Explanatory Memorandum to The Food Additives (Wales) Regulations 2009.

This Explanatory Memorandum has been prepared by the Food Standards Agency Wales and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 24.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Food Additives (Wales) Regulations 2009. I am satisfied that the benefits outweigh any costs.

GWENDA THOMAS A.M
Deputy Minister for Health and Social Services

21 December 2009

1. Description

The instrument enforces Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives in relation to food additives which protect consumer health by ensuring that products put into foods for a technological purpose have been evaluated for safety, and facilitates trade. The instrument also implements Directive 2009/10/EC amending Directive 2008/84/EC on purity criteria for additives other than sweeteners and colours.

2. Matters of special interest to the Subordinate Legislation Committee

None.

3. Legislative background

Welsh Ministers have the powers to make these Regulations under sections 16(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 enable these Regulations to be made. Functions transferred to the National Assembly for Wales are now exercisable by Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006.

Current food additives legislation is complex and amendments are by co-decision of the European Council and Parliament. Regulation (EC) No. 1333/2008 will revoke and re-enact on a transitional basis certain (but not all) provisions of three separate EC Directives (95/2/EC on food additives other than colours and sweeteners, 94/35/EC on sweeteners for use in foods and 94/36/EC on colours for use in foods) and introduce the comitology route[1] for amendment to the Annexes to those Directives. The transitional phase will end once additives currently approved under those Directives are transferred to the relevant Annexes to the Regulation – by June 2011, at which point compliance with the provisions of the Regulation will be required instead of compliance with the surviving provisions of the Directives.

As indicated above, these Regulations will also implement Directive 2009/10. Details are provided in the Annex to this Memorandum as to how that will be achieved.

4. Purpose & intended effect of the legislation

Consumers need to be confident that their food is safe to eat and that they can make an informed choice about what they consume.

Food additives legislation has been subject to harmonised legislative EC controls since 1994/5 in order to maintain a high level of consumer protection and to ensure the free movement of safe and wholesome food. Regulation (EC) No. 1333/2008 offers rationalisation of the current complex legislation, which has been subject to more than 6 amendments, and permits amendments to the positive list of food additives by the comitology route. Moreover, provisions in the Regulation provide additional safeguards on additive use for consumers i.e. controls on the use of

[1] Regulatory Procedure with Scrutiny, subject to any consequent change from the Lisbon Treaty.

additives in additives, additional requirements for the authorisation of additives derived from Genetically Modified Organisms (GMOs) and the addition of a mandatory warning label for six colours which were identified by an FSA funded study carried out by Southampton University, as possibly having an adverse effect on children's behaviour.

In the interest of clarity and efficiency, current food additives legislation has been replaced by Regulation (EC) No. 1333/2008 of the European Parliament and of the Council of 16 December 2008 on Food Additives.

The UK has negotiated in Council during development of these provisions and supports the published Regulation. As an EC Regulation it is directly applicable in the UK, i.e. it has the force of law automatically in the UK, however Statutory Instruments (SI) are required in each of England, Scotland, Wales and Northern Ireland. The first (The Food Additives Regulations 2009) is to enforce the EC Regulation and prescribe penalties for non-compliance. A second, separate SI (The Food (Jelly Mini-cups) (Emergency Control) Regulations 2009) is required to ensure legal continuity with regard to these products. The substantive requirements relating to jelly mini-cups with which it is necessary to comply, however, are not changed at all.

The EC Regulation is part of a package of European Parliament and Council measures on Food Improvement Agents (the other Regulations cover enzymes and flavourings). A single EC Regulation on food additives has been adopted which is intended to replace and repeal, subject to transitional provisions, Directive 89/107/EEC (the food additives framework Directive), Directives 95/2/EC on food additives other than colours and sweeteners, Directive 94/35/EC on sweeteners for use in foodstuffs and Directive 94/36/EC on colours for use in foodstuffs.

The key objectives of the measure are as follows:

- To simplify food additives legislation by creating a single instrument for principles for authorisation and use of additives.

- To confer on the Commission powers to update the EC list of authorised food additives (this is currently carried out under co-decision procedure).

- To make clear the role of the European Food Safety Authority (EFSA) in the evaluation of the safety aspects of food additives.

- To require the authorisation under Regulation (EC) No. 1829/2003 on GM food and feed of additives that consist of, contain, or are produced from a GMO.

- To introduce controls over the use of all additives used in other additives and in enzymes, and carriers used in nutrients (currently only certain additives are controlled when used in other additives and in flavourings).

