Draft Regulations laid before Senedd Cymru under paragraph 1(8) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of Senedd Cymru.

DRAFT WELSH STATUTORY INSTRUMENTS

2022 No. (W.)

EXITING THE EUROPEAN UNION, WALES

AGRICULTURE, WALES

FOOD, WALES

The Food and Feed (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2022

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are principally made in exercise of the powers conferred by paragraph 1(1) of Schedule 2, and paragraph 21(b) of Schedule 7, to the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

Regulations 4(2)(a)(ii) and 5(2)(a) are made in exercise of the powers conferred by sections 66(1), 74A(1) and 84 of the Agriculture Act 1970, in order to correct existing errors.

These Regulations, make amendments to various Welsh statutory instruments relating to food and feed. In particular, the amendments remove cross-references to EU Directives and transpose certain Annexes to those Directives, as they had effect immediately before implementation period completion day (11pm, 31 December 2020), as new Schedules to the instruments concerned.

Regulation 2 (and Schedule 1) amends the Materials and Articles in Contact with Food (Wales) Regulations

2012 (S.I. 2012/2705 (W. 291)). In particular, Annex 2 to Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (OJ No L 172, 30.6.2007, p. 71–82) is transposed into the Regulations as a new Schedule 6.

Regulation 3 (and Schedule 2) amends to the Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013 (S.I. 2013/2591 (W. 255)). In particular, Annex 1 to Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ No L 141, 6.6.2009, p. 3–11) is transposed into the Regulations as a new Schedule 4A.

Regulation 4 (and Schedule 3) amends the Animal Feed (Composition, Marketing and Use) (Wales) Regulations 2016 (S.I. 2016/386 (W. 120)). In particular—

- the Annex to Commission Directive 82/475/EEC laying down the categories of feed materials which may be used for the purposes of labelling compound feedingstuffs for pet animals (OJ No L 213, 21.7.1982, p. 27–28) is transposed into the Regulations as a new Schedule 1A;
- Annexes 1 and 2 to Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed (OJ No L 140, 30.5.2002, p. 10–22) are transposed into the Regulations as new Schedules 1B and 1C;
- the tertiary legislation-making powers of the EU Commission in Articles 7 and 8 of Directive 2002/32/EC to amend the lists of undesirable substances in Annexes 1 and 2 that Directive, and to define acceptability criteria for detoxification processes, are retained. Regulation 4(8) inserts a new Regulation 15A into the Regulations, conferring corresponding regulation-making powers on the Welsh Ministers, exercisable in relation to Wales.

Regulation 5 makes minor amendments to the Animal Feed (Hygiene, Sampling etc. and Enforcement) (Wales) Regulations 2016 (S.I. 2016/387 (W. 121)).

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.

Draft Regulations laid before Senedd Cymru under paragraph 1(8) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of Senedd Cymru.

D R A F T W E L S H S T A T U T O R Y I N S T R U M E N T S

2022 No. (W.)

EXITING THE EUROPEAN UNION, WALES

AGRICULTURE, WALES

FOOD, WALES

The Food and Feed (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2022

Made	***
Coming into force	*31 December 2022*

The Welsh Ministers make these Regulations in exercise of the powers conferred by—

- paragraph 1(1) of Schedule 2 and paragraph 21(b) of Schedule 7 to the European Union (Withdrawal) Act 2018(**1**), and
- sections 66(1), 74A(1) and 84 of the Agriculture Act 1970(**2**).

(**1**) 2018 c. 16. See section 20(1) for the meaning of "devolved authority". Paragraph 21 of Schedule 7 was amended by section 41(4) of, and paragraphs 38 and 53(2) of Schedule 5 to, the European Union (Withdrawal Agreement) Act 2020 (c. 1).

(**2**) 1970 c. 40. See section 66(1) for the meaning of "the Ministers", "prescribed" and "regulations". 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, and subsequently transferred to the Welsh Ministers by section 162 of, and paragraph 30 of Schedule 11 to, the Government of Wales Act 2006 (c. 32). Section 74A was inserted by paragraph 6 of Schedule 4 to the European Communities Act 1972 (c. 68). Section 84 was amended by S.I. 2004/3254.

A draft of this instrument has been laid before, and approved by a resolution of, Senedd Cymru in accordance with paragraph 1(8) of Schedule 7 to the European Union (Withdrawal) Act 2020(**1**).

There has been consultation as 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(**2**) or, in the case of provisions relating to feed for non food-producing animals, of section 84(1) of the Agriculture Act 1970.

Title and commencement

1. The title of these Regulations is the Food and Feed (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2022 and they come into force on 31 December 2022.

Amendment to the Materials and Articles in Contact with Food (Wales) Regulations 2012

2.—(1) The Materials and Articles in Contact with Food (Wales) Regulations 2012(**3**) are amended as follows.

(2) In regulation 2—

(a) in paragraph (1), omit the definition of "Directive 2007/42/EC";

(b) in paragraph (3)—

(i) omit "or to an Annex to Directive 2007/42/EC";

(ii) omit "or that Annex".

(3) In regulation 11, omit paragraph (3).

(4) In regulation 12—

(a) in paragraph (1)—

(i) for "Annex II", in both places it occurs, substitute "Schedule 6";

(ii) for "that Annex" substitute "that Schedule";

(**1**) The references in the European Union (Withdrawal) Act 2018 to the National Assembly for Wales now have effect as references to Senedd Cymru by virtue of section 150A(2) of the Government of Wales Act 2006 (c. 32). See paragraph 38 of Schedule 7 to the European Union (Withdrawal) Act 2018 for provision about the procedure that applies to this instrument.

(**2**) EUR 2002/178, to which there are amendments not relevant to these Regulations.

(**3**) S.I. 2012/2705 (W. 291), amended by S.I. 2017/832 (W. 202), 2018/913 (W. 179) and 2019/425 (W. 99); there are other amending instruments but none is relevant.

(b) in paragraph (2), for "the first part of Annex II" substitute "table 1 of Schedule 6".

(5) After Schedule 5, insert the Schedule 6 set out in Schedule 1 to these Regulations.

Amendment to the Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013

3.—(1) The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013(**1**) are amended as follows.

(2) In regulation 2—

(a) in paragraph (1)—

(i) omit the definition of "Directive 2009/32";

(ii) in the definition of "the EU Regulations", before "EU" insert "retained";

(b) in paragraph (2), omit "EU";

(c) in paragraph (3), omit "EU";

(d) in paragraph (4), omit "EU" and "Directive 2009/32,".

(3) Omit regulation 9.

(4) In regulation 10(a), for "Annex I" substitute "Schedule 4A".

(5) In regulation 11(a)—

(a) in sub-paragraph (i), for "Annex I" substitute "Schedule 4A";

(b) in sub-paragraph (ii), for "that Annex" substitute "Schedule 4A";

(c) after sub-paragraph (iii), insert an "and";

(d) after sub-paragraph (iv), for ", and" substitute "; or";

(e) omit sub-paragraph (v) and the "or" after it.

(6) In regulation 14(1)(a), for "Annex 1" substitute "Schedule 4A".

(7) In regulation 16, before "EU Regulations" insert "retained".

(8) In regulation 19(2), before "EU Regulations" insert "retained".

(9) After Schedule 4, insert the Schedule 4A set out in Schedule 2 to these Regulations.

(**1**) S.I. 2013/2591 (W. 255), amended by S.I. 2020/1581 (W. 331); there are other amending instruments but none is relevant.

Amendment to the Animal Feed (Composition, Marketing and Use) (Wales) Regulations 2016

4.—(1) The Animal Feed (Composition, Marketing and Use) (Wales) Regulations 2016(**1**) are amended as follows.

