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.)

(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), it complies with the requirements of regulation 25 and is for the purposes of administration in accordance with regulation 26, 27 or 28.

(3) A person, other than a veterinary surgeon, shall not, 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), a person shall not 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) 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 the requirements of regulation 25 and is administered in accordance with regulation 26, 27 or 28, as appropriate.

Prohibition of administration of animals of unlicensed substances or unlicensed products

6.—(1) If any person contravenes the prohibition in Article 14 of the Council Regulation on the administration to food-producing animals of authorised veterinary medicinal products containing pharmacologically 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), a person shall not administer or knowingly cause or permit to be administered to an animal any unlicensed substance or unlicensed product.

(3) Nothing in paragraph (2) shall prohibit the administration of any authorised 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(**14**).

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) A person shall not 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) A person shall not 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

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

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) A person shall not sell, or supply for slaughter, for human consumption any animal—

(a) which contains or to which there has been administered an unauthorised substance or unlicensed 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 an authorised veterinary medicinal product administered to that animal has not expired.

(2) Subject to paragraph (3), a person shall not 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) shall prohibit the sale of any—

(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) A person shall not 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) A person shall not sell for human consumption any animal product which contains—

(a) an unauthorised substance; or

(b) 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, a person shall not 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 served pursuant to 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 paragraphs (2) to (5).

(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 he may reasonably consider necessary.

(5) Where the examination (the result of which shall be served by an authorised officer on the owner by notice in writing) confirms that any animal product referred to in paragraph (4) 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).

(2) Except where the official sample is of a kind described in paragraph (3) 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 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 serve a copy thereof on the relevant person.

(2) Where the primary analysis does not show anything requiring a primary analysis certificate to be given under paragraph (1), 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 (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 serve a copy thereof on the relevant person.

(3) The relevant person may, on the basis of a contradictory analysis and by notice in writing serve 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), 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(**15**); and

(b) in relation to a reference analysis, in accordance with methods authorised by Commission Decision 93/257/EEC(**16**).

Certificates of analysis

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

(a) shall be signed by the analyst; and

(**15**) O.J. No. L.118, 14.5.93, p. 64
(**16**) O.J. No. L.118, 14.5.93, p. 75

(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); 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), 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 served on 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 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 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) in relation to such an animal or batch of animals.

(2) An authorised officer may—

(a) serve a notice in writing on 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 be so moved except to a place specified in the notice; and

(iii) no animal, other than one within sub-paragraph (ii), 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 serve a notice in writing on the owner of the animal or batch of animals in accordance with paragraphs (2) to (5).

(2) Where such an examination shows than 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 an unauthorised 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 served in accordance with paragraph (4) prohibiting the slaughter of any animal or batch of animals may at any time be withdrawn by a further notice in writing served by an authorised officer on the owner of the animal or batch of animals and a notice served in accordance with paragraph (4) 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) 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 Department may make a charge of an amount equal to the amount of expenses reasonably incurred by its authorised officer in the exercise of the powers conferred on him under—

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

(b) paragraph (6).

(8) The charge referred to in paragraph (7) shall be payable by the person in default and shall be recoverable by the Department.

Part IV

Offences, Defences and Exceptions

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 served on 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).

(2) A person guilty of an offence under paragraph (1) or regulation 6(1) or 7 is liable on summary conviction to a fine not exceeding the statutory maximum 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) A prosecution for an offence under paragraph (1) or regulation 6(1) or 7 shall not 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) or 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).

(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 an authorised veterinary medicinal product containing oestradiol 17β, testosterone or progesterone or a derivative of any of these substances which readily yields the parent compound on hydrolis 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) 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 animal 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 an authorised 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 an authorised 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 an authorised 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 an authorised veterinary medicinal product having an androgenous action and carried out on a 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 of that EEA State 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 unlicensed 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 Article 20(1), (5) and (6) of the Order, 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 kept a record of particulars relating to the administration of any authorised 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 authorised veterinary medicinal product;

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

(d) identification of the animal or batch of animals to which the authorised 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 authorised veterinary medicinal products.

(4) Any person required to keep a record by paragraph (1), (2) or (3) 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) if an authorised officer directs a person to produce for inspection a record which paragraph (1), (2) or (3) requires him to keep, he shall comply with the direction.

(6) An authorised officer shall not give a direction under paragraph (5) in relation to a record after the end of the appropriate period mentioned in paragraph (4).

(7) The requirement in paragraph (4) to keep records in a permanent and legible form shall not prevent their being kept by means of computer.

(8) Where a record is so kept, the duty under paragraph (5) 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 manufacturer's licences

33. The powers of suspension or revocation of a manufacturer's licence given by section 28 of the Medicines Act 1968(**17**) 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 unlicensed products, and the relevant provisions of Schedule 2 to that Act shall apply accordingly.