- To introduce new rules so that food (and drink) placed on the market containing any of the 6 colours used in the study carried out by Southampton University

should carry additional label information that consumption may have an adverse effect on activity and attention in children.

Regulation (EC) No. 1333/2008 is directly applicable in the UK; however a Welsh Statutory Instrument (SI) is required to enforce the Regulation and identify penalties for non-compliance in Wales. The Food Additives (Wales) Regulations 2009 make it an offence to place on the market, use or fail to label a food colour, miscellaneous food additive or sweetener that is not on the approved EC list as contained in the Annexes to Regulation (EC) No. 1333/2008. Definitions of 'food colour', 'miscellaneous food additive' and 'sweetener' are provided in the EC Regulation. Separate but parallel legislation will be made for England, Scotland and Northern Ireland.

5. Consultation

In September 2006 the FSA launched a 12 week public consultation on the Commission's proposal for a new Enzyme Regulation (as well as the rest of the Food Improvement Agents Package). Across the UK, approximately 450 stakeholders were consulted and 22 responses were received. A proportion of these related to food additives and consumer groups and industry were generally content with the proposal. There were no responses to the consultation from stakeholders in Wales.

Consumer representatives have welcomed the review of the legislation. However they have some concerns as to whether authorisation of individual additives should be by comitology rather than co-decision, considering the latter may be more open and transparent. They would like to see clear, transparent criteria by which authorisation decisions will be made and they are in favour of an automatic ten-year review of additives., However, we feel that the agreed on-going evaluation will provide a more focused risk-based solution which is proportionate and allows action to be taken sooner, if concerns arise. In response to consumer views, it has been made clear in the legislation that the Commission is to consult widely on the authorisation of new additives and that where the Commission disagrees with an EFSA opinion, it is to explain its reasoning openly.

Industry has generally welcomed the proposals which will simplify existing legislation. Their key views are support for the simplification of existing legislation and for the move to comitology. (They are concerned about the costs of data provision during re-evaluation of a substance. However, the re-evaluation of all existing food additives by the European Food Safety Authority is already underway and will continue regardless of whether this proposal is adopted. Any costs arising from the re-evaluation are not a result of this proposal and so have not been factored into the RIA.)

The enforcement authorities have also welcomed the proposed simplification of the legislation.

In July 2009, the FSA consulted publically for 12 weeks, on the new SI on food enzymes. Across the UK, approximately 450 stakeholders were consulted. Only one response was directly relevant to the food additives SI: the Local Authority Co-ordinators of Regulatory Services (LACORS) UK provided comments on the text of

the SI and these have been considered when drafting the final SI. There were no responses to the consultation from stakeholders in Wales.

REGULATORY IMPACT ASSESSMENT

6. Options

1) Do nothing. Food additives would continue to be regulated subject to the current provisions.

2) Accept the EC Regulation as drafted and provide for its enforcement in the UK.

Option 2 is preferred. This option will ensure that the UK is in line with the EC and will ensure a high level of protection for consumers. Industry can continue to benefit from uniform safety measures and free trade across the European Community.

7. Costs & benefits

Benefits

Option 1 **–** Under this option, the current legislation would remain in place, with which industry and enforcement authorities are familiar. There are therefore no incremental benefits to this option.

Option 2 – This option would benefit:-

- food manufacturing industry and the enforcement authorities because of the consolidation and simplification of this much revised legislation (the sweeteners Directive has been amended three times, and the miscellaneous additives Directive six times). The Commission is proposing to replace the 11 Annexes in the three Directives listing permitted additives and the foods in which they can be used with two Annexes in the new Regulation. This will be based on the Codex General Standard on Food Additives (GSFA) food categorisation system and will contain a comprehensive list of foods and show all the additives (colours, sweeteners and miscellaneous additives) that can be used in each type of food and the levels of use. Both industry and enforcement authorities will benefit from this change to the current Annexes (which list foods and permitted additives in an unsystematic way) as they will be able to see at a glance which additives are permitted in which food. We estimate that the changes being made are likely to save an organisation one person-day per year[2] with total savings in the order of £1.23 million per year.
- the food additives supply industry and consumers, because a change to comitology in decision-making may permit a new additive, or a new use for an existing additive, to be brought to market up to 12 months earlier than if decision-making by co-decision is maintained. Benefits would arise from the improved product being available for a longer time period

[2] Median hourly wage rates excluding overtime (2008) for Science and Technology professionals of £17.83 (£23.18 including overheads at 30% in line with standard cost model) and Environmental Health Officers £14.94 (£19.42 including overheads) (source: Annual Survey of Household Earnings (2008)); 7 hr day; 7,195 UK food manufacturing companies (source: Inter-Departmental Business Register 2008) and 469 UK local authorities.