(2) In regulation 2—

(a) in paragraph (1)—

(i) omit the definitions of "Directive 82/475" and "Directive 2002/32";

(ii) in the definition of "feed authority", for "67(1)" substitute "67(1A)";

(b) in paragraph (2), before "EU" insert "retained";

(c) in paragraph (3), in both places it occurs, omit "EU".

(3) In regulation 12(2), for "the Annex to Directive 82/475" substitute "Schedule 1A".

(4) In regulation 13(2)(b), for "appropriate authority" substitute "Welsh Ministers".

(5) For the heading of Part 6 substitute—

"Undesirable substances in products intended for animal feed"

(6) In regulation 14, omit paragraph (a) and the "and" after it.

(7) In regulation 15—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "Annex I" substitute "a table in Schedule 1B";

(ii) in the words after sub-paragraph (b), for "Annex" substitute "table";

(b) in paragraph (2)—

(i) in sub-paragraph (a), for "Annex I" substitute "a table in Schedule 1B";

(ii) in sub-paragraph (b), for "Annex" substitute "table";

(c) in paragraph (3)—

(i) for "Annex I" substitute "a table in Schedule 1B";

(ii) for "Annex", in the second place it occurs, substitute "table";

(d) in paragraph (5)—

(i) for "Annex I" substitute "a table in Schedule 1B";

(**1**) S.I. 2016/386 (W. 120), amended by S.I. 2018/806 (W. 162), 2019/1046 (W. 185) and 2020/1381 (W. 307); there is another amending instrument not relevant to these Regulations.

(ii) for "Annex", in the second place it occurs, substitute "table";

(e) in paragraph (7)—

(i) after sub-paragraph (c) omit the "and";

(ii) after sub-paragraph (d) insert—

"(e) peat;

(f) leonardite."

(f) after paragraph (8) insert—

"(9) In order to reduce or eliminate sources of undesirable substances in products intended for animal feed, feed authorities must carry out investigations to identify the sources of undesirable substances, in cases where the maximum levels are exceeded and in cases where increased levels of such substances are detected, taking into account background levels.

(10) In cases of increased levels of undesirable substances listed in Schedule 1C, action thresholds to trigger investigations are set out in that Schedule.

(11) Feed authorities must send to the Agency all relevant information and findings of the source and the measures taken to reduce the level of, or eliminate, undesirable substances."

(8) After regulation 15 insert—

"Regulations amending Schedules 1B and 1C

15A.—(1) Where paragraph (2) applies, the Welsh Ministers may, by regulations, make provision to amend, add, or remove an entry in Schedule 1B or 1C.

(2) This paragraph applies where—

(a) the Welsh Ministers consider that the presence in feed of an undesirable substance not listed in Schedule 1B, or at a level permitted in accordance with Schedule 1B, presents, or would present, a danger to animal or human health or to the environment, or

(b) the Welsh Ministers consider it necessary in order to adapt to scientific and technical developments.

(3) The Welsh Ministers may, by regulations, define acceptability criteria for detoxification processes through which an undesirable substance listed in Schedule 1B is on purpose removed from feed.

(4) A power to make regulations under this Regulation—

(a) is exercisable by statutory instrument;

(b) includes the power to make different provision for different purposes;

(c) includes the power to make incidental, supplementary, consequential, transitional, transitory or saving provision (including provision amending, repealing or revoking enactments or retained direct EU legislation).

(5) A statutory instrument that contains regulations under this Regulation is subject to annulment in pursuance of a resolution of Senedd Cymru."

(9) After Schedule 1 insert the Schedules 1A, 1B and 1C set out in Schedule 3 to these Regulations.

Amendment to the Animal Feed (Hygiene, Sampling etc. and Enforcement) (Wales) Regulations 2016

5.—(1) The Animal Feed (Hygiene, Sampling etc. and Enforcement) (Wales) Regulations 2016(**1**) is amended as follows.

(2) In regulation 2—

(a) in paragraph (1), in the definition of "feed authority", for "67(1)" substitute "67(1A)";

(b) in paragraph (5)—

(i) in the English language text, for "an" substitute "a";

(ii) in both places it occurs, omit "EU".

(3) In regulation 4(1)(a), for "20(2), 21(1) and 22(2)(b)" substitute "19(3) and (7) and 21(1)";

(4) In regulation 30(1)(b), for "Article 4.2 of Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed" substitute "regulation 15(9) of the Animal Feed (Composition, Marketing and Use) (Wales) Regulations 2016".

Name
Deputy Minister for Mental Health and Wellbeing, under the authority of the Minister for Health and Social Services, one of the Welsh Minister
Date

(**1**) S.I. 2016/387 (W. 121), amended by S.I. 2018/806 (W. 162), 2020/1381 (W. 307), 2020/1487 (W.317); there are other amending instruments but none is relevant.

SCHEDULE 1 Regulation 2(5)

New Schedule 6 to the Materials and Articles in Contact with Food (Wales) Regulations 2012

"SCHEDULE 6 Regulation 12(1) and (2)

LIST OF SUBSTANCES AUTHORISED IN THE MANUFACTURE OF REGENERATED CELLULOSE FILM

Notes:

- The percentages in this Schedule are expressed in weight/weight (w/w) and are calculated in relation to the quantity of anhydrous uncoated regenerated cellulose film.
- The usual technical denominations are given in square brackets.
- The substances used shall be of good technical quality as regards the purity criteria.

Table 1

Uncoated regenerated cellulose film

Denominations	***Restrictions***
A. Regenerated cellulose	Not less than 72% (w/w)
B. Additives	
1. *Softeners*	Not more than 27% (w/w) in total
— Bis (2-hydroxyethyl) ether [= diethyleneglycol]	Only for films intended to be coated and then used for foods which are not moist, namely which do not contain water which is physically free at the surface. The total amount of bis(2-hydroxyethyl)ether and ethanediol present in foods that have been in contact with film of this type may not exceed 30mg/kg of the foodstuff.
— Ethanediol [= monoethyleneglycol]	
— 1,3-butanediol	
— Glycerol	
— 1,2-propanediol [= 1,2 propyleneglycol]	
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 250 and 1200.
— 1,2-polypropylene oxide [= 1,2 polypropyleneglycol]	Average molecular weight not greater than 400 and free 1.3-propanediol content not greater than 1% (w/w) in substance.
— Sorbitol	
— Tetraethyleneglycol	
— Triethyleneglycol	
— Urea	

2. *Other Additives*	Not more than 1% (w/w) in total.
First class	The quantity of the substance or group of substances in each indent may not exceed 2mg/dm^2 of the uncoated film.
— Acetic acid and its NH_4, Ca, Mg, K and Na salts	
— Ascorbic acid and its NH_4, Ca, Mg, K and Na salts	
— Benzoic acid and sodium benzoate	
— Formic acid and its NH_4, Ca, Mg, K and Na salts	
— Linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also behenic and ricinoleic acids and the NH_4, Ca, Mg, K, Na, Al and Zn salts of these acids	
— Citric, d- and l-lactic, maleic, l-tartaric acids and their Na and K salts	
— Sorbic acid and its NH_4, Ca, Mg, K and Na salts	
— Amides of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also the amides of behenic and ricinoleic acids	
— Natural edible starches and flours	
— Edible starches and flours modified by chemical treatment	
— Amylose	
— Calcium and magnesium carbonates and chlorides	
— Esters of glycerol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and/or with adipic, citric, 12-hydroxystearic (oxystearin), ricinoleic acids	
— Esters of polyoxyethylene (8 to 14 oxyethylene groups) with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
— Esters of sorbitol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
— Mono-and/or di-esters of stearic acid with ethanediol and/or bis (2-hydroxyethyl) ether and/or triethylene glycol	
— Oxides and hydroxides of aluminium, calcium, magnesium and silicon and silicates and hydrated silicates of aluminium, calcium, magnesium and potassium	
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 1200 and 4000.
— Sodium propionate	