Application and modification of provisions of the Food Safety (Northern Ireland) Order 1991

34.—(1) The following provisions of the Order shall apply for the purposes of these Regulations and any reference in them to the Order shall be construed for the purposes of these Regulations as a reference to these Regulations—

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

(b) Article 4 (presumption that food is intended for human consumption);

(c) Article 19 (offences due to fault of another person);

(d) Article 20(1), (5) and (6) (defence of due diligence);

(e) Article 21 (defence of publication in the course of business);

(f) Article 34 (obstruction etc. of officers);

(g) Article 36 (punishment of offences) in so far as it relates to offences under Article 34(1) and (2); and

(h) Article 43 (protection of public analyst acting in good faith).

(2) Article 8 of the Order (inspection and seizure of suspected food) shall, subject to paragraph (3), 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) Article 8 of the Order shall apply for the purposes of these Regulations subject to the modification that the reference in paragraph (5)(a) thereof to Articles 6 and 7 of the Order shall be construed as a reference to these Regulations.

(4) Article 29 of the Order (procurement of samples) shall apply for the purposes of these Regulations subject to the modification that for the words "Article 33" in paragraph (b)(ii) thereof shall be substituted "Article 33 as applied by this regulation".

(5) Articles 30 and 31 of the Order (analysis etc. of samples) shall apply for the purposes of these Regulations subject to the modification that in each case after the words "Article 29" there shall be inserted the words ", other than an official sample,".

(6) Article 33 of the Order (powers of entry) shall apply for the purposes of these Regulations with the omission of the word "food" in paragraph (6) thereof and the references to "regulations" in paragraph (1) thereof shall be construed as including a reference to Articles 5 and 14 of the Council Regulation.

Amendments

35.—(1) In the Food Safety (Sampling and Qualifications) Regulations (Northern Ireland) 1991(**18**) 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 (Northern Ireland) 1992 in the left hand column and their reference in the right hand column shall

(**17**) 1968 c. 67
(**18**) S.R. 1991 No. 198; the relevant amending Regulations are S.R. 1992 No. 39 and S.R. 1995 No. 107

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 Dairy Products (Hygiene) Regulations (Northern Ireland) 1995(**19**) 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, as amended, concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action 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".

(3) In the Poultry Meat, Farmed Game Bird Meat and Rabbit Meat (Hygiene and Inspection) Regulations (Northern Ireland) 1995(**20**) 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".

(4) In the Meat (Hygiene, Inspection and Examination for Residues) (Charges) Regulations (Northern Ireland) 1995(**21**) in paragraph (2) 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 (Northern Ireland) 1998;".

(5) In the Fresh Meat (Hygiene and Inspection) Regulations (Northern Ireland) 1997(**22**) 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 (Northern Ireland) 1992" there shall be substituted "the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations (Northern Ireland) 1998".

Revocations

36. The Regulations specified in Schedule 2 are hereby revoked.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 3

L.S.

Noel Cornick
Assistant Secretary

30th June 1998.

(**19**) S.R. 1995 No. 201; to which there are amendments not relevant to these Regulations
(**20**) S.R. 1995 No. 396
(**21**) S.R. 1997 No. 431
(**22**) S.R. 1997 No. 493

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on

L.S.

W. B. Smith
30th June 1998. Assistant Secretary

SCHEDULE 1

Regulation 2(1)

The Council Regulation
Official Journal of the Communities References

Council Regulation (EEC) No. 2377/90 laying down a Community procedure for the maximum residue limits of veterinary medicinal products in foodstuffs of animal origin as amended by—	O.J. No. L244, 18.8.90, p. 1
(a) (a) Commission Regulation (EEC) No. 2701/94	O.J. No. L287, 8.11.94, p. 7
(b) (b) Commission Regulation (EEC) No. 2703/94	O.J. No. L287, 8.11.94, p. 19
(c) (c) Commission Regulation (EEC) No. 3059/94	O.J. No. L323, 16.12.94, p. 15
(d) (d) Commission Regulation (EEC) No. 1102/95	O.J. No. L110, 17.5.95, p. 22
(e) (e) Commission Regulation (EC) No. 1441/95	O.J. No. L143, 27.6.95, p. 22
(f) (f) Commission Regulation (EC) No. 1442/95	O.J. No. L143, 27.6.95, p. 26
(g) (g) Commission Regulation (EC) No. 2796/95	O.J. No. L290, 5.12.95, p. 1
(h) (h) Commission Regulation (EC) No. 2804/95	O.J. No. L291, 6.12.95, p. 8
(i) (i) Commission Regulation (EC) No. 281/96	O.J. No. L37, 15.2.96, p. 9
(j) (j) Commission Regulation (EC) No. 282/96	O.J. No. L37, 15.2.96, p. 12
(k) (k) Commission Regulation (EC) No. 1140/96	O.J. No. L151, 26.6.96, p. 6
(l) (l) Commission Regulation (EC) No. 1147/96	O.J. No. L151, 26.6.96, p. 26
(m) (m) Commission Regulation (EC) No. 1311/96	O.J. No. L170, 9.7.96, p. 4
(n) (n) Commission Regulation (EC) No. 1312/96	O.J. No. L170, 9.7.96, p. 8
(o) (o) Commission Regulation (EC) No. 1433/96	O.J. No. L184, 24.7.96, p. 21
(p) (p) Commission Regulation (EC) No. 1742/96	O.J. No. L226, 7.9.96, p. 5
(q) (q) Commission Regulation (EC) No. 1798/96	O.J. No. L236, 18.9.96, p. 23

