WELSH STATUTORY INSTRUMENTS

2019 No. 569 (W. 125)

FOOD, WALES

The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Wales) Regulations 2019

Made - - - -	*13th March 2019*
Laid before the National Assembly for Wales - -	*14th March 2019*
Coming into force - -	*28th March 2019*

The Welsh Ministers have been 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 Welsh Ministers make the following Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A of Schedule 2(**4**) 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(**5**).

The Welsh Ministers have 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(**6**).

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Welsh Ministers that it is expedient for any reference in these Regulations to provisions of EU instruments to be construed as a reference to those provisions as amended from time to time.

(**1**) 1972 c. 68.
(**2**) S.I. 2008/1792.
(**3**) S.I. 2010/2690.
(**4**) Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c. 51).
(**5**) 1990 c. 16. Section 16(1) was amended by paragraph 8 of Schedule 5 to the Food Standards Act 1999 (c. 28) ("the 1999 Act"). Section 17(1) and (2) was amended by paragraphs 8 and 12(a) of Schedule 5 to the 1999 Act and S.I. 2011/1043. Section 48(1) was amended by paragraph 8 of Schedule 5 to the 1999 Act. Functions formerly exercisable by "the Ministers" so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act, and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32).
(**6**) OJ No L 31, 1.2.2002, p. 1, as last amended by Commission Regulation (EU) 2017/228 (OJ No L 35, 10.2.2017, p. 10).

PART 1

Introductory

Title, application and commencement

1.—(1) The title of these Regulations is the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Wales) Regulations 2019.

(2) These Regulations apply in relation to Wales.

(3) These Regulations come into force on 28 March 2019.

Interpretation

2.—(1) In these Regulations—

"the Act" ("*y Ddeddf*") means the Food Safety Act 1990;

"analysis" ("*dadansoddi*") includes any technique for establishing the composition of an official sample;

"analyst" ("*dadansoddydd*") means the person having the management or control of an approved laboratory;

"animal" ("*anifail*") includes aquaculture animals;

"animal product" ("*cynnyrch anifeiliaid*") includes meat, meat products, processed products derived from animals, milk, honey and eggs;

"approved laboratory" ("*labordy a gymeradwywyd*") means—

(a) a laboratory approved by the Secretary of State 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(**7**) of the Act;

"authorised officer" ("*swyddog awdurdodedig*") 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" ("*carcas*") 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" ("*gweithrediad masnachol*"), in relation to an animal or batch of animals, means any of the following—

(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;

(**7**) Section 27 has been amended by the Food Standards Act 1999 (c. 28), section 40(1), Schedule 5, paragraphs 7 and 8, 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.

"Council Directive 96/22" ("*Cyfarwyddeb y Cyngor 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/EEC(**8**);

"Council Directive 96/23" ("*Cyfarwyddeb y Cyngor 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(**9**);

"enforcement authority" ("*awdurdod gorfodi*") means the Welsh Ministers and—

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

(b) where enforcement is other than in relation to food or food sources, a local authority within its area;

"examination" ("*archwiliad*", "*archwilio*") 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" ("*fferm wreiddiol*"), 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" ("*sylwedd hormonaidd*") means any substance within either of the following categories—

(a) stilbenes and thyrostatic substances;

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

"list A substance" ("*sylwedd rhestr A*") means a substance named in List A of Annex II to Council Directive 96/22;

"list B substance" ("*sylwedd rhestr B*") means a substance named in List B of Annex II to Council Directive 96/22;

"local authority" ("*awdurdod lleol*") means in relation to an area the county council or county borough council for that area;

"marketing authorisation" ("*awdurdodiad marchnata*") 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(**10**);

"maximum residue limit" ("*terfyn gweddillion uchaf*") means the maximum concentration of residue, or residues, resulting from the use of a veterinary medicinal product (expressed in µg/kg or µg/L on a fresh weight basis) that the Secretary of State has established in relation to a substance classified under Article 14 of Regulation 470/2009 as being necessary or appropriate for the protection of human health;