Second Class	The total quantity of the substances may not exceed 1mg/dm^2 of the uncoated film and the quantity of the substance or group of substances in each indent may not exceed 0.2mg/dm^2 (or a lower limit where one is specified) of the uncoated film.
— Sodium alkyl (C_8-C_{18}) benzene sulphonate	
— Sodium isopropyl naphthalene sulphonate	
— Sodium alkyl (C_8-C_{18}) sulphate	
— Sodium alkyl (C_8-C_{18}) sulphonate	
— Sodium dioctylsulphosuccinate	
— Distearate of dihydroxyethyl diethylene triamine monoacetate	Not more than 0.05mg/dm^2 of the uncoated film.
— Ammonium, magnesium and potassium lauryl sulphates	
— N,N′-distearoyl diaminoethane, N,N′-dipalmitoyl diaminoethane and N,N′-dioleoyl diaminoethane	
— 2-heptadecyl-4,4-bis(methylene-stearate) oxazoline	
— Polyethylene-aminostearamide ethylsulphate	Not more than 0.1 mg/dm^2 of the uncoated film.
Third class — Anchoring agent	The total quantity of substances may not exceed 1mg/dm^2 of the uncoated film.
— Condensation product of melamine-formaldehyde unmodified, or which may be modified with one or more of the following products: • butanol • diethylenetriamine • ethanol • triethylenetetramine • tetraethylenepentamine • tri-(2-hydroxyethyl) amine • 3,3′-diaminodipropylamine • 4,4′-diaminodibutylamine	Free formaldehyde content not greater than 0.5mg/dm^2 of the uncoated film. Free melamine content not greater than 0.3mg/dm^2 of the uncoated film.
— Condensation product of melamine-urea-formaldehyde modified with tris-(2-hydroxyethyl)amine	Free formaldehyde content not greater than 0.5mg/dm^2 of the uncoated film. Free melamine content not greater than 0.3mg/dm^2 of the uncoated film.

— Cross-linked cationic polyalkyleneamines: • polyamide-epichlorhydrin resin based on diaminopropylmethylamine and epichlorhydrin • polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine • polyamide-epichlorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin, or a mixture of epichlorhydrin and ammonia • polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, dimethyl adipate and diethylenetriamine • polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, adipamide and diaminopropylmethylamine	
— Polyethyleneamines and polyethyleneimines;	Not more than 0.75mg/dm^2 of the uncoated film.
— Condensation product of urea-formaldehyde unmodified, or which may be modified with one or of the following products: • aminomethylsulphonic acid • sulphanilic acid • butanol • diaminobutane • diaminodiethylamine • diaminodipropylamine • diaminopropane • diethylenetriamine • ethanol • guanidine • methanol • tetraethylenepentamine • triethylenetetramine • sodium sulphite	Free formaldehyde content not greater than 0.5mg/dm^2 of the uncoated film.
Fourth class	The total quantity of substances may not exceed 0.01mg/dm^2 of the uncoated film.
— Products resulting from the reaction of the amines of edible oils with polyethylene oxide	
— Monoethanolamine lauryl sulphate	

Table 2

Coated regenerated cellulose film

Denominations	***Restrictions***
A. Regenerated cellulose	See table 1.
B. Additives	See table 1.
C. Coating	
1. *Polymers*	The total quantity of substances may not exceed 50mg/dm^2 of the coating on the side in contact with food.
— Ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	
— Cellulose nitrate	Not more than 20mg/dm^2 of the coating on the side in contact with food; nitrogen content between 10.8% (w/w) and 12.2% (w/w) in the cellulose nitrate.
2. *Resins*	The total quantity of substances may not exceed 12.5mg/dm^2 of the coating on the side in contact with food and solely for the preparation of regenerated cellulose films with cellulose nitrate based coatings.
— Casein	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation and their esters of methyl, ethyl or C_2 to C_6 polyvalent alcohols, or mixtures of these alcohols	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation condensed with acrylic, maleic, citric, fumaric and/or phthalic acids and/or 2,2 bis (4-hydroxyphenyl) propane formaldehyde and esterified with methyl ethyl or C_2 to C_6 polyvalent alcohols or mixtures of these alcohols	
— Esters derived from bis(2-hydroxyethyl) ether with addition products of betapinene, and/or dipentene, and/or diterpene and maleic anhydride	
— Edible gelatine	
— Castor oil and its products of dehydration or hydrogenation and its condensation products with polyglycerol, adipic, citric, maleic, phthalic and sebacic acids	
— Natural gum [= damar]	
— Poly-beta-pinene [= terpenic resins]	
— Urea-formaldehyde resins (see anchoring agents)	
3. *Plasticisers*	The total quantity of substances may not exceed 6mg/dm^2 of the coating on the side in contact with food.
— Acetyl tributyl citrate	
— Acetyl tri(2-ethylhexyl) citrate	

— Di-isobutyl adipate	
— Di-n-butyl adipate	
— Di-n-hexyl azelate	
— Dicyclohexyl phthalate	Not more than 4.0mg/dm^2 of the coating on the side in contact with food.
— 2-ethylhexyl diphenyl phosphate (synonym: phosphoric acid diphenyl 2 ethylhexyl ester)	The amount of 2-ethylhexyl diphenyl phosphate shall not exceed: (a) 2.4mg/kg of the foodstuff in contact with this type of film; or (b) 0.4mg/dm^2 in the coating on the side in contact with food.
— Glycerol monoacetate [= monoacetin]	
— Glycerol diacetate [= diacetin]	
— Glycerol triacetate [= triacetin]	
— Di-butyl sebacate	
— Di-n-butyl tartrate	
— Di-isobutyl tartrate	
4. *Other additives*	The total quantity of substances may not exceed 6mg/dm^2 in the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with food.
4.1 Additives listed in table 1	Same restrictions as in table 1 (however the quantities in mg/dm^2 refer to the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with food).
4.2 Specific coating additives	The quantity of the substance or group of substances in each indent may not exceed 2mg/dm^2 (or a lower limit where one is specified) of the coating on the side in contact with food.
— 1-hexadecanol and 1-octadecanol	
— Esters of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and of ricinoleic acid with ethyl, butyl, amyl and oleyl linear alcohols	
— Montan waxes, comprising purified montanic (C_{26} to C_{32}) acids and/or their esters with ethanediol and/or 1,3 butanediol and/or their calcium and potassium salts	
— Carnauba wax	
— Beeswax	
— Esparto wax	

— Candelilla wax	
— Dimethylpolysiloxane	Not more than 1mg/dm^2 of the coating on the side in contact with food.
— Epoxidised soya-bean oil (oxirane content 6 to 8%)	
— Refined paraffin and microcrystalline waxes	
— Pentaerythritol tetrastearate	
— Mono and bis(octadecyldiethyleneoxide)-phosphates	Not more than 0.2mg/dm^2 of the coating on the side in contact with food.
— Aliphatic acids (C_8 to C_{20}) esterified with mono- or di-(2-hydroxyethyl)amine	
— 2- and 3-tert.butyl-4-hydroxyanisole [= butylated hydroxyanisole — BHA]	Not more than 0.06mg/dm^2 of the coating on the side in contact with food.
— 2,6-di-tert.butyl-4-methylphenol [= butylated hydroxytoluene — BHT]	Not more than 0.06mg/dm^2 of the coating on the side in contact with food.
— Di-n-octyltin-bis(2-ethylhexyl) maleate	Not more than 0.06mg/dm^2 of the coating on the side in contact with food.
5. *Solvents*	The total quantity of substances may not exceed 0.6mg/dm^2 of the coating on the side in contact with food.
— Butyl acetate	
— Ethyl acetate	
— Isobutyl acetate	
— Isopropyl acetate	
— Propyl acetate	
— Acetone	
— 1-butanol	
— Ethanol	
— 2-butanol	
— 2-propanol	
— 1-propanol	
— Cyclohexane	
— Ethyleneglycol monobutyl ether	
— Ethyleneglycol monobutyl ether acetate	
— Methyl ethyl ketone	
— Methyl isobutyl ketone	
— Tetrahydrofuran	
— Toluene	Not more than 0.06mg/dm^2 of the coating on the side in contact with food.”

