STATUTORY INSTRUMENTS

2015 No. 787

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

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

(b) any laboratory under the direction or control of a public analyst appointed in accordance with section 27(**1**) 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—

(**1**) 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.

(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;

"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(**2**), 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(**3**);

"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(**4**);

"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;

"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(**5**);

(**2**) S.I. 1994/867; to which there are amendments not relevant to these Regulations.
(**3**) 1994 c.39. Section 2 was amended by the Environment Act 1995 (c.25), section 120(1) and Schedule 22, paragraph 232(1).
(**4**) OJNo. L311, 28.11.2001, p.1. Article 5 was replaced by Directive 2004/28/EC (OJ No. L136, 30.4.2004, p.58).
(**5**) OJ No. L152, 16.6.2009, p.11.

"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 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 Regulation 470/2009 have, in so far as the context admits, the same meaning as they bear in those Directives or that Regulation, as appropriate.

(4) Any reference in these Regulations to an Annex to Council Directive 96/22, Council Directive 96/23 or Regulation 37/2010 is a reference to that Annex as amended from time to time.

PART 2

Prohibitions and Exceptions

Prohibition on the sale of list A and list B substances

3.—(1) Subject to paragraph (2), no person may sell for administration to any animal any product which is, or which contains, a list A substance or a list B substance, if the animal or any product of that animal is intended for human consumption.

(2) Paragraph (1) does not apply to the sale of a product that complies with the requirements of regulation 25 and which is for administration in accordance with regulation 27.

(3) Any product sold which is, or which contains, a list A substance or a list B substance is to be presumed, unless the contrary is proven, to have been sold for administration to an animal which is, or any product of which is, intended for human consumption.

Prohibition on possession of beta-agonists

4. No person, other than a veterinary surgeon, may possess on a farm any veterinary medicinal product containing a beta-agonist which is authorised to be used for induction purposes in the treatment of tocolysis.

Prohibition on administration of beta-agonists or hormonal substances

5.—(1) Subject to paragraph (2), no person may administer or knowingly cause or permit to be administered to any animal any product which is, or which contains, a substance listed in Annex II or III to Council Directive 96/22.

(2) The prohibition in paragraph (1) does not apply to the administration of a compliant veterinary medicinal product—

(a) containing testosterone, progesterone or a derivative of these substances which readily yields the parent compound on hydrolysis after absorption at the site of application, if the administration is in accordance with regulation 26;

(b) containing allyl trenbolone or a beta-agonist, if the administration is in accordance with regulation 27; or

(c) having oestrogenic action (but not containing oestradiol 17b or its ester-like derivatives), androgenic action or gestagenic action, if the administration is in accordance with regulation 28.

(3) In paragraph (2), "compliant veterinary medicinal product" means a veterinary medicinal product which complies with the requirements of regulation 25.

Prohibition of administration to animals of unlicensed substances or products

6.—(1) Subject to paragraph (2), no person may administer or knowingly cause or permit to be administered to an animal any unlicensed substance.

(2) Nothing in paragraph (1) prohibits the administration of any veterinary medicinal product in accordance with an exemption specified in paragraphs 1, 5 and 9 of Schedule 4 to the Veterinary Medicines Regulations 2013(**6**).

(**6**) S.I. 2013/2033, to which there is an amendment not relevant to these Regulations.

Prohibition of administration of Table 2 substances

7. It is an offence to contravene Article 14(6) of Regulation 470/2009 (prohibition on administration of substances to food-producing animals in certain circumstances).

Prohibition of possession or slaughter of animals and of processing

8.—(1) No person may 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 substance listed in Annex II or Annex III to Council Directive 96/22.

(2) No person may process the meat of an animal intended for human consumption where—

(a) that animal contains, or

(b) the presence in has been established of, or

(c) to which there has been administered,

any substance listed in Annex II or Annex III to Council Directive 96/22.

(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 is presumed, until the contrary is proven, to have been slaughtered or possessed for such use and an animal commonly used for human consumption from which meat is processed is presumed, until the contrary is proven, to be an animal for such use.

