. 1995/2836.

""the Residues Regulations" means the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997;".

(3) In the Fresh Meat (Hygiene and Inspection) Regulations 1995(**14**) in paragraphs (n) and (p) of paragraph 1(1) of Schedule 9 (slaughter and dressing practices—requirements applicable in slaughterhouses and farmed game processing facilities) for the words "the Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations 1991" there shall be substituted "the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997".

(4) In the Poultry Meat, Farmed Game Bird Meat and Rabbit Meat (Hygiene and Inspection) Regulations 1995(**15**) in paragraph 5 of Part I (general requirements) of Schedule 9 (post-mortem health inspection) for the words "Group A III and Group B I(a) and (c) and II(a) of Annex I to Directive 86/469/EEC, as amended by Decision 89/187/EEC" there shall be substituted the words "Group A (1), (2), (3), (4), (5) and (6) and Group B (1), (2)(a), (b), (c) and (e) and (3)(a), (c) and (d) of Annex I to Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC".

(5) In the Dairy Products (Hygiene) Regulations 1995(**16**) and the Dairy Products (Hygiene) (Scotland) Regulations 1995(**17**) in paragraph 1(e) of Part I (animal health standards) of Schedule 3 (requirements for raw milk) for the words "Council Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, as amended, and Council Directive 88/146/EEC prohibiting the use in livestock farming of certain substances having a hormonal action" there shall be substituted the words "Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC".

Revocations

36. The Regulations specified in columns 1 and 2 of Schedule 2 shall be revoked to the extent specified in column 3 of that Schedule.

Jeff Rooker
Minister of State, Ministry of Agriculture,
Fisheries and Food

15th July 1997

Signed by authority of the Secretary of State for Health

Tessa Jowell
Minister of State for Public Health,
Department of Health

16th July 1997

(**14**) S.I. 1995/539; to which there are amendments not relevant to these Regulations.
(**15**) S.I. 1995/540.
(**16**) S.I. 1995/1086; to which there are amendments not relevant to these Regulations.
(**17**) S.I. 1995/1372.

Signed by the authority of the Secretary of State for Wales

Win Griffiths
Parliamentary Under Secretary of State, Welsh Office

18th July 1997

Sewel
Parliamentary Under Secretary of State, Scottish Office

14th July 1997