SCHEDULE 2

Regulation 3(9)

New Schedule 4A to the Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013

"SCHEDULE 4A

Regulations 10, 11 and 14

Extraction solvents which may be used during the processing of raw materials, of food, of food components or of food ingredients

Table 1

Extraction solvents to be used in compliance with good manufacturing practice for all uses[(1)]

Name:
Propane
Butane
Ethyl Acetate
Ethanol
Carbon dioxide
Acetone[(2)]
Nitrous oxide

[(1)] An extraction solvent is considered as being used in compliance with good manufacturing practice if its use results only in the presence of residues or derivatives in technically unavoidable quantities presenting no danger to human health.

[(2)] Acetone is not permitted for use in the refining of olive-pomace oil.

Table 2

Extraction solvents for which conditions of use are specified

Name	***Conditions of use (summary description of extraction)***	***Maximum residue limits in the extracted foodstuff or food ingredient***
Hexane[(1)]	Production or fractionation of fats and oils and production of cocoa butter	1 mg/kg in the fat or oil or cocoa butter
	Preparation of defatted protein products and defatted flours	10 mg/kg in the food containing the defatted protein products and the defatted flours
		30 mg/kg in the defatted soya products as sold to the final consumer
	Preparation of defatted cereal germs	5 mg/kg in the defatted cereal germs
Methyl acetate	Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in the coffee or tea

	Production of sugar from molasses	1 mg/kg in the sugar
Ethylmethylketone[2]	Fractionation of fats and oils	5 mg/kg in the fat or oil
	Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in the coffee or tea
Dichloromethane	Decaffeination of, or removal of irritants and bitterings from coffee and tea	2 mg/kg in the roasted coffee and 5 mg/kg in the tea
Methanol	For all uses	10 mg/kg
Propan-2-ol	For all uses	10 mg/kg
Dimethyl ether	Preparation of defatted animal protein products including gelatine[3]	0.009 mg/kg in the defatted animal protein products including gelatine
	Preparation of collagen[4] and collagen derivatives, except gelatine	3 mg/kg in the collagen and collagen derivatives, except gelatine

[1] Hexane means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. Combined use of Hexane and Ethymethylketone is not permitted.

[2] The level of n-Hexane in this solvent should not exceed 50 mg/kg. Combined use of Hexane and Ethymethylketone is not permitted.

[3] 'Gelatine' means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals, in accordance with the relevant requirements of Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin.

[4] 'Collagen' means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of Regulation (EC) No 853/2004.

Table 3

Extraction solvents for which conditions of use are specified

Name	***Maximum residue limits in the foodstuff due to the use of extraction solvents in the preparation of flavourings from natural flavouring materials***
Diethyl ether	2 mg/kg
Hexane[1]	1 mg/kg
Cyclohexane	1 mg/kg
Methyl acetate	1 mg/kg
Butan-1-ol	1 mg/kg
Butan-2-ol	1 mg/kg
Ethylmethylketone[1]	1 mg/kg
Dichloromethane	0.02 mg/kg
Propan-1-ol	1 mg/kg
1,1,1,2-tetrafluoroethane	0.02 mg/kg
Methanol	1.5 mg/kg
Propan-2-ol	1 mg/kg

[1] Combined use of Hexane and Ethymethylketone is not permitted."

SCHEDULE 3 Regulation 4(9)

New Schedules 1A, 1B and 1C to the Animal Feed (Composition, Marketing and Use) (Wales) Regulations 2016

"SCHEDULE 1A Regulation 12(2)

Categories of feed materials which may be indicated in place of individual feed materials

Description of the category	***Definition***
1. Meat and animal derivatives	— All the fleshy parts of slaughtered warm-blooded land animals, fresh or preserved by appropriate treatment, and —All products and derivatives of the processing of the carcase or parts of the carcase of warm-blooded land animals.
2. Milk and milk derivatives	All milk products, fresh or preserved by appropriate treatment, and derivatives from the processing of those products.
3. Eggs and egg derivatives	All egg products fresh or preserved by appropriate treatment and derivatives from the processing of those products.
4. Oils and fats	All animal and vegetable oils and fats.
5. Yeasts	All yeasts, the cells of which have been killed and dried.
6. Fish and fish derivatives	Fish or parts of fish, fresh or preserved by appropriate treatment, and derivatives from the processing of those products.
7. Cereals	All types of cereal, regardless of their presentation, or products made from the starchy endosperm.
8. Vegetables	All types of vegetables and legumes, fresh or preserved by appropriate treatment.
9. Derivatives of vegetable origin	Derivatives resulting from the treatment of vegetable products, in particular cereals, vegetables, legumes and oil seeds.
10. Vegetable protein extracts	All products of vegetable origin in which the proteins have been concentrated by an adequate process to contain at least 50% crude protein, as related to the dry matter, and which may be restructured (textured).
11. Minerals	All inorganic substances suitable for animal feed.
12. Various sugars	All types of sugar.
13. Fruit	All types of fruit, fresh or preserved by appropriate treatment.
14. Nuts	All kernels from shells.
15. Seeds	All types of seeds as such or roughly crushed.
16. Algae	Algae, fresh or preserved by appropriate treatment.

17. Molluscs and crustaceans	All types of molluscs, crustaceans, shellfish, fresh or preserved by appropriate treatment, and their processing derivatives.
18. Insects	All types of insects and their stages of development.
19. Bakery products	All bread, cakes, biscuits and pasta products.

SCHEDULE 1B

Regulations 15 and 15A

Maximum levels of undesirable substances

Table 1

Inorganic contaminants and nitrogenous compounds

Undesirable substance	***Products intended for animal feed***	***Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%***
1. Arsenic(1)	**Feed materials**	2
	with the exception of:	
	— meal made from grass, from dried lucerne and from dried clover, and dried sugar beet pulp and dried molasses sugar beet pulp;	4
	— palm kernel expeller;	4
	— peat, leonardite;	5
	— phosphates, calcareous marine algae;	10
	— calcium carbonate; calcium and magnesium carbonate(2), calcareous marine shells;	15
	— magnesium oxide, magnesium carbonate;	20
	— fish, other aquatic animals and products derived from them;	25
	— seaweed meal and feed materials derived from seaweed.	40
	Iron particles used as tracer	50
	Feed additives belonging to the functional group of compounds of trace elements	30
	with the exception of:	
	— cupric sulphate pentahydrate, cupric carbonate, dicopper chloride trihydroxide, ferrous carbonate, dimanganese chloride trihydroxide;	50
	— zinc oxide, manganous oxide, cupric oxide.	100
	Complementary feed	4
	with the exception of:	
	— mineral feed;	12