Prohibition on the sale of animals

9.—(1) Subject to paragraph (2), no person may sell or supply, for slaughter for human consumption, any animal—

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

(b) to which there has been administered a substance in contravention of regulation 5;

(c) that is an aquaculture animal to which a substance listed in Annex II or III of Council Directive 96/22 has been administered;

(d) to which a list A substance or a substance listed in Annex III of Council Directive 96/22 has been administered;

(e) which contains a Table 1 substance at a concentration exceeding the maximum residue limit; or

(f) to which a medicinal product has been administered if the withdrawal period for that product has not expired.

(2) Nothing in paragraph (1)(f) prohibits the sale before the end of the withdrawal period of any high-value horse to which has been administered allyl trenbolone or a beta-agonist in accordance with regulation 5, provided that the type and date of treatment was entered on the horse's passport by the veterinary surgeon directly responsible for the treatment.

Prohibition of the sale of animal products

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

(2) No person may 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 further to a notice referred to in regulation 22(3), no person may dispose of the carcase or offal of that animal or of any animal of that batch of animals, or any part of such carcase or offal, for human or animal consumption.

Exception to prohibition on slaughter

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

(2) Notice of the proposed date and place of slaughter must 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), must 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 must be retained in such place and manner as an authorised officer may specify, while it is subjected to such examination as an authorised officer may reasonably consider necessary.

(5) Where the examination (the result of which is to be given by an authorised officer to 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 must be disposed of for a purpose other than human consumption.

PART 3

Sampling and Analysis

Procurement of samples

13. An authorised officer may—

(a) take a sample of any article or substance which is found by that officer on or in any premises which the officer is authorised to enter and which the officer 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 that officer on or in any such premises.

Primary analysis of official samples

14.—(1) An official sample is to 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 is to be subjected to a primary analysis and the remainder is to be retained for any reference analysis.

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

Results of primary analysis

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

(a) an unauthorised substance;

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

(c) in the case of a sample taken from an animal or batch of animals, its excrement or body fluids or from its tissues, an authorised substance at a concentration which is notified to the analyst by an authorised officer as one which causes the officer 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 is to record that information in a primary analysis certificate and provide a copy of that certificate to an authorised officer who is to then give that copy to 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 is to notify an authorised officer of that fact and the authorised officer is to then notify the relevant person.

(3) For the purposes of this regulation and regulations 16 and 17, "relevant person" means the owner of the premises where the sample was taken or, where another person is the owner of the animal, animal product or other article or substance from which the sample was taken, whichever one of them the authorised officer considers appropriate.

Reference analysis

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

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

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

(2) The analyst is to record the results of the reference analysis in a reference analysis certificate and provide a copy of that certificate to an authorised officer who is to then give a copy to the relevant person.

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

(4) Where, in accordance with paragraph (3), the relevant person challenges the finding specified in a primary analysis certificate that person is 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 is to 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 is to 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 must be carried out in accordance with methods authorised by Commission Decision 2002/657/EC implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results(**7**).

Certificates of analysis

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

(a) must be signed by the analyst; and

(b) must specify the name of the authorised officer who submitted the sample for analysis and—

(i) if that officer is an officer of an enforcement authority, the name and address of the enforcement authority of which that person is an officer, or

(ii) if that officer is not the officer of an enforcement authority, the name and address of the organisation for which that officer works.

(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 that party by the other party as being a copy of such a certificate,

is 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.

Animal inspections

20.—(1) An authorised officer may, by giving written notice, require—

(a) the detention of an animal or a batch of animals in the place where the animal or the batch is located; or

(b) the removal to, and the detention at, another place of an animal or batch of animals,

in order to carry out an inspection.

(2) An inspection under paragraph (1) is to be undertaken to ascertain whether—

(a) any animal contains any unauthorised substance or a residue of any other substance which the authorised officer reasonably suspects may result in any animal product derived from the animal containing an unauthorised substance or a Table 1 substance at a concentration exceeding the maximum residue limit; or

(b) any withdrawal period has expired.

(3) Where detention alone is required, the notice is to be served on the owner of the premises where the animal or batch of animals is located.

