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STATUTORY INSTRUMENTS

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**2009 No. 3378 (W.300)**

**FOOD, WALES**

**The Food Additives (Wales) Regulations 2009**

<i>Made</i>	- - - -	<i>21 December 2009</i>
<i>Laid before the National Assembly for Wales</i>	- -	<i>23 December 2009</i>
<i>Coming into force</i>	- -	<i>20 January 2010</i>

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 1 (1)(a), (e) and (f), 17(1) and (2), 26(1)(a) and (b), (2)(e) and (3), and 48(1) of the Food Safety Act 1990<sup>(1)</sup>, and paragraph 1A of Schedule 2 to the European Communities Act 1972<sup>(2)</sup>.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Welsh Ministers that it is expedient for any reference to an Annex to an EU instrument that is specified in regulation 2(6) to be construed as a reference to that Annex as amended from time to time.

In accordance with section 48(4A) of that Act, they have had regard to relevant advice given by the Food Standards Agency.

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<sup>(3)</sup>, there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

**Title, application and commencement**

1. These Regulations are called the Food Additives (Wales) Regulations 2009, apply in relation to Wales and come into force on 20 January 2010.

**Interpretation**

2.—(1) In these Regulations—

“acid” (“*asid*”) means any substance which increases the acidity of a food and/or imparts a sour taste to it;

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(1) 1990 c. 16. Functions of the Secretary of State under the Food Safety Act 1990 are conferred on the Welsh Ministers by virtue of paragraph 30 of and Schedule 11 to the Government of Wales Act 2006 (c. 32).

(2) 1972 c. 68.

(3) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny — Part Four (OJ No. L188, 18.7.2009, p.14).

“acidity regulator” (“*rheolydd asidedd*”) means any substance which alters or controls the acidity or alkalinity of a food;

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

“anti-caking agent” (“*cyfrwng gwrthdalpio*”) means any substance which reduces the tendency of individual particles of a food to adhere to each other;

“anti-foaming agent” (“*cyfrwng gwrthewynnu*”) means any substance which prevents or reduces foaming;

“antioxidant” (“*gwrthocsidydd*”) means any substance which prolongs the shelf-life of a food by protecting it against deterioration caused by oxidation, including fat rancidity and colour changes;

“bulking agent” (“*cyfrwng swmpuso*”) means any substance which contributes to the volume of a food without contributing significantly to its available energy value;

“carrier” (“*cludydd*”) and “carrier solvent” (“*toddydd cludo*”) have the meanings respectively given to them in Directive 95/2;

“colour” (“*lliw*”) has the meaning given to it in Directive 94/36;

“Directive 88/388” (“*Cyfarwyddeb 88/388*”) means Council Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production<sup>(4)</sup>;

“Directive 94/35” (“*Cyfarwyddeb 94/35*”) means European Parliament and Council Directive 94/35/EC on sweeteners for use in foodstuffs<sup>(5)</sup>;

“Directive 94/36” (“*Cyfarwyddeb 94/36*”) means European Parliament and Council Directive 94/36/EC on colours for use in foodstuffs<sup>(6)</sup>;

“Directive 95/2” (“*Cyfarwyddeb 95/2*”) means European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners<sup>(7)</sup>;

“Directive 08/0” (“*Cyfarwyddeb 08/60*”) means Commission Directive 2008/0/EC laying down specific purity criteria concerning sweeteners for use in foodstuffs<sup>(8)</sup>;

“Directive 08/84” (“*Cyfarwyddeb 08/84*”) means Commission Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners<sup>(9)</sup>;

“Directive 08/128” (“*Cyfarwyddeb 08/128*”) means Commission Directive 2008/128/EC laying down specific purity criteria concerning colours for use in foodstuffs<sup>(10)</sup>;

“Directive 09/39” (“*Cyfarwyddeb 09/39*”) means Directive 2009/39/EC of the European Parliament and of the Council on foodstuffs for particular nutritional uses (recast)<sup>(11)</sup>;

“emulsifier” (“*emylsydd*”) means any substance which makes it possible to form or maintain a homogenous mixture of two or more immiscible phases, such as oil and water, in a food;

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(4) OJ No. L184, 15.7.1988, p.61, as last amended by Regulation (EC) No. 1882/2003 of the European Parliament and of the Council adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty (OJ No. L284, 31.10.2003, p.1).

(5) OJ No. L237, 10.9.1994, p.3, as last amended by Directive 2006/52/EC of the European Parliament and of the Council amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs. (OJ No. L204, 20.7.2006, p.10).

(6) OJ No. L237, 10.9.1994, p.13.

(7) OJ No. L61, 18.3.1995, p.1, as read with the Corrigendum at OJ No. L248, 14.10.1995, p.60 and as last amended by Directive 2006/52/EC.

(8) OJ No. L158, 18.6.2008, p.1.

(9) OJ No. L253, 20.9.2008, p.1. amended by Commission Directive 2009/10/EC amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners (OJ No. L44, 14.2.2009, p.62).

(10) OJ No. L6, 10.1.2009, p.20.

(11) OJ No. L124, 20.05.2009, p.21.