"offal" ("*offal*") means meat other than that of the carcase whether or not naturally connected to the carcase;

"official sample" ("*sampl swyddogol*") means a sample taken by an authorised officer for analysis for the purposes of these Regulations which bears a reference to the type, the amount

(**8**) OJ No L125, 23.5.1996, p. 3, as last amended by Directive 2008/97/EC (OJ No L318, 28.11.2008, p. 9).
(**9**) OJ No L125, 23.5.1996, p. 10, as last amended by Directive 2013/20/EU (OJ No. L158, 10.6.2013, p. 234).
(**10**) OJ No L311, 28.11.2011, p. 1. Article 5 was replaced by Directive 2004/28/EC (OJ No. L136, 30.4.2004, p. 58).

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" ("*perchennog*") 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" ("*meddu*") in relation to any farm animal or aquaculture animal does not include possession under official control;

"primary analysis" ("*dadansoddiad sylfaenol*") means an analysis of an official sample carried out by an approved laboratory;

"primary analysis certificate" ("*tystysgrif dadansoddiad sylfaenol*") means an analyst's certificate specifying the finding of a primary analysis;

"prohibited substance" ("*sylwedd gwaharddedig*") means any beta-agonist or hormonal substance administered to an animal contrary to the prohibition in regulation 5;

"reference analysis" ("*dadansoddiad cyfeirio*") means an analysis carried out by an approved laboratory to check the finding of a primary analysis;

"reference analysis certificate" ("*tystysgrif dadansoddiad cyfeirio*") means an analyst's certificate specifying the finding of a reference analysis;

"Regulation 470/2009" ("*Rheoliad 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(**11**);

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

"Table 1 substance" ("*sylwedd Tabl 1*") means a substance classified under Article 14(2)(a), (b) or (c) of Regulation 470/2009;

"Table 2 substance" ("*sylwedd Tabl 2*") means a substance classified under Article 14(2)(d) of Regulation 470/2009;

"unauthorised substance" ("*sylwedd diawdurdod*") 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" ("*sylwedd didrwydded*") means a substance—

(a) for which a maximum residue limit has been established under Regulation 470/2009, and

(b) which has been—

(i) administered (or is intended for administration) in the United Kingdom to an animal or a batch of animals, or

(ii) administered to an animal outside the United Kingdom,

where at the time of administration neither that substance, nor any product containing it, was authorised for use in that animal in that country of administration;

"veterinary surgeon" ("*milfeddyg*") means a person registered in the register of veterinary surgeons or in the supplementary veterinary register;

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

"withdrawal period" ("*cyfnod cadw'n ôl*"), 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 established for a pharmacologically active substance has been exceeded for the purposes of these Regulations—

(a) the presence of the drug or drug metabolite (or combination thereof) as specified in the marker residue for that pharmacologically active substance 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, as specified in the target tissues for that substance;

(b) the maximum residue limit (if any) 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 or Council Directive 96/23 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 26 and which is for administration in accordance with regulation 28.

(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 27;

(b) containing allyl trenbolone or a beta-agonist, if the administration is in accordance with regulation 28; or

(c) having oestrogenic action (but not containing oestradiol 17b or its ester-like derivatives), adrogenic action or gestagenic action, if the administration is in accordance with regulation 29.

(3) In paragraph (2), "compliant veterinary medicinal product" means a veterinary medicinal product which complies with the requirements of regulation 26.

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(**12**).

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.

(**12**) S.I. 2013/2033.

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 to Council Directive 96/22 has been administered;

(d) to which a list A substance or a substance listed in Annex III to 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 veterinary 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 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 a 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 then to 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(**13**).

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.

(**13**) 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).

(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 of animals 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.

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 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.

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, 32(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 on summary conviction 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.

Corporate offences

24.—(1) If an offence under these Regulations committed by a body corporate is shown—

(a) to have been committed with the consent or connivance of an officer; or

(b) to be attributable to any neglect on their part,

the officer as well as the body corporate is liable to prosecution.

