STATUTORY RULES OF NORTHERN IRELAND

1998 No. 237

FOOD

Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations (Northern Ireland) 1998

Made - - - -	*30th June 1998*
Coming into operation	*30th June 1998*

The Department of Agriculture and the Department of Health and Social Services, acting jointly as the Department concerned(**1**), in exercise of the powers conferred on them by Articles 15(1)(a) (b) and (f) and (3), 16(1) and (2), 25(1), (2)(a) and (b) and (3), 26(3), 30(9), 31(3), 32(1) and (2)(c), (d), (e), (f), and (h), 44(1) and (2) and 47(2) of, and paragraphs 3(1)(b) and 7(1) to (3) of Schedule 1 to, the Food Safety (Northern Ireland) Order 1991(**2**) ("the Order") and being Departments designated(**3**) for the purposes of section 2(2) of the European Communities Act 1972(**4**) in relation to the common agricultural policy of the European Community and in relation to medicinal products, acting jointly, in exercise of the powers conferred on them by the said section 2(2), and of all other powers enabling them in that behalf; after consultation in accordance with Article 47 of the Order with such organisations as appear to them to be representative of interests likely to be substantially affected by the Regulations (in so far as the Regulations are made in exercise of the powers conferred by the said Articles of the Order), hereby make the following Regulations:

Part I

Introductory

Citation and commencement

1. These Regulations may be cited as the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations (Northern Ireland) 1998 and shall come into operation on 30th June 1998.

(**1**) *See* Article 2(2) of S.I.1991/762 (N.I. 7); the definition of "the Department concerned"was substituted by Article 3(1)(a) of S.I. 1996/1633 (N.I. 12)
(**2**) S.I. 1991/762 (N.I. 7) as amended by S.I. 1996/1633 (N.I. 12)
(**3**) *See* S.I. 1972/1811
(**4**) 1972 c. 68

Interpretation

2.—(1) In these Regulations—

"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;

"approved laboratory" means—

(a) a laboratory approved by the Department 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 Article 27 of the Order;

"authorised officer" means—

(a) except in regulations 12, 20, 21, 22 and 23(1)(b), 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; or

(b) in regulations 12, 20, 21, 22 and 23(1)(b) any person who is authorised in writing by the Department, either generally or specially, to act in matters arising under those regulations;

"authorised veterinary medicinal product" has the same meaning as in the Medicines (Restriction on the Administration of Veterinary Medicinal Products) Regulations 1994(**5**) except that it excludes neither additives for feedingstuffs to which the provisions of Council Directive 70/524/EEC(**6**) apply nor medicated feedingstuffs;

"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(**7**);

"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(**8**);

(**5**) S.I. 1994/2987. The relevant amendment is S.I. 1997/2884
(**6**) O.J. No. L.270, 14.12.70
(**7**) O.J. No. L.125, 23.5.96, p. 3
(**8**) O.J. No. L.125, 23.5.96, p. 10

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

"the Department" means the Department of Agriculture for Northern Ireland;

"EEA Agreement" means the Agreement on the European Economic Area(**9**) signed at Oporto on 2nd May 1992, as adjusted by the Protocol(**10**) signed at Brussels on 17th March 1993;

"EEA State" means a State other than the United Kingdom which is a Contracting Party to the EEA Agreement;

"enforcement authority", means the Department or a district council within its district, or both;

"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 the following categories—

(a) stilbenes and thyrostatic substances; or

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

"marketing authorisation" means a marketing authorisation within the meaning of the Marketing Authorisations Regulations or a product licence granted under the Medicines Act 1968(**11**);

"the Marketing Authorisations Regulations" means the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**12**);

"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;

"the Order" means the Food Safety (Northern Ireland) Order 1991;

"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;

(**9**) O.J. No. L.1, 3.1.94, p. 1
(**10**) O.J. No. L.1, 3.1.94, p. 571
(**11**) 1968 c. 67
(**12**) S.I. 1994/3142

"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;

"unauthorised substance" means any Annex IV substance, prohibited substance or unlicensed substance;

"unlicensed product" means an authorised 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 medicinal product licence" means a product licence granted under the Medicines Act 1968 in respect of an authorised veterinary medicinal product;

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

"withdrawal period", in relation to an authorised veterinary medicinal product or product which is, or which contains, a beta-agonist or hormonal substance, in either case 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 administration to the animal or batch of animals of 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 Regulations, as appropriate.

(4) The Interpretation Act (Northern Ireland) 1954(**13**) shall apply to these Regulations as it applies to a Measure of the Northern Ireland Assembly.

Part II

Prohibitions and Exceptions

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

3.—(1) A person shall not 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), a person shall not 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) 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, until the contrary is proven, to be intended for human consumption.

Prohibition of possession of beta-agonists or hormonal substances

4.—(1) A person shall not be in possession of any beta-agonist or hormonal substance unless—

(a) subject to paragraph (3), 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 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) A persons shall not 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;

(**13**) 1954 c. 33 (N.I.)