“emulsifying salt” (“*halwyn mylsio*”) means any substance which converts proteins contained in cheese into a dispersed form, thereby bringing about homogenous distribution of fat and other components;

“firming agent” (“*cyfrwng sadio*”) means any substance which makes or keeps tissues of fruit or vegetables firm or crisp or which interacts with a gelling agent to produce or strengthen a gel;

“flavour enhancer” (“*sylwedd gwella blas*”) means any substance which enhances the existing taste and/or odour of a food;

“flavouring” (“*cyflasyn*”) has the meaning that it bears in Article 1.2 of Directive 88/388;

“flour treatment agent” (“*cyfrwng trin blawd*”) means a substance added to flour or dough to improve its baking quality, but does not include any emulsifier;

“foaming agent” (“*cyfrwng ewynnu*”) means any substance which makes it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid food;

“food” (“*bwyd*”) means food sold, or intended for sale, for human consumption and, for the purposes of regulation 16 and in regulation 17, includes a colour, a sweetener and a food additive;

“food additive” (“*ychwanegyn bwyd*”)—

- (a) subject to paragraphs (b) and (c), means any substance, whether or not it has nutritive value, that is not normally consumed as a food in itself or used as a characteristic ingredient of food, and which, if added intentionally for a technological purpose to food in its manufacture, processing, preparation, treatment, packaging, transport or storage, results, or may reasonably be expected to result, in the substance or its by-products becoming directly or indirectly a component of the food concerned;
- (b) in the definition of “food” and for the purposes of regulations 8 to 10, 16 and 17, includes a carrier or carrier solvent; and
- (c) for the purposes of regulations 8 to 10, does not include—
  - (i) any substance used for the treatment of drinking water as provided for in Council Directive 98/83/EC on the quality of water intended for human consumption<sup>(12)</sup>,
  - (ii) any product containing pectin and derived from dried apple pomace or peel of citrus fruit, or from a mixture of both, by the action of dilute acid followed by partial neutralisation with sodium or potassium salts (liquid pectin),
  - (iii) chewing gum bases,
  - (iv) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolytic enzymes,
  - (v) ammonium chloride,
  - (vi) blood plasma, edible gelatine, protein hydrolysates and their salts, milk protein and gluten,
  - (vii) amino acids and their salts (other than glutamic acid, glycine, cysteine and cystine and their salts) having no additive function,
  - (viii) caseinates and casein, and
  - (ix) inulin;

“food authority” (“*awdurdod bwyd*”), subject to paragraph (3), has the meaning that it bears by virtue of section 5(1A) of the Act;

(12) OJ No. L330, 5.12.1998, p.32.

“food for infants or young children” (“*bwyd ar gyfer babanod neu blant ifanc*”) means food covered by Article 1.1, 2 and 3(c) of Directive 09/39, but also includes any food for infants or young children who are not in good health;

“gelling agent” (“*cyfrwng gelio*”) means any substance which gives a food texture through the formation of a gel;

“glazing agent” (“*cyfrwng sgleinio*”) means any substance which, when applied to the external surface of a food, imparts a shiny appearance or provides a protective coating, and includes lubricants;

“humectant” (“*gwlybyrydd*”) means any substance which prevents a food from drying out by counteracting the effect of an atmosphere having a low degree of humidity, or which promotes the dissolution of a powder in an aqueous medium;

“infants” (“*babanod*”) means children under the age of one year;

“miscellaneous additive” (“*ychwanegyn amrywiol*”) means any food additive which is used or intended to be used primarily as an acid, acidity regulator, anti-caking agent, anti-foaming agent, antioxidant, bulking agent, carrier, carrier solvent, emulsifier, emulsifying salt, firming agent, flavour enhancer, flour treatment agent, foaming agent, gelling agent, glazing agent, humectant, modified starch, packaging gas, preservative, propellant, raising agent, sequestrant, stabiliser or thickener, but does not include any processing aid or any enzyme except invertase or lysozyme;

“modified starch” (“*startsh addasedig*”) means any substance obtained by one or more chemical treatments of edible starch, which may have undergone a physical or enzymatic treatment, and may be acid or alkali thinned or bleached;

“packaging gas” (“*nwy pecynnu*”) means any gas, other than air, which is introduced into a container before, during or after the placing of a food in that container;

“permitted colour” (“*lliw a ganiateir*”) means any colour listed in Annex I to Directive 94/36 which satisfies the specific purity criteria for that colour set out in the Annex to Directive 08/128;

“permitted miscellaneous additive” (“*ychwanegyn amrywiol a ganiateir*”) means any miscellaneous additive listed in Annex I, III, IV or V of Directive 95/2 which satisfies the purity criteria (if any) for that additive;

“permitted sweetener” (“*melysydd a ganiateir*”) means any sweetener specified in the second column of the Annex to Directive 94/35 which satisfies the specific purity criteria for that sweetener set out in the Annex to Directive 08/60;

“placing on the market” (“*rhoi ar y farchnad*”) has the meaning given to it in Article 3.8 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;

“preservative” (“*cadwolyn*”) means any substance which prolongs the shelf-life of a food by protecting it against deterioration caused by micro-organisms;

“processing aid” (“*cymhorthyn prosesu*”) means any substance not consumed as a food by itself, which is intentionally used in the processing of raw materials, foods or their ingredients to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, but only if those residues do not present any health risk and do not have any technological effect on the finished product;

“propellant” (“*gyrrydd*”) means any gas, other than air, which expels a food from a container;

“purity criteria” (“*meini prawf purdeb*”), in relation to a miscellaneous additive, means the purity criteria set out in relation to that additive in Annex I to Directive 08/84/EC;

“raising agent” (“*codydd*”) means any substance or combination of substances which liberates gas and thereby increases the volume of a dough or a batter;

“Regulation 1333/2008” (“*Rheoliad 1333/2008*”) means Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives<sup>(13)</sup>;

“relevant food additive” (“*ychwanegyn bwyd perthnasol*”) means any miscellaneous additive, colour or sweetener, or an enzyme which is not acting as a processing aid;