	— complementary feed for pet animals containing fish, other aquatic animals and products derived from them and/or seaweed meal and feed materials derived from seaweed; — long-term supply formulations of feed for particular nutritional purposes with a concentration of trace elements higher than 100 times the established maximum content in complete feed.	10 30
	Complete feed with the exception of: — complete feed for fish and fur animals; — complete feed for pet animals containing fish, other aquatic animals and products derived from them and/or seaweed meal and feed materials derived from seaweed.	2 10 10
2. Cadmium	**Feed materials of vegetable origin**	1
	Feed materials of animal origin	2
	Feed materials of mineral origin with the exception of: — phosphates.	2 10
	Feed additives belonging to the functional group of compounds of trace elements with the exception of:	10
	— cupric oxide, manganous oxide, zinc oxide and manganous sulphate monohydrate.	30
	Feed additives belonging to the functional groups of binders and anti-caking agents	2
	Premixtures(3)	15
	Complementary feed with the exception of: — mineral feed; – containing < 7% phosphorus(4); – containing ≥ 7% phosphorus(4); — complementary feed for pet animals; — long-term supply formulations of feed for particular nutritional purposes with a concentration of trace elements higher than 100 times the established maximum content in complete feed.	0.5 5 0.75 per 1% phosphorus(4) with a maximum of 7.5 2 15
	Complete feed with the exception of: — complete feed for cattle (except calves), sheep (except lambs), goats (except kids) and fish; — complete feed for pet animals.	0.5 1 2

3. Fluorine[5]	**Feed materials**	150
	with the exception of:	
	— feed materials of animal origin except marine crustaceans such as marine krill; calcareous marine shells;	500
	— marine crustaceans such as marine krill;	3,000
	— phosphates;	2,000
	— calcium carbonate, calcium and magnesium carbonate[2];	350
	— magnesium oxide;	600
	— calcareous marine algae.	1,250
	Vermiculite (E 561)	3,000
	Complementary feed	
	— containing ≤ 4% phosphorus[4];	500
	— containing > 4% phosphorus[4].	125 per 1% phosphorus[4]
	Complete feed	150
	with the exception of:	
	— complete feed for pigs;	100
	— complete feed for poultry (except chicks) and fish;	350
	— complete feed for chicks;	250
	— complete feed for cattle, sheep and goats	
	– in lactation;	30
	– otherwise.	50
4. Lead[6]	**Feed materials**	10
	with the exception of:	
	— forage[7]	30
	— phosphates, calcareous marine algae and calcareous marine shells;	15
	— calcium carbonate, calcium and magnesium carbonate[2];	20
	— yeasts.	5
	Feed additives belonging to the functional group of compounds of trace elements	100
	with the exception of:	
	— zinc oxide;	400
	— manganous oxide, ferrous carbonate, cupric carbonate, copper (I) oxide.	200
	Feed additives belonging to the functional groups of binders and anti-caking agents	30
	with the exception of:	
	— clinoptilolite of volcanic origin, natrolite-phonolite.	60
	Premixtures[3]	200

	Complementary feed with the exception of: — mineral feed; — long-term supply formulations of feed for particular nutritional purposes with a concentration of trace elements higher than 100 times the established maximum content in complete feed.	10 15 60
	Complete feed	5
5. Mercury[8]	**Feed materials** with the exception of: — fish, other aquatic animals and products derived from them intended for the production of compound feed for food producing animals; — fish, other aquatic animals and products derived from them intended for the production of compound feed for dogs, cats, ornamental fish and fur animals; — fish, other aquatic animals and products derived from them as canned wet feed material for direct feeding of dogs and cats; — calcium carbonate; calcium and magnesium carbonate[2].	0.1 0.5 1.0[9] 0.3 0.3
	Compound feed with the exception of: — mineral feed; — compound feed for fish; — compound feed for dogs, cats, ornamental fish and fur animals.	0.1 0.2 0.2 0.3
6. Nitrite[10]	**Feed materials** with the exception of: — fishmeal; — silage; — products and by-products from sugar beet and sugarcane and from starch and alcoholic drink production.	15 30 — —
	Complete feed with the exception of: — complete feed for dogs and cats with a moisture content exceeding 20%.	15 —
7. Melamine[11]	**Feed** with the exception of: — canned pet food; — the following feed additives: – guanidino acetic acid (GAA); – urea;	2.5 2.5[12] 20 —

	– biuret.	—

(1) The maximum levels refer to total arsenic.

(2) Calcium and magnesium carbonate refers to the natural mixture of calcium carbonate and magnesium carbonate as described in Commission Regulation (EU) No. 68/2013 on the Catalogue of feed materials.

(3) The maximum level established for premixtures takes into account the additives with the highest level of lead and cadmium and not the sensitivity of the different animal species to lead and cadmium. As provided in Article 16 of Regulation 1831/2003, in order to protect animal and public health, it is the responsibility of the producer of premixtures to ensure that, in addition to compliance with the maximum levels for premixtures, the instructions for use of the premixture are in accordance with the maximum levels for complementary and complete feed.

(4) The % of phosphorus is relative to a feed with a moisture content of 12%.

(5) Maximum levels refer to an analytical determination of fluorine, whereby extraction is performed with hydrochloric acid 1 N for 20 minutes at ambient temperature. Equivalent extraction procedures can be applied for which it can be demonstrated that the used extraction procedure has an equal extraction efficiency.

(6) For the determination of lead in kaolinitic clay and in feed containing kaolinitic clay, the maximum level refers to an analytical determination of lead, whereby extraction is performed in nitric acid (5% w/w) for 30 minutes at boiling temperature. Equivalent extraction procedures can be applied for which it can be demonstrated that the used extraction procedure has an equal extraction efficiency.

(7) Forage includes products intended for animal feed such as hay, silage, fresh grass, etc.

(8) The maximum levels refer to total mercury.

(9) The maximum level is applicable on wet weight basis.

(10) The maximum levels are expressed as sodium nitrite.

(11) The maximum level refers to melamine only. The inclusion of the structurally related compounds cyanuric acid, ammeline and ammelide in the maximum level will be considered at a later stage.

(12) The maximum level is applicable to canned pet food as sold.

Table 2

Mycotoxins

Undesirable substance	***Products intended for animal feed***	***Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%***
1. Aflatoxin B_1	**Feed materials**	0.02
	Complementary and complete feed with the exception of: — compound feed for dairy cattle and calves, dairy sheep and lambs, dairy goats and kids, piglets and young poultry animals, — compound feed for cattle (except dairy cattle and calves), sheep (except dairy sheep and lambs), goats (except dairy goats and kids), pigs (except piglets) and poultry (except young animals).	0.01 0.005 0.02
2. Rye ergot (*Claviceps purpurea)*	**Feed materials and compound feed containing unground cereals**	1000

Table 3

Inherent plant toxins

Undesirable substance	*Products intended for animal feed*	*Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%*
1. Free gossypol	**Feed materials** with the exception of: — cottonseed; — cottonseed cakes and cottonseed meal.	20 6000 1200
	Complete feed with the exception of: — complete feed for cattle (except calves); — complete feed for sheep (except lambs) and goats (except kids); — complete feed for poultry (except laying hens) and calves; — complete feed for rabbits, lambs, kids and pigs (except piglets).	20 500 300 100 60
2. Hydrocyanic acid	**Feed materials** with the exception of: — linseed; — linseed cakes; — manioc products and almond cakes.	50 250 350 100
	Complete feed with the exception of: — complete feed for young chickens (< 6 weeks).	50 10
3. Theobromine	**Complete feed** with the exception of: — complete feed for pigs; — complete feed for dogs, rabbits, horses and fur animals.	300 200 50
4. Vinyl thiooxazolidone (5-vinyloxazolidine-2-thione)	**Complete feed for poultry** with the exception of: — complete feed for laying hens.	1000 500
5. Volatile mustard oil(1)	**Feed materials** with the exception of: — Camelina seed and products derived from it(2), products derived from mustard seed(2), rape seed and products derived from it.	100 4000
	Complete feed with the exception of: — complete feed for cattle (except calves), sheep (except lambs) and goats (except kids);	150 1000

	— complete feed for pigs (except piglets) and poultry.	500

(1) The maximum levels are expressed as allyl isothiocyanate.