(r)	(r) Commission Regulation (EC) No. 2010/96	O.J. No. L269, 22.10.96, p. 5
(s)	(s) Commission Regulation (EC) No. 2017/96	O.J. No. L270, 23.10.96, p. 2
(t)	(t) Commission Regulation (EC) No. 2034/96	O.J. No. L272, 25.10.96 p. 2
(u)	(u) Commission Regulation (EC) No. 17/97	O.J. No. L5, 9.1.97, p. 12
(v)	(v) Commission Regulation (EC) No. 211/97	O.J. No. L35, 5.2.97, p. 1
(w)	(w) Commission Regulation (EC) No. 270/97	O.J. No. L45, 15.2.97, p. 8
(x)	(x) Council Regulation (EC) No. 434/97	O.J. No. L67, 7.3.97, p. 1
(y)	(y) Commission Regulation (EC) No. 716/97	O.J. No. L106, 24.4.97, p. 10
(z)	(z) Commission Regulation (EC) No. 748/97	O.J. No. L110, 26.4.97, p. 21
(aa)	(aa) Commission Regulation (EC) No. 749/97	O.J. No. L110, 26.4.97, p. 26

SCHEDULE 2

Regulation 36

Revocations

Column 1 *Regulations revoked*	Column 2 *References*
The Medicines (Hormone Growth Promoters) (Prohibition of Use) Regulations 1988	S.I. 1988/705
The Animals and Fresh Meat (Hormonal Substances) Regulations 1988	S.I. 1988/849
The Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations (Northern Ireland) 1992	S.R. 1992 No. 39
The Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations (Northern Ireland) 1995	S.R. 1995 No. 97

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations revoke and replace provisions formerly contained in the Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations (Northern Ireland) 1992, the Medicines (Hormone Growth Promoters) (Prohibition of Use) Regulations 1988 and the Animals and Fresh Meat (Hormonal Substances) Regulations 1988.

The Regulations implement as respects Northern Ireland Council Directive 96/22/EC (O.J. No. L125, 23.5.96, p. 3) 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. The Regulations also implement as respects Northern Ireland Council Directive 96/23/EC (O.J. No. L125, 23.5.96, p. 10) 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 and provide for the enforcement and execution of the prohibition in Articles 5 and 14 of Council Regulation (EEC) No. 2377/90 (O.J. No. L224, 18.8.90 p. 1).

The prohibition on administration of "unlicensed products" in regulation 6, as read with the definition of such products in regulation 2(1), gives effect to the judgment in the Case C-297, Dominique Bruyere and Others v. Belgium, in so far as that judgement relates to the administration of authorised veterinary medicinal products to animals within the meaning of Directives 96/22/EC and 96/23/EC.

The Regulations—

(a) prohibit the sale, possession or administration to animals of specified unauthorised substances (regulations 3, 4, 5, 6 and 7);

(b) prohibit the possession, slaughter or processing the meat of, animals intended for human consumption which contain, or which have been administered with, specified unauthorised substances (regulation 8);

(c) prohibit the sale or supply for slaughter of animals if the appropriate withdrawal period has not expired and prohibit supply for slaughter or, subject to exceptions, the sale, of animals or the sale of animal products which contain unauthorised substances or an excess of authorised substances (regulations 9 and 10);

(d) prohibit, subject to an exception, the disposal for human or animal consumption of slaughtered animals containing specified unauthorised substances (regulations 11 and 12);

(e) empower authorised officers to inspect and examine animals and to take samples and provide for the analysis of official samples (regulations 13, 14, 15, 16, 17, 18, 19, 20, 21 and 22);

(f) provide for offences and penalties and for enforcement by each enforcement authority as defined in regulation 2(1) (regulation 23);

(g) provide specific defences (regulations 24, 25, 26, 27, 28 and 29);

(h) deny to processors a due diligence defence in specified circumstances (regulations 30 and 31);

(i) specify requirements relating to the keeping of records and provide for the suspension or revocation of manufacturer's licences (regulation 32 and 33);

(j) apply, with some modifications, provisions of the Food Safety (Northern Ireland) Order 1991 including the defence of due diligence (regulation 34); and

(k) amend and revoke other legislation (regulations 35 and 36 and Schedule 2).