“sell” (“*gwerthu*”) includes possess for sale, and offer, expose or advertise for sale, and “sale” (“*gwerthiant*”) and “sold” (“*gwerthwyd*”) are construed accordingly;

“sequestrant” (“*secwestrydd*”) means any substance which forms a chemical complex with metallic ions;

“specified permitted colour” (“*lliw penodedig a ganiateir*”) means any permitted colour other than—

- (a) E123 Amaranth;
- (b) E127 Erythrosine;
- (c) E128 Red 2G;
- (d) E154 Brown FK;
- (e) E160b Annatto, bixin, norbixin;
- (f) E161g Canthaxanthin;
- (g) E173 Aluminium; and
- (h) E180 Litholrubine BK;

“specified Regulation 1333/2008 provision” (“*darpariaeth Rheoliad 1333/2008 benodedig*”) means any provision of Regulation 1333/2008 that is specified in the first column of the Schedule and whose subject matter is described in the second column of that Schedule;

“stabiliser” (“*sefydlogydd*”) has the meaning given to it in Directive 95/2;

“sweetener” (“*melysydd*”) means any food additive which is used or intended to be used—

- (a) to impart a sweet taste to food; or
- (b) as a table-top sweetener;

“thickener” (“*tewychydd*”) means any substance which increases the viscosity of a food; and

“young children” (“*plant ifanc*”) means children aged between one and three years.

(2) Other expressions used in these Regulations and in Directive 94/35, 94/36 or 95/2 have, in so far as the context admits, the same meaning as they bear in the Directive concerned.

(3) Where any functions under the Act are assigned—

- (a) by an order under section 2 or 7 of the Public Health (Control of Disease) Act 1984<sup>(14)</sup>, to a port health authority;
- (b) by an order under section 6 of the Public Health Act 1936<sup>(15)</sup>, to a joint board for a united district; or
- (c) by an order under paragraph 15(6) of Schedule 8 to the Local Government Act 1985<sup>(16)</sup>, to a single authority for a metropolitan county,

any reference in these Regulations to a food authority is construed, so far as relating to those functions, as a reference to the authority to whom they are so assigned.

<sup>(13)</sup> OJ No. L354, 31.12.2008, p.16.

<sup>(14)</sup> 1984 c. 22; section 7(3)(d) was substituted by paragraph 27 of Schedule 3 to the Food Safety Act 1990 (1990 c. 16).

<sup>(15)</sup> 1936 c. 49; section is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.

<sup>(16)</sup> 1985 c. 51; paragraph 15(6) was amended by paragraph 31(b) of Schedule 3 to the Food Safety Act 1990.

- (4) Any reference in these Regulations to—
- (a) a maximum level of permitted colour in or on a food is a reference to the maximum amount, in milligrams, of colouring principle contained in that permitted colour per kilogram or, as the case may be, per litre, of food which is ready to eat and which has been prepared according to any instructions for use;
  - (b) a maximum level of permitted miscellaneous additive in or on a food, or in respect of a food additive, is a reference to the maximum level of that permitted miscellaneous additive in or on the food, or in respect of the food additive, as sold, unless otherwise indicated; or
  - (c) *quantum satis*, means, in relation to the use of permitted colours or permitted miscellaneous additives in or on food, that no maximum level of permitted colour or permitted miscellaneous additive has been laid down for use in or on certain food but that a permitted colour or permitted miscellaneous additive may be used in or on the food in accordance with good manufacturing practice at a level not higher than is necessary to achieve the intended purpose and only if such use does not mislead the consumer.
- (5) Any reference in these Regulations to an Annex to an EU instrument that is specified in paragraph (6) is a reference to that Annex as amended from time to time.
- (6) The EU instruments are Directive 94/35, Directive 95/2 and Regulation 1333/2008.

### **Use of colours in or on food**

- 3.—(1) No person may use in or on any food any colour other than a permitted colour.
- (2) No person may use any permitted colour in or on any food listed in Annex II to Directive 94/36 except in accordance with paragraph (3)(a).
- (3) Subject to paragraph (4) and to regulations 4 and 5, no person may use any permitted colour in or on any food unless—
- (a) the food is one listed—
    - (i) in the first column of Annex III to Directive 94/36, in which case there may be used in or on such food any permitted colour which is listed in relation to it in the second column of that Annex in an amount not exceeding the maximum level for such permitted colour in or on such food as listed in the third column of that Annex,
    - (ii) in the second column of Annex IV to Directive 94/36, in which case there may be used in or on such food any permitted colour which is listed in relation to it in the first column of that Annex in an amount not exceeding the maximum level for such permitted colour in or on such food as listed in the third column of that Annex; or
    - (iii) in the first column of the Table in Part 2 of Annex V to Directive 94/36, in which case there may be used in or on such food any permitted colour which is listed in Parts I or 2 of that Annex in accordance with the conditions contained in that Annex governing the use of such colour in or on such food; or
  - (b) the food is listed neither in Annex II to Directive 94/36 nor in the first column of Annex III to that Directive, in which case there may be used in or on such food any one or more of the permitted colours listed in Part I of Annex V to that Directive up to an amount (in each case) of *quantum satis*.
- (4) No person may use any permitted colour listed in the first column of Annex IV to Directive 94/36 in or on any food other than the food or foods listed in relation to that permitted colour in the second column of that Annex.

### Health marking etc. of certain meat and meat products

4. No person may use any colour for the purpose of the health marking required by Article 5.1(a) of Regulation (EC) No. 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin<sup>(17)</sup> or any other marking required on any meat product, other than the permitted colours—

- (a) E155 Brown HT;
- (b) E133 Brilliant Blue FCF;
- (c) E129 Allura Red AC; or
- (d) an appropriate mixture of (b) and (c).