(2) If the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and defaults of a member in connection with their functions of management as if they were a director of the body.

(3) If an offence under these Regulations committed by a partnership is shown—

(a) to have been committed with the consent or connivance of a partner; or

(b) to be attributable to any neglect on their part,

the partner as well as the partnership is liable to prosecution.

(4) If any offence under these Regulations committed by an unincorporated association, other than a partnership, is shown—

(a) to have been committed with the consent or connivance of an officer of the association or a member of its governing body; or

(b) to be attributable to any neglect on the part of such an officer or member,

that officer or member as well as the association is liable to prosecution.

(5) In this regulation—

"officer" ("*swyddog*"), in relation to a body corporate or unincorporated association, means a director, member of the committee of management, chief executive, manager, secretary or other similar officer of the body, or a person purporting to act in any such capacity; and

"partner" ("*partner*") includes a person purporting to act as a partner.

Defences and exceptions

25.—(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 to 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

26.—(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 1 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

27.—(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 in 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

28.—(1) Subject to paragraphs (2) and (3), administration of any product which is, or which contains, allyl trenbolone 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

29.—(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

30. 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

31. 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 33, in any proceedings alleging a contravention of regulation 8 or 10 if that person has contravened regulation 30.

Keeping and retention of records

32.—(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

33.—(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); and

(g) section 35(1) to (3) (punishment of offences) in so far as it relates to offences under section 33(1) and (2).

(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 was 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 is substituted the words "enforcement authority"; and

(b) the reference in subsection (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 paragraph (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 subsection (5) and the references to "regulations" in subsection (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

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

Lesley Griffiths
Minister for Environment, Energy and Rural Affairs, one of the Welsh Ministers

13 March 2019

SCHEDULE

Regulation 34

Revocations

(1)	*(2)*	*(3)*
Title	*Reference*	*Extent of revocation*
The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997	S.I. 1997/1729	The whole of the instrument
The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2001	S.I. 2001/3590	The whole of the instrument
The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2004	S.I. 2004/147	The whole of the instrument
The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2006	S.I. 2006/755	The whole of the instrument
The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2009	S.I. 2009/1925	The whole of the instrument
The Agriculture, Animals, Environment and Food etc. (Miscellaneous Amendments) Order 2012	S.I. 2012/2897	Article 2
The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2013	S.I. 2013/804	The whole of the instrument

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke the statutory instruments listed in the Schedule, consolidating their provisions. The Regulations implement 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 Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products, and provide for the execution and enforcement of 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.

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 or slaughter of, or the processing of the meat of, animals intended for human consumption to which there has been administered, which contains, or in which the presence has been established of, specified unauthorised substances (regulation 8);

(c) prohibit the sale or supply, for slaughter for human consumption, of animals to which substances have been administered in certain circumstances including, subject to an exception, where the withdrawal period for the product administered has not expired (regulation 9);

(d) prohibit the sale for human consumption of any animal product derived from an animal the sale or supply for slaughter of which is prohibited under regulation 9 or any animal product which contains an unauthorised substance or an excess of an authorised substance (regulation 10);

(e) prohibit, subject to an exception, the disposal for human or animal consumption of the carcase or offal of an animal or an animal from a batch of animals where that animal or an animal of that batch has been slaughtered further to a notice referred to in regulation 22(3) (examination shows specified unauthorised substance) (regulations 11 and 12);

(f) give authorised officers the power to take samples and provide for the analysis of official samples (regulations 13, 14, 15, 16, 17, 18 and 19);

(g) give authorised officers the power to inspect and examine animals and provide for the subsequent service of notices (regulations 20, 21 and 22);

(h) provide for offences, penalties and enforcement (regulations 23 and 24);

(i) provide specific defences and exceptions (regulations 25, 26, 27, 28 and 29);

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

(k) specify requirements relating to the keeping of records (regulation 32);

(l) apply, with some modifications, provisions of the Food Safety Act 1990, including the defence of due diligence (regulation 33); and

(m) revoke the instruments specified in the Schedule (regulation 34).

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.