- consumers and industry by making clear the authorisation route for additives which fall within scope of Regulation (EC) No. 1829/2003 on GM food and feed. There are currently none of these but the number could grow as industry innovates.
- consumers by introducing controls on all additives used in other additives. This will ensure consumers are not exposed to additives used in such situations which have not been properly assessed.
- consumers (particularly parents of young children) by introducing a compulsory warning on foods containing the six "Southampton" colours which will alert them to the possible effects on their children.
- the UK by not being out of step with the EC and so not vulnerable to infraction proceedings.

Costs

Option 1 - There would be no new direct costs to industry.

Option 2 – There are new controls on additives used in additives, new labelling requirements.

The Food Additive and Ingredient Association consider there will be no extra costs from the control of additives within additives. This is because only a small group of chemicals are currently being used in this way and because they are already approved as additives (eg preservatives) in their own right.

We have no indication from industry of the magnitude of additional costs arising from the new requirement for the compulsory warning labelling of the 6 Southampton study colours. Whilst the Agency is working with industry to achieve a voluntary withdrawal of these colours from all food and drink by the end of 2009, we understand that there are around 1000 products on the UK market which still contain these colours (Food Commission, January 2009). Any company whose products still contain these colours will need to make appropriate labelling changes.

Products that contain one or a combination of the 6 Southampton colours tend to be confectionary, cakes, cereals and snacks. Information on the frequency at which businesses re-label products in these categories is limited. Discussions between the Agency and stakeholders have indicated that a re-labelling cycle of 3 years would be a reasonable assumption, and re-labelling costs tend to fall in the range of £1,000 - £1,500 per product.

	Cost per product (£)		Total cost (£)	
No. of products	**Lower bound**	**Upper bound**	**Lower bound**	**Upper bound**
1,000	1,000	1,500	1,000,000	1,500,000
667	1,000	1,500	667,000	1,000,000
333	1,000	1,500	333,000	500,000

Estimates of the total cost of re-labelling are detailed in the above table. The number of products currently containing the 6 Southampton colours is estimated at 1,000. The upper and lower bound of the total costs are calculated by multiplying the number of products by the upper and lower bounds of the cost per product respectively (£1,000 and £1,500). Assuming a 3 year re-labelling cycle it is likely

that some products will be re-labelled as part of their re-labelling cycle before July 2010 when the legislation will come into force. It is also likely that in anticipation of the forthcoming legislation that these re-labelled products will display information relating to the Southampton colours. As this would be part of the standard re-labelling cycle for these products, the associated costs are not a result of the legislation. We assume that 33% (1/3) of the applicable products will be re-labelled before the legislation comes into force. However, we estimate that about 67% (2/3) of products will require re-labelling when the legislation comes into force and this will not be within their usual cycle and hence the new requirements incur additional costs for 667 products. Taking the mid point of the upper and lower bound of the total cost gives a best estimate of the one off total cost to industry of re-labelling of approximately £830,000.

It is thought that the one-off costs incurred by businesses and local authorities from time taken to become familiar with the new regulations will be a total of £0.5 million.[3]

Summary table of costs and benefits – (Option 2)

Change	**Benefit**	**Cost**
Consolidation/Simplification of existing legislation	Estimated to be £1.23 million per year savings for industry and enforcement bodies.	Estimated to be a one off cost of £0.5 million for industry and enforcement bodies.
Move from co-decision to comitology	Savings for industry –likely to be in the region of hundreds of thousands of pounds for each new additive.	0
Clear authorisation route for additives which fall within scope of Regulation 1829/2003 on GM food and feed.	Ensures consumer protection.	0
Controls on additives used in additives.	Ensures consumer protection.	0
Labelling of 6 Southampton Study colours	Ensures consumer protection	Estimated to be a one off cost of £0.83 million to industry.

Overall we estimate the savings outweigh the costs of this proposal.

Administrative Burden Costs

[3] Median hourly wage rates excluding overtime (2008) for Science and Technology professionals of £17.83 (£23.18 including overheads at 30% in line with standard cost model) and Environmental Health Officers £14.94 (£19.42 including overheads) (source: Annual Survey of Household Earnings (2008)); time required 3 hrs per organisation, 7,195 UK food manufacturing companies (source: Inter-Departmental Business Register 2008) and 469 UK local authorities.