### Use of colours on eggshells

5. No person may use any colour for—

- (a) the decorative colouring of eggshells, or
- (b) the marking of eggshells (as provided for in Regulation (EC) No. 1234/2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation))<sup>(18)</sup>,

other than a permitted colour.

### Sale of colours and food containing colours

6.—(1) No person may sell any colour for use in or on food unless such colour is a permitted colour.

(2) No person may sell direct to the consumer any colour other than a specified permitted colour.

(3) No person may sell any food having in or on it any added colour other than a permitted colour that has been used in or on that food without contravening any of the provisions of regulation 3, 4 or 5.

### Transitional provision

7. In any proceedings for an offence consisting of a contravention of regulation 3, 4, 5 or, it is a defence to prove that—

- (a) the colour or food which is the subject of the proceedings was placed on the market or labelled before 1 April 2005; and
- (b) the matter constituting the offence would not have constituted an offence under the Colours in Food Regulations 1995<sup>(19)</sup> as they stood immediately before the coming into force of the Colours in Food (Amendment) (Wales) Regulations 2005<sup>(20)</sup>.

<sup>(17)</sup> OJ No. L139, 30.4.2004, p.55. The revised text of Regulation (EC) No. 853/2004 is now set out in a Corrigendum (OJ No. L226, 25.6.2004, p.22) which should be read with a further Corrigendum (OJ No. L204, 4.8.2007, p.26). Regulation (EC) No. 853/2004 was last amended by Commission Regulation (EC) No. 1020/2008 amending Annexes II and III to Regulation (EC) No. 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and Regulation (EC) No. 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products (OJ No. L277, 18.10.2008, p.8).

<sup>(18)</sup> OJ No. L299, 16.11.2007, p.1, as last amended by Commission Regulation (EC) No. 183/2009 amending Annex VI to Council Regulation (EC) No. 1234/2007 as regards the adjustment of the quotas for the 2009/10 marketing year in the sugar sector (OJ No. L63, 7.3.2009, p.9).

<sup>(19)</sup> S.I. 1995/3124 as amended.

<sup>(20)</sup> S.I. 2005/1628 (W.122).

### **Use of miscellaneous additives**

8.—(1) No person may use in or on any food any miscellaneous additive other than a permitted miscellaneous additive.

(2) Subject to the first paragraph of Note 3 to Annex I to Directive 95/2, no person may use any permitted miscellaneous additive listed in that Annex in or on any food which is listed in Article 2.3(a) of that Directive but not in the first column of Annex II to that Directive.

(3) Subject to the first paragraph of Note 3 to Annex I to Directive 95/2, no person may use any permitted miscellaneous additive listed in that Annex in or on any food which is listed in the first column of Annex II to that Directive, except a permitted miscellaneous additive which is listed, or referred to, in relation to that food in the second column of that Annex in an amount not exceeding the maximum level (if any) for such additive in or on such food as listed in the third column of that Annex.

(4) No person may use any permitted miscellaneous additive listed in Annex I to Directive 95/2 in or on any food which is listed neither in Article 2.3(a) of that Directive nor in the first column of Annex II to that Directive and is not food for infants or young children, in an amount higher than *quantum satis* or otherwise than in compliance with Note 2 to and the second paragraph of Note 3 to Annex I to that Directive.

(5) No person may use any permitted miscellaneous additive listed in Annex III or IV to Directive 95/2 in or on any food which is not food for infants or young children, other than a food which is listed in either of those Annexes in relation to that additive and in accordance with the provisions contained in those Annexes governing the use of such additive in or on such food.

(6) No person may use any miscellaneous additive primarily as a carrier or carrier solvent unless that additive is a permitted miscellaneous additive listed in Annex V to Directive 95/2 and its use complies with the restrictions (if any) mentioned in relation to that additive in the third column of that Annex.

(7) Subject to the first paragraph of Note 3 to Annex I to Directive 95/2, no person may use any permitted miscellaneous additive in or on any food for infants or young children unless that additive is listed in Annex VI to Directive 95/2, in which case it may be used only in accordance with the conditions contained in that Annex.

(8) No person may use in or on any food for infants or young children any relevant food additive in combination with a miscellaneous additive which has been used primarily as a carrier or carrier solvent unless that miscellaneous additive is listed in Annex VI to Directive 95/2 and its presence in or on the food is in accordance with the conditions contained in that Annex.

### **Sale of food additives and food containing miscellaneous additives**

9.—(1) No person may sell any miscellaneous additive for use in or on food unless that additive is a permitted miscellaneous additive.

(2) No person may sell any miscellaneous additive for use primarily as a carrier or carrier solvent unless that additive is a permitted miscellaneous additive listed in Annex V to Directive 95/2.

(3) No person may sell direct to the consumer any miscellaneous additive other than a permitted miscellaneous additive.

(4) No person may sell any food having in it or on it any miscellaneous additive unless it is a permitted miscellaneous additive which has been used, or is present, in or on that food without contravening any of the provisions of regulation 8(1), (2), (3), (4), (5), (7) or (8).

(5) No person may sell any relevant food additive in combination with a miscellaneous additive which has been used primarily as a carrier or carrier solvent unless that miscellaneous additive has been used in respect of that relevant food additive without contravening the provisions of regulation 8(6).

