STATUTORY INSTRUMENTS

2015 No. 787

FOOD, ENGLAND
FOOD, SCOTLAND

The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015

Made - - - -	*18th March 2015*
Laid before Parliament	*20th March 2015*
Coming into force - -	*1st July 2015*

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(**1**) ("the 1972 Act") in relation to measures in the veterinary and phytosanitary fields for the protection of public health(**2**) and in relation to the common agricultural policy of the European Union(**3**).

The Secretary of State has carried out the consultation required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**4**).

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Secretary of State that it is expedient for any reference in these Regulations to the Annexes to 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(**5**), to Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products(**6**) and to Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin(**7**) to be construed as a reference to those Annexes as amended from time to time.

(**1**) 1972 c. 68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c.7).
(**2**) S.I. 1999/2027.
(**3**) S.I. 1972/1811.
(**4**) OJNo. L31, 1.2.2002, p.1, as last amended by Regulation (EU) No. 652/2014 (OJ No. L189, 27.6.2014, p.1).
(**5**) OJ No L125, 23.5.1996, p.3, as last amended by Directive 2008/97/EC (OJ No L318, 28.11.2008, p.9).
(**6**) OJ No.L125, 23.5.1996, p.10, as last amended by Directive 2013/20/EU (OJ No. L158, 10.6.2013, p.234).
(**7**) OJ No. L15, 20.1.2010, p.1, as last amended by Commission Implementing Regulation (EU) No. 967/2014 (OJ No. L272, 13.9.2014, p.3).

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A of Schedule 2(**8**) to, the 1972 Act, and by sections 16(1)(a), (b) and (f) and (3), 17(1) and (2), 26(1) and 48(1) of, and paragraph 7 of Schedule 1 to, the Food Safety Act 1990(**9**), and section 14A of the Interpretation Act 1978(**10**) and now vested in the Secretary of State(**11**).

PART 1

INTRODUCTORY

Title, commencement and application

1.—(1) These Regulations may be cited as the Animals and Animal Products (Examination for Residues and Maximum Residue Limits)(England and Scotland) Regulations 2015 and come into force on 1st July 2015.

(2) These Regulations apply in relation to England and Scotland only.

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;

"appropriate Minister" means, as respects England, the Secretary of State and, as respects Scotland, the Scottish Ministers;

"approved laboratory" means—

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

(**8**) Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c.51) and amended by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c.7).

(**9**) 1990 c. 16.

(**10**) 1978 c.30. Section 14A was inserted by section 59(1) and (2) of the Enterprise and Regulatory Reform Act 2013 (c.24).

(**11**) The powers, so far as they are exercisable in relation to England, were transferred by article 2(6) of the Transfer of Functions (Agriculture and Food) Order 1999 (S.I. 1999/3141) to the Minister of Agriculture, Fisheries and Food and the Secretary of State acting jointly, and by article 2(3) of the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002 (S.I. 2002/794) to the Secretary of State. In so far as they are exercisable in relation to Scotland, they were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (c. 46) but the Secretary of State retains a concurrent power to exercise them under section 57(1) of that Act. In so far as they are exercisable in relation to Wales, they were transferred to the National Assembly for Wales by article 2(a) of and Schedule 1 to the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) and then transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32). However the Ministers of the Crown responsible retained a concurrent power to exercise them under paragraph 5 of Schedule 3 to the Government of Wales Act 1998 (c. 38); that concurrent power became vested in the Secretary of State in consequence of section 40 of and Schedules 5 and 6 to the Food Standards Act 1999 (c. 28), but subject to any power of the Minister of Agriculture, Fisheries and Food, saved by regulation 13 of the Food Standards Act 1999 (Transitional and Consequential Provisions and Savings) (England and Wales) Regulations 2000 (S.I. 2000/656), to join in making regulations in relation to residues of veterinary products; that joint power was transferred to the Secretary of State by article 2(3) of the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002. Schedule 3 to the Government of Wales Act 1998 was repealed by the Government of Wales Act 2006 (c. 32); the concurrent power of Ministers of the Crown is now contained in paragraph 5 of Schedule 3 to that Act.

(b) any laboratory under the direction or control of a public analyst appointed in accordance with section 27(**12**) 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—

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

(d) 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—

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

(f) consigning or delivering by way of sale;

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

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

(i) 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 repealing Directives 81/602/EEC, 88/146/EEC and 88/299/ECC;

"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;

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

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

(k) 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—

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

(m) 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—

(n) stilbenes and thyrostatic substances;

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

"list A substance" means a substance named in List A of Annex II to Council Directive 96/22;

(**12**) Section 27 has been amended by the Food Standards Act 1999 (c.28) section 40(1), Schedule 5 paragraphs 7 and 8, the Local Government Changes for England Regulations 1994 (S.I. 1994/867) regulation 24 and the Local Government and Public Involvement in Health Act 2007 (c.28) sections 22 and 241, Schedule 1, Part 2 paragraph 17 and Schedule 18 Part 1.

"list B substance" means a substance named in List B of Annex II to Council Directive 96/22;

"local authority" means—

(p) 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(**13**), a unitary authority for the local government area, that authority;

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

(q) in relation to Scotland, a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994(**14**);

"marketing authorisation" has the same meaning as it bears in Article 5 of Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products(**15**);

"maximum residue limit" means, in relation to a concentration of a substance specified in the first column of Table 1 in the tissues or body fluids of an animal or in an animal product, the limit (if any) 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 farm of 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;

(**13**) S.I. 1994/867; to which there are amendments not relevant to these Regulations.
(**14**) 1994 c.39. Section 2 was amended by the Environment Act 1995 (c.25), section 120(1) and Schedule 22, paragraph 232(1).
(**15**) OJ No. L311, 28.11.2001, p.1. Article 5 was replaced by Directive 2004/28/EC (OJ No. L136, 30.4.2004, p.58).

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

"Regulation 470/2009" means Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council(**16**);

"Regulation 37/2010" means Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin;

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

"Table 1" means Table 1 of the Annex to Regulation 37/2010, and "Table 1 substance" means a substance specified in the first column of Table 1;

"Table 2 substance" means a substance specified in Table 2 of the Annex to Regulation 37/2010;

"unauthorised substance" means a Table 2 substance, a prohibited substance and any other substance or product the administration of which to animals is prohibited by or under EU legislation;

"unlicensed substance" means a substance, other than a hormonal substance, beta-agonist or Table 2 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 Union 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—

(a) the presence of the drug or drug metabolite (or combination thereof) specified in the second column (marker residue) of Table 1 opposite the corresponding entry in the first column (pharmacologically active substance) of that Table is to 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 corresponding entry in the fifth column (target tissues) of that Table; and

(b) the maximum residue limit (if any) specified in the fourth column of that Table in the entry corresponding to that substance is to apply in respect of the presence in such part of an

(**16**) OJ No. L152, 16.6.2009, p.11.