(4) Where removal and detention elsewhere is required the notice is to be served on the owner of the premises where the animal or batch of animals is located unless another person is the owner of the animal or batch of animals, in which case the authorised officer is to serve the notice on whichever one of them the officer considers appropriate.

(**7**) OJ No. L221, 17.8.2002, p.8, as last amended by Commission Decision 2004/25/EC (OJ No. L6, 10.1.2004, p.38).

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 the officer reasonably suspects may result in any animal product derived from that animal or batch of animals containing an authorised substance at a concentration exceeding the relevant maximum residue limit or that the withdrawal period in relation to any animal has not expired, an authorised officer has the powers specified in paragraph (2) in relation to such an animal or batch of animals.

(2) An authorised officer may—

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

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

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

(iii) no animal, other than as permitted by sub-paragraph (ii), is to 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 is to give notice in writing to the owner of the animal or batch of animals in accordance with the following paragraphs of this regulation.

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

(3) Where the examination shows that an animal or batch of animals contains a prohibited substance, an unlicensed substance or a Table 2 substance the notice is to so declare, is to specify the result of the examination and is to 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 is to so declare, is to specify the result of the examination and, subject to regulation 12, is to prohibit the slaughter of that animal or batch of animals for human consumption.

(5) A notice given 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 given by an authorised officer to the owner of the animal or batch of animals; and a notice given in accordance with paragraph (4) is to 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 enforcement authority may make a charge of an amount equal to the amount of expenses reasonably incurred by the authorised officer in the exercise of the powers conferred on the officer under—

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

(b) paragraph (6).

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

PART 4

Offences and Penalties

Offences, penalties and enforcement

23.—(1) A person who—

(a) contravenes regulation 3, 4, 5, 6, 8, 9, 10, 11, 31(1), (2), (3) or (4) or any provision of a notice given to that person under these Regulations; or

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

is guilty of an offence.

(2) A person guilty of an offence under paragraph (1) or regulation 7 is liable—

(a) in England, on summary conviction or on conviction on indictment to a fine; and

(b) in Scotland, on summary conviction to a fine not exceeding the statutory maximum or on conviction on indictment to a fine.

(3) Each enforcement authority is to enforce these Regulations and is to 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) In England, the Secretary of State may delegate to the Director of Public Prosecutions functions in relation to the prosecution of an offence under these Regulations.

(5) Where an offence under these Regulations which has been committed by a Scottish partnership is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner, that partner as well as the partnership is guilty of the offence and is liable to be proceeded against and punished accordingly.

(6) No prosecution for an offence under paragraph (1) or regulation 7 may 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 regulation 4 it is a defence for the person charged to prove that the veterinary medicinal product to which the allegation relates is intended for purposes other than administration to an animal.

(2) In any proceedings for an offence alleging a contravention of regulation 8 it is a defence for the person charged to prove that the substance listed in Annex II or Annex III of Council Directive 96/22 contained or present in the animal or which has been administered to the animal was administered in accordance with regulation 5.

Compliant products

25.—(1) A product which is, or which contains, a substance listed in Annex II or Annex III to Council Directive 96/22 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.

Exception to prohibition on administration for testosterone and progesterone

26.—(1) Subject to paragraph (2), administration of any product which is, or which contains, testosterone or progesterone is in accordance with this regulation if it is carried out by a veterinary surgeon for a therapeutic purpose on a farm animal by injection.

(2) Paragraph (1) does not apply to the treatment of ovarian dysfunction, in which case administration is accordance with this regulation if it is carried out by a veterinary surgeon using a product in the form of vaginal spirals.

Exception to prohibition on administration for allyl trenbolone and beta-agonists

27.—(1) Subject to paragraphs (2) and (3), administration of any product which is, or which contains, allyl trenbolene or beta-agonists is in accordance with this paragraph if it is carried out for a therapeutic purpose and it is carried out by a veterinary surgeon or under the direct responsibility of that surgeon.