### **Transitional provisions and exemption**

**10.**—(1) In any proceedings for an offence consisting of a contravention of regulation 8(1) where it is alleged that a miscellaneous additive failed to satisfy the purity criteria for that additive, it is a defence for the accused to show—

- (a) that the miscellaneous additive concerned is E431-E43 or polyethylene glycol 6000 and that the miscellaneous additive concerned or any food in or on which it was used was placed on the market or labelled before 1 November 2004; or
- (b) that the miscellaneous additive concerned is E407, E407A, E1517 or E1519 and that the miscellaneous additive concerned or any food in or on which it was used was placed on the market or labelled before 1 April 2005,

and that the matter constituting the offence would not have constituted an offence under the Miscellaneous Food Additives Regulations 1995<sup>(21)</sup> had the amendments made to them by regulation 3 of the Miscellaneous Food Additives (Amendment) (Wales) Regulations 2005<sup>(22)</sup> not been in force when that matter occurred.

(2) In any proceedings for an offence consisting of a contravention of regulation 8 or 9 in respect of any food additive, food or flavouring, it is a defence to prove that—

- (a) the food additive, food or flavouring concerned was placed on the market or labelled before 27 January 2006; and
- (b) the matter constituting the offence would not have constituted an offence under the Miscellaneous Food Additives Regulations 1995 had the amendments made to them by regulations 3 to 6, 7(b), 8(a) and (b), 9(a), 10 and 11(a) to (c), (e) to (i) and (k) to (l) of the Miscellaneous Food Additives (Amendment) (No.2) (Wales) Regulations 2005<sup>(23)</sup> not been in force when the food additive, food or flavouring was placed on the market or labelled.

(3) In any proceedings for an offence consisting of a contravention of regulation 8 or 9 in respect of any food additive or food, it is a defence to prove that—

- (a) the food additive or food concerned was placed on the market or labelled before 15 August 2008; and
- (b) the matter constituting the offence would not have constituted an offence under the Miscellaneous Food Additives Regulations 1995 had the amendments made to them by regulations 5(a), 6(a), (b) and (d), and 8 of the Miscellaneous Food Additives and the Sweeteners in Food (Amendment) (Wales) Regulations 2008<sup>(24)</sup> not been in force when the food additive or food was placed on the market or labelled.

### **Placing on the market and use of sweeteners**

**11.**—(1) No person may place on the market any sweetener which is intended—

- (a) for sale to the ultimate consumer; or
- (b) for use in or on any food,

other than a permitted sweetener.

(2) No person may use any sweetener in or on any food except a permitted sweetener that—

- (a) is used in or any food that is listed in the third column of the Annex to Directive 94/35 in an amount not exceeding the maximum usable dose for that sweetener that is listed in relation to that food in the fourth column of that Annex; and

<sup>(21)</sup> S.I. 1995/3187 as amended.

<sup>(22)</sup> S.I. 2005/259 (W.25).

<sup>(23)</sup> S.I. 2005/1311 (W.93).

<sup>(24)</sup> S.I. 2008/138 (W.20).

(b) is listed in relation to that food in the second column of that Annex.

### **Sale of food containing sweeteners**

**12.** No person may sell any food having in or on it any sweetener other than a permitted sweetener which has been used in or on that food without contravening paragraph (2) of regulation 11.

### **Transitional provision**

**13.** In any proceedings for an offence consisting of a contravention of regulation 11 or 12, it is a defence to prove that—

- (a) the act constituting the offence was committed before 29 January 2006;
- (b) the act constituting the offence was that of—
  - (i) selling a sweetener or food, or
  - (ii) using a sweetener in or on food,which in either case was placed on the market before 29 July 2005; and
- (c) the act constituting the offence would not have constituted an offence under the Sweeteners in Food Regulations 1995<sup>(25)</sup> had the amendments made by regulations 3(1)(a) and (c) and (2) and 4, 5, 6 and 7 of the Sweeteners in Food (Amendment) (Wales) Regulations 2005<sup>(26)</sup> not been in force when the act occurred.

### **Offences and penalties**

**14.—(1)** A person who contravenes or fails to comply with any provision of regulation 3, 4, 5, 6, 8, 9, 11 or 12 is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(2) Subject to the transitional provisions contained in Article 34 of Regulation 1333/2008, a person who contravenes or fails to comply with—

- (a) any specified Regulation 1333/2008 provision;
- (b) before 1 January 2011, Article 4.2 (as read with Articles 12, 13.2, 18.3 and 35) of Regulation 1333/2008 (requirement to use, in food additives, food enzymes or food flavourings, only food additives included in Part 1 or 4 of Annex III to that Regulation and to use them in accordance with any conditions specified in that Annex);
- (c) on or after 1 January 2011, Article 4.2 (as read with Articles 12, 13.2, 18.3 and 35) of Regulation 1333/2008 (requirement to use, in food additives, food enzymes or food flavourings, only food additives included in Annex III to that Regulation and to use them in accordance with any conditions specified in that Annex);
- (d) on or after 20 January 2011, Article 23.4 of Regulation 1333/2008 (requirement that manufacturers of table-top sweeteners make available by appropriate means the information necessary to allow their safe use by consumers); or
- (e) on or after 20 July 2010, Article 24.1 (as read with Article 24.2 and the third paragraph of Article 31) of Regulation 1333/2008 (requirement that the labelling of food containing the food colours listed in Annex V to that Regulation include the additional information set out in that Annex),

is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

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<sup>(25)</sup> S.I. 1995/3123 as amended.

<sup>(26)</sup> S.I. 2005/1156 (W.73).