(2) Upon request of the competent authorities, the responsible operator must perform an analysis to demonstrate that the content of total glucosinolates is lower than 30 mmol/kg. The method of analysis of reference is BS EN ISO 9167:2019 "*Rapeseed and rapeseed meals. Determination of glucosinolates content. Method using high-performance liquid chromatography*". Published by the British Standards Institution on 30 June 2019 (ISBN 978 0 539 07739 1). Available from the British Standards Institution https://knowledge.bsigroup.com.

Table 4

Organochlorine compounds (except dioxins and polychlorinated biphenyls (PCBs))

Undesirable substance	***Products intended for animal feed***	***Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%***
1. Aldrin(1)	**Feed materials and compound feed** with the exception of:	0.01(2)
	—fats and oils;	0.1(2)
	— compound feed for fish.	0.02(2)
2. Dieldrin(1)	**Feed materials and compound feed** with the exception of:	0.01(2)
	— fats and oils;	0.1(2)
	— compound feed for fish.	0.02(2)
3. Camphechlor (toxaphene) – sum of indicator congeners CHB 26, 50 and 62(3)	**Fish, other aquatic animals and products derived from them** with the exception of:	0.02
	— fish oil.	0.2
	Complete feed for fish	0.05
4. Chlordane (sum of cis- and trans-isomers and of oxychlordane, expressed as chlordane)	**Feed materials and compound feed** with the exception of:	0.02
	— fats and oils.	0.05
5. DDT (sum of DDT-, DDD- (or TDE-) and DDE-isomers, expressed as DDT)	**Feed materials and compound feed** with the exception of:	0.05
	— fats and oils.	0.5
6. Endosulfan (sum of alpha- and beta-isomers and of endosulfansulphate expressed as endosulfan)	**Feed materials and compound feed** with the exception of:	0.1
	— cotton seed and products derived from the processing of it, except crude cotton seed oil;	0.3
	— soybean and products derived from the processing of it, except crude soybean oil;	0.5
	— crude vegetable oil;	1.0

	— complete feed for fish except for Salmonids; — complete feed for Salmonids.	0.005 0.05
7. Endrin (sum of endrin and of delta-ketoi-endrin, expressed as endrin)	**Feed materials and compound feed** with the exception of: — fats and oils.	0.01 0.05
8. Heptachlor (sum of heptachlor and of heptachlorepoxide, expressed as heptachlor)	**Feed materials and compound feed** with the exception of: — fats and oils.	0.01 0.2
9. Hexachlorobenzene (HCB)	**Feed materials and compound feed** with the exception of: — fats and oils.	0.01 0.2
10. Hexachlorocyclohexane (HCH)		
— alpha-isomers	**Feed materials and compound feed** with the exception of: — fats and oils.	0.02 0.2
— beta-isomers	**Feed materials** with the exception of: — fats and oils.	0.01 0.1
	Compound feed with the exception of: — compound feed for dairy cattle.	0.01 0.005
— gamma-isomers	**Feed materials and compound feed** with the exception of: — fats and oils.	0.2 2.0

(1) Singly or combined expressed as dieldrin.

(2) Maximum level for aldrin and dieldrin, singly or combined, expressed as dieldrin.

(3) Numbering system according to Parlar, prefixed by either CHB or 'Parlar':

— CHB 26: 2-endo,3-exo,5-endo,6-exo,8,8,10,10-octochlorobornane,

— CHB 50: 2-endo,3-exo,5-endo,6-exo,8,8,9,10,10-nonachlorobornane,

— CHB 62: 2,2,5,5,8,9,9,10,10-nonachlorobornane.

Table 5 (Part 1)

Dioxins and polychlorinated biphenyls (PCBs)

Undesirable substance	*Products intended for animal feed*	*Maximum content in ng WHO-PCDD/F-TEQ/kg (ppt)[1] relative to a feed with a moisture content of 12%*
1. Dioxins (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005)[2])	**Feed materials of plant origin** with the exception of: — vegetable oils and their by-products.	0.75 0.75
	Feed materials of mineral origin	0.75
	Feed materials of animal origin: — Animal fat, including milk fat and egg fat; — Other land animal products including milk and milk products and eggs and egg products; — Fish oil; — Fish, other aquatic animals, and products derived from them with the exception of fish oil, hydrolysed fish protein containing more than 20% fat[3] and crustacea meal; — Hydrolysed fish protein containing more than 20% fat and crustacea meal.	 1.50 0.75 5.0 1.25 1.75
	Feed additives belonging to the functional groups of binders and anti-caking agents[4]	0.75
	Feed additives belonging to the functional group of compounds of trace elements	1.0
	Premixtures	1.0
	Compound feed with the exception of: — compound feed for pet animals and fish; — compound feed for fur animals.	0.75 1.75 —

Undesirable substance	*Products intended for animal feed*	*Maximum content in ng WHO-PCDD/F-PCB-TEQ/kg (ppt)*[(1)] *relative to a feed with a moisture content of 12%*
2. Sum of dioxins and dioxin-like polychlorinated biphenyls (PCBs) (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors), 2005[(2)])	**Feed materials of plant origin** with the exception of: — vegetable oils and their by-products.	1.25 1.5
	Feed materials of mineral origin	1.0
	Feed materials of animal origin: — Animal fat, including milk fat and egg fat; — Other land animal products including milk and milk products and eggs and egg products; — Fish oil; — Fish, other aquatic animals, and products derived from them with the exception of fish oil and hydrolysed fish protein containing more than 20% fat[(3);] — Hydrolysed fish protein containing more than 20% fat.	 2.0 1.25 20.0 4.0 9.0
	Feed additives belonging to the functional groups of binders and anti-caking agents[(4)]	1.5
	Feed additives belonging to the functional group of compounds of trace elements	1.5
	Premixtures	1.5
	Compound feed with the exception of: — compound feed for pet animals and fish; — compound feed for fur animals.	1.5 5.5 —
Undesirable substance	*Products intended for animal feed*	*Maximum content in µg/kg (ppb) relative to a feed with a moisture content of 12%*[(1)]

3. Non-dioxin-like polychlorinated biphenyls (PCBs) (sum of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180 (ICES – 6)[(1)])	**Feed materials of plant origin**	10
	Feed materials of mineral origin	10
	Feed materials of animal origin:	
	— Animal fat, including milk fat and egg fat;	10
	— Other land animal products including milk and milk products and eggs and egg products;	10
	— Fish oil;	175
	— Fish, other aquatic animals and products derived from them with the exception of fish oil and hydrolysed fish protein containing more than 20% fat[(5)];	30
	— Hydrolysed fish protein containing more than 20% fat.	50
	Feed additives belonging to the functional groups of binders and anti-caking agents[(4)]	10
	Feed additives belonging to the functional group of compounds of trace elements	10
	Premixtures	10
	Compound feed	10
	with the exception of:	
	— compound feed for pet animals and fish;	40
	— compound feed for fur animals.	—

(1) Upper-bound concentrations; upper-bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification.

(2) See Table 5 (Part 2) for TEFs (= toxic equivalency factors) for dioxins, furans and dioxin-like polychlorinated biphenyls (PCBs): WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation (WHO) – International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (Martin van den Berg et al., The 2005 World Health Organisation Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological Sciences 93(2), 223–241 (2006)).