(2) Paragraph (1) only applies to a veterinary medicinal product which is, or which contains, allyl trenbolone if it is authorised for oral administration, it is administered in accordance with the manufacturer's instructions and it is administered to an animal which is not a production animal.

(3) Paragraph (1) only applies to a veterinary medicinal product which is, or which contains, a beta-agonist if it is administered to—

(a) a member of the *equidae* Family; or

(b) a calving cow, by injection by a veterinary surgeon, to induce tocolysis during labour.

Exception to prohibition on administration for products having oestrogenic, androgenic or gestagenic action

28.—(1) Administration is in accordance with this regulation if, in the case of farm animals other than production animals—

(a) the administration is carried out for the purpose of zootechnical treatment;

(b) the administration is carried out—

(i) 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

(ii) in any other case, by a veterinary surgeon; and

(c) the veterinary surgeon responsible for the treatment issues a prescription for the products to be administered, whether the surgeon supplies them or not.

(2) Administration is in accordance with this regulation if, in the case of fish aged three months or less, the administration is of products with an androgenic action for sex inversion purposes.

PART 5

Miscellaneous

Responsibilities of processors

29. The owner of an establishment of initial processing of animal products must, 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.

Unavailability of defence

30. It is hereby declared that a person is not entitled to rely on the defence provided by section 21(1), (5) and (6) of the Act, as applied by regulation 32, in any proceedings alleging a contravention of regulation 8 or 10 if that person has contravened regulation 29.

Keeping and retention of records

31.—(1) The owner of an establishment of initial processing of animal products must 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.

(2) Persons holding a manufacturing or wholesale dealer's authorisation granted under the Veterinary Medicines Regulations 2013, for purposes relating to a marketing authorisation for a product to which regulation 4 applies, must, 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.

(3) Any person required to keep a record by paragraph (1) or (2) must keep that record in a permanent and legible form and must 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 must be retained for a period of five years from the date of the commencement of the withdrawal period to which it relates.

(4) Subject to paragraph (5) if an authorised officer directs a person to produce for inspection a record which paragraph (1) or (2) requires that person to keep, the person must comply with the direction.

(5) No direction may be given under paragraph (4) after the end of the period mentioned in paragraph (3).

(6) The requirement in paragraph (3) to keep records in a legible form is not to be taken to prevent their being kept by means of computer.

(7) Where a record is so kept, the duty under paragraph (4) to produce it for inspection, is a duty to produce it in a form in which it can be taken away.

Application and modification of provisions of the Food Safety Act 1990

32.—(1) The following provisions of the Act apply for the purposes of these Regulations and, unless the context otherwise requires, any reference in them to that Act is 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) applies, subject to paragraph (3), 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 applies with the following modifications—

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

(b) the reference in sub-section (5)(a) to section 7 of the Act is construed as a reference to these Regulations.

(4) Section 29 of the Act (procurement of samples) applies subject to the modification that for the words "section 32 below" in sub-section (b)(ii) there is substituted the words "section 32 of the Act as applied by this regulation".

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

(6) Section 32 of the Act (powers of entry) applies with the omission of the word "food" in sub-section (5) and the references to "regulations" in sub-section (1) are, for the purposes of these Regulations, construed as including a reference to Articles 14(6) and 16 of Regulation 470/2009.

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

Revocations

33. The instruments specified in the first column of the Schedule are revoked to the extent specified in the third column of the Schedule.

Review

34.—(1) This regulation does not apply in respect of the application of these Regulations in Scotland.

(2) The Secretary of State must from time to time—

(a) carry out a review of these Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(3) In carrying out the review the Secretary of State must, so far as is reasonable, have regards to how Council Directive 96/22 and Council Directive 96/23 (which are implemented by these Regulations) are implemented in other member States.

(4) The report must in particular—

(a) set out the objectives intended to be achieved by these Regulations;

(b) assess the extent to which the objectives have been achieved;

(c) assess whether the objectives remain appropriate and, if so, the extent to which they could be achieved in a less burdensome way.

(5) The first report under this regulation must be published before the end of the period of five years beginning with 6th May 2013.

(6) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

George Eustice
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

18th March 2015