## Execution and enforcement

15. Each food authority will execute and enforce within its area these Regulations and Regulation 1333/2008.

## Application of various sections of the Food Safety Act 1990

16.—(1) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof is construed as a reference to these Regulations—

- (a) section 2 (extended meaning of sale etc.);
- (b) section 20 (offences due to fault of another person);
- (c) section 21 (defence of due diligence)(27) with the modification that—
  - (i) subsections (2) to (4) apply in relation to an offence under these Regulations as they apply in relation to an offence under section 14 or 15, and
  - (ii) in subsection (4)(b) the references to “sale” are deemed to include references to “placing on the market”;
- (d) section 22 (defence of publication in the course of business);
- (e) section 30(8) (which relates to documentary evidence);
- (f) section 35(1) (punishment of offences)(28), in so far as it relates to offences under section 33(1) as applied by paragraph (3)(b);
- (g) section 35(2) and (3)(29), in so far as it relates to offences under 33(2) as applied by paragraph (3)(c);
- (h) section 36 (offences by bodies corporate); and
- (i) section 36A (offences by Scottish partnerships)(30).

(2) In the application of section 32 of the Act (powers of entry) for the purposes of these Regulations, the references in subsection (1) to the Act are to be construed as including references to Regulation 1333/2008.

(3) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act is to be construed as including a reference to Regulation 1333/2008 and these Regulations—

- (a) section 3 (presumption that food is intended for human consumption) with the modification that the references to “sold” and “sale” are deemed to include references to “placed on the market” and “placing on the market” respectively;
- (b) section 33(1) (obstruction etc.of officers);
- (c) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” is deemed to be a reference to any such requirement as is mentioned in that subsection as applied by sub-paragraph (b); and
- (d) section 44 (protection of officers acting in good faith).

(4) Section 34 of the Act (time limit for prosecutions) applies to offences under these Regulations as it applies to offences punishable under section 35(2) of the Act.

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(27) Section 21 was amended by S.I. 2004/3279.

(28) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c. 44), Schedule 26, para 42, from a date to be appointed.

(29) Section 35(3) was amended by S.I. 2004/3279.

(30) Section 36A was inserted by the 1999 Act, Schedule 5, paragraph 16.

## Condemnation of food

17. Where any food is certified by a food analyst as being food which it is an offence under these Regulations to use, sell, or place on the market, that food may be treated for the purposes of section 9 of the Act (under which food may be seized and destroyed under an order of a justice of the peace) as failing to comply with food safety requirements.

## Consequential amendments

18.—(1) In the Mineral Hydrocarbons in Food Regulations 1966(31) in regulation 3 (exemptions), for sub-paragraph (d) of paragraph (1), in so far as that provision applies to Wales, there is substituted the following sub-paragraph—

“(d) any food containing mineral hydrocarbon that is used in the food as a miscellaneous additive as defined in the Food Additives (Wales) Regulations 2009 in compliance with the provisions of those Regulations.”.

(2) In the Fruit Juices and Fruit Nectars (Wales) Regulations 2003(32), for paragraph 6 of Schedule 3 (additional ingredients permitted in particular designated products) there is substituted the following paragraph—

“6. In any designated product, any substance permitted pursuant to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives may be added.”.

(3) In the Condensed Milk and Dried Milk (Wales) Regulations 2003(33) for paragraph (a) of Note 1 to Schedule 1 (partly or wholly dehydrated preserved milk products and their reserved descriptions) there is substituted the following Note—

“(a) Any designated product may contain—

- (i) any substance permitted pursuant to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives, and
- (ii) vitamins and minerals in accordance with the requirements of Regulation (EC) No. 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods(34).”.

(4) In the Meat Products (Wales) Regulations 2004(35), for the first Note to Schedule 3 (added ingredients which are not required to be indicated in the name of the food in the case of a meat product to which regulation 5 applies) there is substituted the following Note—

“For the purposes of item 1 of this Schedule, “additive” means any substance permitted for use in food pursuant to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives or Regulation (EC) No. 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No. 1601/91, Regulations (EC) No. 2232/96 and (EC) No. 110/2008 and Directive 2000/13/EC.”(36).

(5) In the Jam and Similar Products (Wales) Regulations 2004(37)—

(a) in paragraph (1) of regulation 2 (interpretation) for the definition of “permitted sweetener” there is substituted the following definition—

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(31) S.I. 1966/1073 as amended.

(32) S.I. 2003/3041 (W.286).

(33) S.I. 2003/3053 (W.291) as amended.

(34) OJ No. L404, 30.12.2006, p.26, as amended by Regulation (EC) No. 108/2008 of the European Parliament and of the Council amending Regulation (EC) No. 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ No. L39, 13.2.2008, p.11).

(35) S.I. 2004/1396 (W.141) as amended.

(36) OJ No. L354, 31.12.2008, p.34.

(37) S.I. 2004/553 (W.56).

““permitted sweetener” (“*melysydd a ganiateir*”) means any sweetener in so far as its use is permitted in specified jam or similar product by the Food Additives (Wales) Regulations 2009;” and

- (b) in Schedule 2 (permitted additional ingredients and authorised treatments for products described in items 1 to 7 of Schedule 1), for sub-paragraph (m) of paragraph (1) there is substituted the following sub-paragraph—

“(m) any substance permitted pursuant to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives.”.

### **Amendment of the Specified Sugar Products (Wales) Regulations 2003**

**19.** In the Specified Sugar Products (Wales) Regulations 2003<sup>(38)</sup>, for Note 7 to Schedule 1 (specified sugar products and their reserved descriptions) there is substituted the following Note—

“**7.** Specified sugar products may contain any substance permitted pursuant 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 (Recast)<sup>(39)</sup> or Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives.”.

