STATUTORY INSTRUMENTS

1997 No. 1729

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

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(**1**) 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.

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—

(**1**) 1968 c. 67.

(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(**2**) 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(**3**) in paragraph (1) of regulation 2 (interpretation) for the definition of "the Residues Regulations" there shall be substituted the following—

> ""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(**4**) 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(**5**) 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(**6**) and the Dairy Products (Hygiene) (Scotland) Regulations 1995(**7**) in paragraph 1(e) of Part I (animal health standards) of Schedule 3

(**2**) S.I.1990/2463; to which there are amendments not relevant to these Regulations.
(**3**) S.I. 1995/361; relevant amending instrument is S.I. 1995/2836.
(**4**) S.I. 1995/539; to which there are amendments not relevant to these Regulations.
(**5**) S.I. 1995/540.
(**6**) S.I. 1995/1086; to which there are amendments not relevant to these Regulations.

(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.

(7) S.I. 1995/1372.