WELSH STATUTORY INSTRUMENTS

2019 No. 569

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

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(**1**) 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

(**1**) 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.

(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;

"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(**2**);

"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(**3**);

"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;

(**2**) OJ No L125, 23.5.1996, p. 3, as last amended by Directive 2008/97/EC (OJ No L318, 28.11.2008, p. 9).
(**3**) OJ No L125, 23.5.1996, p. 10, as last amended by Directive 2013/20/EU (OJ No. L158, 10.6.2013, p. 234).

"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(**4**);

"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 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(**5**);

"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;

(**4**) 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).
(**5**) OJ No. L152, 16.6.2009, p. 11.

"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;

"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.