### **Revocations**

**20.** The following Regulations are revoked in so far as they apply to Wales—

- (a) the Food Additives Labelling Regulations 1992<sup>(40)</sup>;
- (b) the Sweeteners in Food Regulations 1995;
- (c) the Colours in Food Regulations 1995; and
- (d) the Miscellaneous Food Additives Regulations 1995.

*Gwenda Thomas*  
Deputy Minister for Social Services under  
authority of the Minister for Health and Social  
Services, one of the Welsh Ministers

21 December 2009

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<sup>(38)</sup> S.I. 2003/3047 (W.290).

<sup>(39)</sup> OJ No. L141, 6.6.2009, p.3.

<sup>(40)</sup> S.I. 1992/1978 as amended.

## THE SCHEDULE

Regulation 2(1)

### SPECIFIED REGULATION 1333/2008 PROVISIONS

Provision of Regulation 1333/2008	Subject — matter
Article 4.1 (as read with Articles 11.3 and 4, 12, 13.2, 15, 16 and 18.1(a), 2 and 3)	Requirement that only food additives included in the list in Annex II to Regulation 1333/2008 be placed on the market as such and that they be used in accordance with any conditions specified in that Annex.
Article 4.5	Requirement that food additives comply with the specifications referred to in Article 14 of Regulation 1333/2008.
Article 5	Prohibition on placing on the market of food additives or food containing food additives if the use of the food additive does not comply with Regulation 1333/2008.
Article 11.2	Requirement to use food additives in accordance with the <i>quantum satis</i> principle where no maximum numerical level fixed for the additive concerned.
Article 15	Prohibition on use of food additives in unprocessed foods except where provided in Annex II to Regulation 1333/2008.
Article 16	Prohibition on use of food additives in foods for infants and young children (including dietary foods for infants and young children for special medical purposes) except where provided in Annex II to Regulation 1333/2008.
Article 17	Requirement to use only food colours listed in Annex II to Regulation 1333/2008 for the purpose of health marking meat or meat products, decorative colouring of eggshells or stamping of eggshells.
Article 18.1(b) (as read with Article 18.2)	Requirement that food additives be present in food to which a food additive, food enzyme or food flavouring has been added, only if the additive is permitted in the additive, enzyme or flavouring under Regulation 1333/2008, has been carried over to the food via the additive, enzyme or flavouring and has no technological function in the final food.
Article 18.1(c) (as read with Article 18.2)	Requirement that food additives be present in foods to be used solely in the preparation of a compound food only if the compound food complies with Regulation 1333/2008.
Article 18.4	Requirement that food additives be used as sweeteners in compound foods with no added

Provision of Regulation 1333/2008	Subject — matter
	sugars, energy reduced compound foods with no added sugars, energy reduced compound foods, compound dietary foods intended for low calorie diets, non cariogenic compound foods and compound foods with an increased shelf life only if the sweetener is permitted in any of the ingredients of the compound food.
Article 21.1	Requirement that food additives not intended for sale to the final consumer be labelled, in accordance with Article 22 of Regulation 1333/2008, visibly, clearly legibly and indelibly and in a language easily understandable to purchasers.
Article 22.1 (as read with Article 22.4 and 5 and the second paragraph of Article 31)	Requirement that food additives not intended for sale to the final consumer be sold only if their packaging or containers bear specified information.
Article 22.2 (as read with Article 22.4 and 5 and the second paragraph of Article 31)	Requirement that food additives mixed with each other and/or with other food ingredients be sold only if their packaging or containers bear a list of ingredients in descending order of their percentage weight of the total.
Article 22.3 (as read with Article 22.4 and 5 and the second paragraph of Article 31)	Requirement that, where substances (including food additives or other food ingredients) are added to food additives to facilitate their storage, sale, standardisation or dissolution, their packaging or containers bear a list of all such substances in descending order of their percentage by weight of the total.
Article 23.1 (as read with Article 23.2 and 5)	Prohibition on marketing of food additives sold singly or mixed with each other and/or other food ingredients and intended for sale to the final consumer unless their packaging contains specified information.
Article 23.3 (as read with Article 23.5)	Requirement that the labelling of table-top sweeteners containing polyols and/or aspartame and/or aspartame — acesulfame salt bear specified warnings.
Article 26.1	Requirement that producers and users of food additives inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the food additive concerned.
Article 26.2	Requirement that producers and users of food additives, at the request of the Commission, inform it of the actual use of the food additive concerned.

## EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations apply in relation to Wales. They revoke in so far as they apply to Wales the Food Additives Labelling Regulations 1992 (S.I.1992/1978), the Sweeteners in Food Regulations 1995 (S.I. 1995/3123), the Colours in Food Regulations 1995 (S.I. 1995/3124) and the Miscellaneous Food Additives Regulations 1995 (S.I. 1995/3187)(each of which extends to the whole of Great Britain) and re-enact with changes and on a transitional basis certain provisions of the last three of those instruments.

2. These Regulations provide for the execution and enforcement in relation to Wales of Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives (OJ No. L354, 31.12.2008, p.16) (“the Regulation”) and give effect in Wales to Commission Directive 2009/10/EC amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners (OJ No. L44, 14.2.2009, p.62).