(3) Fresh fish and other aquatic animals directly delivered and used without intermediate processing for the production of feed for fur animals are not subject to the maximum levels, while maximum levels of 3.5ng WHO-PCDD/F-TEQ/kg product and 6.5ng WHO-PCDD/F-PCB-TEQ/kg product are applicable to fresh fish and 20.0ng WHO-PCDD/F-PCB-TEQ/kg product is applicable to fish liver used for the direct feeding of pet animals, zoo and circus animals or used as feed material for the production of pet food. The products or processed animal proteins produced from these animals (fur animals, pet animals, zoo and circus animals) cannot enter the food chain and cannot be fed to farmed animals which are kept, fattened or bred for the production of food.

(4) The maximum level is also applicable to the feed additives belonging to the functional groups of substances for the control of radionuclide contamination and substances for reduction of the contamination of feed by mycotoxins which also belong to the functional groups of binders and anti-caking agents.

(5) Fresh fish and other aquatic animals directly delivered and used without intermediate processing for the production of feed for fur animals are not subject to the maximum levels, while maximum levels of 75µg/kg product are applicable to fresh fish and 200µg/kg product are applicable to fish liver used for the direct feeding of pet animals, zoo and circus animals or used as feed material for the production of pet food. The products or processed animal proteins produced from these animals (fur animals, pet animals, zoo and circus animals) cannot enter the food chain and cannot be fed to farmed animals which are kept, fattened or bred for the production of food.

Table 5 (Part 2)

TEFs (= toxic equivalency factors) for dioxins, furans and dioxin-like polychlorinated biphenyls (PCBs), for the purposes of table 5.1 footnote 2

Congener	*TEF value*
Dibenzo-para-dioxins ('PCDDs') and Dibenzo-para-furans (PCDFs)	
2,3,7,8-TCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.0003
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.03
2,3,4,7,8-PeCDF	0.3
1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.0003
'Dioxin-like' polychlorinated biphenyls (PCBs): Non-ortho PCBs + Mono-ortho PCBs	
Non-ortho PCBs	
PCB 77	0.0001
PCB 81	0.0003
PCB 126	0.1
PCB 169	0.03
Mono-ortho PCBs	
PCB 105	0.00003
PCB 114	0.00003
PCB 118	0.00003
PCB 123	0.00003
PCB 156	0.00003
PCB 157	0.00003
PCB 167	0.00003

PCB 189	0.00003
Abbreviations used: ‘T’ = tetra; ‘Pe’ = penta; ‘Hx’ = hexa; ‘Hp’ = hepta; ‘O’ = octa; ‘CDD’ = chlorodibenzodioxin; ‘CDF’ = chlorodibenzofuran; ‘CB’ = chlorobiphenyl.	

Table 6

Harmful botanical impurities

Undesirable substance	***Products intended for animal feed***	***Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%***
1. Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination including: — *Datura* sp.	**Feed materials and compound feed**	3000 1000
2. *Crotalaria* spp.	**Feed materials and compound feed**	100
3. Seeds and husks from *Ricinus communis* L., *Croton tiglium* L. and *Abrus precatorius* L. as well as their processed derivatives[(1)], separately or in combination	**Feed materials and compound feed**	10[(2)]
4. Unhusked beech mast — *Fagus sylvatica* L.	**Feed materials and compound feed**	Seeds and fruit as well as their processed derivatives may only be present in feed in trace amounts not quantitatively determinable.
5. Purghera — *Jatropha curcas* L.	**Feed materials and compound feed**	Seeds and fruit as well as their processed derivatives may only be present in feed in trace amounts not quantitatively determinable.
6. Seeds from *Ambrosia* spp.	**Feed materials**[(3)] with the exception of: — Millet (grains of *Panicum miliaceum* L.) and sorghum (grains of *Sorghum bicolor* (L) Moench s.l.) not directly fed to animals[(3)]; — Compound feed containing unground grains and seeds.	50 200 50

7. Seeds from: **— Indian mustard — *Brassica juncea* (L.) Czern. and Coss. ssp. *integrifolia* (West.) Thell.** **— Sareptian mustard — *Brassica juncea* (L.) Czern. and Coss. ssp. *juncea*** **— Chinese mustard — *Brassica juncea* (L.) Czern. and Coss. ssp. *juncea* var. *lutea* Batalin** **— Black mustard — *Brassica nigra* (L.) Koch** **— Ethiopian mustard — *Brassica carinata* A. Braun**	**Feed materials and compound feed**	Seeds may only be present in feed in trace amounts not quantitatively determinable.

(1) Insofar as determinable by analytical microscopy.

(2) Includes also seed husk fragments.

(3) Where unequivocal evidence is provided that the grains and seeds are intended for milling or crushing, there is no need to clean the grains and seeds containing non-compliant levels of *Ambrosia* spp. seeds before milling or crushing on the condition that:

- the consignment is transported as a whole to the milling or crushing plant, and the milling or crushing plant is informed in advance of the presence of high level of *Ambrosia* spp. seeds in order to take additional prevention measures to avoid dissemination into the environment, and
- solid evidence is provided that prevention measures are taken to avoid dissemination of *Ambrosia* spp. seeds into the environment during transport to the crushing or milling plant, and
- the competent authority agrees to the transport, after having ensured that the abovementioned conditions are fulfilled.

Where these conditions are not fulfilled, the consignment must be cleaned before it is transported into Wales and the screenings must be appropriately destroyed.

Table 7

Authorised feed additives in non-target feed following unavoidable carry-over

Coccidiostat	***Products intended for animal feed*(1)**	***Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%***
1. Decoquinate	**Feed materials**	0.4
	Compound feed for: — laying birds and chickens reared for laying (> 16 weeks); — other animal species.	 0.4 1.2
	Premixtures for use in feed in which the use of decoquinate is not authorised	(2)
2. Diclazuril	**Feed materials**	0.03
	Compound feed for: — laying birds and chickens reared for laying (> 16 weeks); — rabbits for fattening and breeding for the period before slaughter in which the use of diclazuril is prohibited (withdrawal feed);	 0.03 0.03

	— other animal species other than chickens reared for laying (< 16 weeks), chickens for fattening, guinea fowl and turkeys for fattening.	0.09
	Premixtures for use in feed in which the use of diclazuril is not authorised	(2)
3. Halofuginone hydrobromide	**Feed materials**	0.03
	Compound feed for: — laying birds, chickens reared for laying and turkeys (> 12 weeks); — chickens for fattening and turkeys (< 12 weeks) for the period before slaughter in which the use of halofuginone hydrobromide is prohibited (withdrawal feed); — other animal species.	 0.03 0.03 0.09
	Premixtures for use in feed in which the use of halofuginone hydrobromide is not authorised	(2)
4. Lasalocid A sodium	**Feed materials**	1.25
	Compound feed for: — dogs, calves, rabbits, equine species, dairy animals, laying birds, turkeys (> 16 weeks) and chickens reared for laying (> 16 weeks); — chickens for fattening, chickens reared for laying (< 16 weeks) and turkeys (< 16 weeks) for the period before slaughter in which the use of lasalocid A sodium is prohibited (withdrawal feed); — pheasants, guinea fowl, quails and partridges (except laying birds) for the period before slaughter in which the use of lasalocid A sodium is prohibited (withdrawal feed); — other animal species.	 1.25 1.25 1.25 3.75
	Premixtures for use in feed in which the use of lasalocid A sodium is not authorised	(2)
5. Maduramicin ammonium alpha	**Feed materials**	0.05
	Compound feed for: — equine species, rabbits, turkeys (> 16 weeks), laying birds and chickens reared for laying (> 16 weeks); — chickens for fattening and turkeys (< 16 weeks) for the period before slaughter in which the use of maduramicin ammonium alpha is prohibited (withdrawal feed); — other animal species.	 0.05 0.05 0.15
	Premixtures for use in feed in which the use of maduramicin ammonium alpha is not authorised	(2)
6. Monensin sodium	**Feed materials**	1.25
	Compound feed for:	