3. These Regulations prohibit—

- (a) the use in or on any food of any colour other than a permitted colour and the use of any permitted colour unless specified requirements are satisfied (the terms “colour” and “permitted colour” are defined in regulation 2(1)) (*regulation 3*);
- (b) the use for health marking and other marking of certain meat and meat products of colours other than certain permitted colours (*regulation 4*);
- (c) the use of a colour for the decorative colouring of eggshells or the marking of eggshells as provided for in a specified EU instrument other than a permitted colour (*regulation 5*);
- (d) the sale—
  - (i) of any colour for use in or on any food unless the colour is a permitted colour,
  - (ii) direct to consumers of any colour other than a specified permitted colour (the term “specified permitted colour” is defined in regulation 2(1)), or
  - (iii) of any food having in or on it any colour other than a permitted colour that has been used in or on the food without contravening specified provisions of these Regulations (*regulation 6*);
- (e) the use in or on any food of any miscellaneous additive other than a permitted miscellaneous additive (the terms “miscellaneous additive” and “permitted miscellaneous additive” are defined in regulation 2(1)) (*regulation 8(1)*);
- (f) subject to a specified EU provision, the use of a permitted miscellaneous additive listed elsewhere in the EU instrument in which that provision appears in or on a food listed in a specified part of that instrument (*regulation 8(2)*);
- (g) subject to a specified EU provision in the case of the prohibition imposed by regulation 8(3), the use of certain permitted miscellaneous additives in or on specified foods unless specified requirements are satisfied (*regulation 8(3), (4) and (5)*);
- (h) the use of any miscellaneous additive primarily as a carrier or carrier solvent unless the additive is a permitted miscellaneous additive listed in a specified EU provision and its use complies with the restrictions, if any, mentioned in relation to the additive in that provision (the terms “carrier” and “carrier solvent” are defined in regulation 2(1)) (*regulation 8(6)*);

- (i) subject to a specified EU provision, the use of any permitted miscellaneous additive in or on food for infants or young children unless it is listed in a specified EU provision and it is used only in accordance with the conditions contained in that provision (the term “food for infants or young children” is defined in regulation 2(1)) (*regulation 8(7)*);
  - (j) the use in or on any food for infants or young children of any relevant food additive in combination with a miscellaneous additive used primarily as a carrier or carrier solvent unless the miscellaneous food additive is listed in a specified EU provision and its presence in or on the food is in accordance with the conditions contained in that provision (the term “relevant food additive” is defined in regulation 2(1)) (*regulation 8(8)*);
  - (k) the sale of any miscellaneous additive for use in or on food other than a permitted miscellaneous additive (*regulation 9(1)*);
  - (l) the sale of any miscellaneous additive for use primarily as a carrier or carrier solvent unless the additive is a certain type of permitted miscellaneous additive (*regulation 9(2)*);
  - (m) the sale direct to consumers of any miscellaneous additive other than a permitted miscellaneous additive (*regulation 9(3)*);
  - (n) the sale of any food having in or on it any miscellaneous additive other than a permitted miscellaneous additive which has been used or is present in or on the food without contravening specified provisions of these Regulations (*regulation 9(4)*);
  - (o) the sale of any relevant food additive in combination with a miscellaneous additive used primarily as a carrier or carrier solvent unless the miscellaneous additive has been used in respect of the relevant food additive without contravening the requirements of regulation 8(6) (*regulation 9(5)*);
  - (p) the placing on the market of any sweetener intended for sale to the ultimate consumer or for use in or on any food other than a permitted sweetener (the terms “sweetener” and “permitted sweetener” are defined in regulation 2(1)) (*regulation 11(1)*);
  - (q) the use of any sweetener in or on any food other than a permitted sweetener which—
    - (i) is used in or on a food listed in a specified EU provision in an amount not exceeding the maximum usable dose for the sweetener that is listed in relation to that food in that provision, and
    - (ii) is listed in relation to that food in that provision (*regulation 11(2)*); and
  - (r) the sale of any food having in or on it any sweetener other than a permitted sweetener which has been used in or on the food without contravening regulation 11(2) (*regulation 12*).
4. These Regulations also—
- (a) re-enact with changes on a transitional basis (see paragraph 1 above) certain provisions included in the Sweeteners in Food Regulations 1995, the Colours in Food Regulations 1995 and the Miscellaneous Food Additives Regulations 1995 (*regulations 7, 10 and 13*);
  - (b) provide that a person who contravenes or fails to comply with specified provisions of these Regulations or (subject to a transitional provision contained in Article 34 of the Regulation) the Regulation, is guilty of a summary offence and liable on conviction to a fine not exceeding level 5 on the standard scale (£5,000) (*regulation 14*);
  - (c) make provision for the execution and enforcement of these Regulations and the Regulation (*regulation 15*);
  - (d) apply with modifications for the purposes of these Regulations certain provisions of the Food Safety Act 1990 (*regulation 16*);
  - (e) provide that, where food is certified as being food which it is an offence under these Regulations to use, sell or place on the market, the food will be treated for the purposes of

section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements (*regulation 17*);

- (f) make consequential amendments to the Mineral Hydrocarbons in Food Regulations 19 in so far as they apply in relation to Wales (S.I. [1966/1073](#)), the Fruit Juices and Fruit Nectars (Wales) Regulations 2003 (S.I. [2003/3041](#) (W.286)), the Condensed Milk and Dried Milk (Wales) Regulations 2003 (S.I. [2003/3053](#) (W.291)), the Meat Products (Wales) Regulations 2004 (S.I. [2004/139](#) (W.141)) and the Jam and Similar Products (Wales) Regulations 2004 (S.I. [2004/553](#) (W.56)) (*regulation 18*); and
- (g) make a minor amendment to the Specified Sugar Products (Wales) Regulations 2003 (S.I. [2003/3047](#) (W.290)) (*regulation 19*).

**5.** A full regulatory impact assessment has been undertaken in respect of these Regulations and is available from the Food Standards Agency, 11th Floor Southgate House, Cardiff, CF10 1EW.