	— equine species, dogs, small ruminants (sheep and goat), ducks, bovine species, dairy cattle, laying birds, chickens reared for laying (> 16 weeks) and turkeys (> 16 weeks); — chickens for fattening, chickens reared for laying (< 16 weeks) and turkeys (< 16 weeks) for the period before slaughter in which the use of monensin sodium is prohibited (withdrawal feed); — other animal species.	1.25 1.25 3.75
	Premixtures for use in feed in which the use of monensin sodium is not authorised	(2)
7. Narasin	**Feed materials**	0.7
	Compound feed for: — turkeys, rabbits, equine species, laying birds and chickens reared for laying (> 16 weeks); — other animal species.	0.7 2.1
	Premixtures for use in feed in which the use of narasin is not authorised	(2)
8. Nicarbazin	**Feed materials**	1.25
	Compound feed for: — equine species, laying birds and chickens reared for laying (> 16 weeks); — other animal species.	1.25 1.25
	Premixtures for use in feed in which the use of nicarbazin (alone or in combination with narasin) is not authorised	(2)
9. Robenidine hydrochloride	**Feed materials**	0.7
	Compound feed for: — laying birds and chickens reared for laying (> 16 weeks); — chickens for fattening, rabbits for fattening and breeding and turkeys for the period before slaughter in which the use of robenidine hydrochloride is prohibited (withdrawal feed); — other animal species.	0.7 0.7 2.1
	Premixtures for use in feed in which the use of robenidine hydrochloride is not authorised	(2)
10. Salinomycin sodium	**Feed materials**	0.7
	Compound feed for: — equine species, turkeys, laying birds and chickens reared for laying (> 12 weeks);	0.7

	— chickens for fattening, chickens reared for laying (< 12 weeks) and rabbits for fattening for the period before slaughter in which the use of salinomycin sodium is prohibited (withdrawal feed); — other animal species.	0.7 2.1
	Premixtures for use in feed in which the use of salinomycin sodium is not authorised	(2)
11. Semduramicin sodium	**Feed materials**	0.25
	Compound feed for: — laying birds and chickens reared for laying (> 16 weeks); — chickens for fattening for the period before slaughter in which the use of semduramicin sodium is prohibited (withdrawal feed); — other animal species.	 0.25 0.25 0.75
	Premixtures for use in feed in which the use of semduramicin sodium is not authorised	(2)

(1) Without prejudice to the authorised levels pursuant to Regulation 1831/2003.

(2) The maximum level of the substance in the premixture is the concentration which shall not result in a level of the substance higher than 50 % of the maximum levels established in the feed when the instructions for use of the premixture are followed.

SCHEDULE 1C

Regulations 15 and 15A

Action thresholds triggering investigations

Table 1 (part 1)

Dioxins and polychlorinated biphenyls (PCBs)

Undesirable substances	***Products intended for animal feed***	***Action threshold in ng WHO-PCDD/F TEQ/kg (ppt)(1) relative to a feedingstuff with a moisture content of 12%***	***Comments and additional information (e.g. nature of investigations to be performed)***
1. Dioxins (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency	**Feed materials of plant origin** with the exception of: — vegetable oils and their by-products.	0.5 0.5	(3) (3)
	Feed materials of mineral origin	0.5	(3)
	Feed materials of animal origin:		

factors, 2005)[2])	— Animal fat, including milk fat and egg fat;	0.75	[3]
	— Other land animal products including milk and milk products and eggs and egg products;	0.5	[3]
	— Fish oil;	4.0	[4]
	— Fish, other aquatic animals and products derived from them with the exception of fish oil, hydrolysed fish protein containing more than 20% fat and crustacea meal;	0.75	[4]
	— Hydrolysed fish protein containing more than 20% fat and crustacea meal.	1.25	[4]
	Feed additives belonging to the functional groups of binders and anti-caking agents	0.5	[3]
	Feed additives belonging to the functional group of compounds of trace elements	0.5	[3]
	Premixtures	0.5	[3]
	Compound feed	0.5	[3]
	with the exception of:		
	— compound feed for pet animals and fish;	1.25	[4]
	— compound feed for fur animals.	—	
2. Dioxin-like polychlorinated biphenyls (PCBs) (sum of polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005)[2])	**Feed materials of plant origin**	0.35	[3]
	with the exception of:		
	— vegetable oils and their by-products.	0.5	[3]
	Feed materials of mineral origin	0.35	[3]
	Feed materials of animal origin:		
	— Animal fat, including milk fat and egg fat;	0.75	[3]
	— Other land animal products including milk and milk products and eggs and egg products;	0.35	[3]
	— Fish oil;	11.0	[4]

	— Fish, other aquatic animals and products derived from them with the exception of fish oil and hydrolysed fish protein containing more than 20% fat[3]; — Hydrolysed fish protein containing more than 20% fat.	2.0 5.0	(4) (4)
	Feed additives belonging to the functional groups of binders and anti-caking agents	0.5	(3)
	Feed additives belonging to the functional group of compounds of trace elements	0.35	(3)
	Premixtures	0.35	(3)
	Compound feed with the exception of: — compound feed for pet animals and fish; — compound feed for fur animals.	0.5 2.5 —	(3) (4)

(1) Upper-bound concentrations; upper-bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification.

(2) See Table 1 (part 2) for TEFs (= toxic equivalency factors) for dioxins, furans and dioxin-like polychlorinated biphenyls (PCBs): WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation (WHO) – International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (Martin van den Berg et al., The 2005 World Health Organisation Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological Sciences 93(2), 223–241 (2006)).

(3) Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination.

(4) In many cases it might not be necessary to perform an investigation into the source of contamination as the background level in some areas is close to or above the action level. However, in cases where the action level is exceeded, all information, such as sampling period, geographical origin, fish species etc., must be recorded with a view to future measures to manage the presence of dioxins and dioxin-like compounds in these materials for animal nutrition.

Table 1 (Part 2)

TEF (= toxic equivalency factors) for dioxins, furans and dioxin-like polychlorinated biphenyls (PCBs), for the purposes of Table 1 (Part 1) footnote 2

Congener	*TEF value*
Dibenzo-para-dioxins ('PCDDs') and Dibenzo-para-furans (PCDFs)	
2,3,7,8-TCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1

1,2,3,4,6,7,8-HpCDD OCDD 2,3,7,8-TCDF 1,2,3,7,8-PeCDF 2,3,4,7,8-PeCDF 1,2,3,4,7,8-HxCDF 1,2,3,6,7,8-HxCDF 1,2,3,7,8,9-HxCDF 2,3,4,6,7,8-HxCDF 1,2,3,4,6,7,8-HpCDF 1,2,3,4,7,8,9-HpCDF OCDF	0.01 0.0003 0.1 0.03 0.3 0.1 0.1 0.1 0.1 0.01 0.01 0.0003
'Dioxin-like' polychlorinated biphenyls (PCBs): Non-ortho PCBs + Mono-ortho PCBs	
Non-ortho PCBs	
PCB 77 PCB 81 PCB 126 PCB 169	0.0001 0.0003 0.1 0.03
Mono-ortho PCBs	
PCB 105 PCB 114 PCB 118 PCB 123 PCB 156 PCB 157 PCB 167 PCB 189	0.00003 0.00003 0.00003 0.00003 0.00003 0.00003 0.00003 0.00003
Abbreviations used: 'T' = tetra; 'Pe' = penta; 'Hx' = hexa; 'Hp' = hepta; 'O' = octa; 'CDD' = chlorodibenzodioxin; 'CDF' = chlorodibenzofuran; 'CB' = chlorobiphenyl."	