This Regulation will introduce two new information obligations (IO) on industry to provide the Commission with safety and usage information on food additives.

The first IO is a requirement for producers or users of food additives, when requested, to inform the Commission of the actual use of a food additive i.e. the categories of food in which it is used, and the levels. EC law (Regulation (EC) No. 178/2002) already requires a comprehensive system of traceability within food businesses, and so we anticipate no new incremental costs.

The second IO requires a producer or user of a food additive to inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the food additive. Information obtained from business on similar information obligations during the Administrative Burdens Measurement Exercise carried out in 2005 suggests that the administrative cost, over and above what a business would do commercially, of providing a dossier to the Commission would be £9 each time. The requirement is likely to be a contingent and rare requirement which will not be a regular burden on industry.

We consider the cost of these new information obligations is justified because of the continued consumer protection they bring.

8. Competition Assessment

The Regulation could potentially affect competition in the markets for intense sweeteners, colours, and preservatives. However, application of the competition filter test indicated that the impact on competition is likely to be small in all three markets. Although the three markets are highly concentrated, with three firms accounting for more than half of the market in the sweeteners and colours markets, there is no reason to believe the proposal would affect some firms disproportionately and modify the structure of the market. By simplifying existing legislation and shortening the time needed to bring a new additive to market, the proposal would also lower barriers to entry into the sector, which would tend to increase competition. The proposed simplification should also have a positive impact on innovation and technological change in the additives sector.

<u>Small Firms Impact Test</u>

Two SMEs in the UK, both manufacturers of colours, have been identified and were consulted on the Commission's original proposal.

The first small business is a manufacturer of food colours which currently produces 12 synthetic colours that are sold throughout the world, and 15 natural colours that are only sold within the EC. The major issue cited by the company was possible costs emanating from the EFSA safety assessment of colours. As indicated earlier these costs have not been included in this RIA as the EFSA review will continue regardless of adoption of this new Regulation.

The second company is a manufacturer of food additives and ingredients, employing 30 staff, with an annual turnover of £5 – 10 million. The contact in the company was unable to identify any significant impact on his business.

9. Post implementation review

Regulation (EC) No. 1333/2008 came into force on 20 January 2009 and applies from 20 January 2010, although some provisions will apply after this date. The requirement for the labelling of the six Southampton study colours will not apply until 20 July 2010. In addition, new controls on the use of additives, of additives in enzymes, and of carriers in nutrients will apply from 1 January 2011. It will be implemented in the UK by secondary legislation which will include enforcement provisions. Separate but parallel legislation is required for England, Scotland, Wales and Northern Ireland.

The new Regulation will be reviewed, in the UK, after 5 years of coming into force. This will allow time for all of its provisions to apply and for any transitional periods to expire.

ANNEX

1. Regulations 8 and 9 of the instrument regulate the use of any "miscellaneous additive" (as defined in regulation 2(1)) and the sale of food additives and food containing miscellaneous additives respectively. In so doing, they carry forward requirements of Directive 95/2/EC which, by virtue of Regulation 1333/2008, preserve during the transitional phase referred to in this Memorandum certain provisions of that Directive.

2. Key requirements are that any miscellaneous additive used in or on food or sold for use in or on food must be a "permitted miscellaneous additive" (as defined in regulation 2(1)).

3. By virtue of the latter definition, a permitted miscellaneous additive is any one of a number of specified additives which also meets the "purity criteria" for that additive.

4. All additives approved within the EU have to comply with specific purity criteria, which define the chemical composition of each additive and ensure the quality and safety of additives used. Although for certain additives the specification will define the source and /or method of manufacture, for the majority this is not the case.

5. In the case of miscellaneous additives, by virtue of the definition of "purity criteria" in regulation 2(1), the purity criteria for individual miscellaneous additives are those prescribed by Commission Directive 2008/84/EC laying down specific purity criteria concerning colours for use in foodstuffs.

6. That Directive has recently been amended by Directive 2009/10/EC.

7. Article 1 of the amending Directive amends the Annex to Directive 2008/84 by substituting revised / added purity criteria for specified additives.

8. Article 2 of the amending Directive requires member States to implement it by 13 February 2009.

9. The instrument to which this memorandum relates implements the amending Directive with effect from 20 January 2010, not 13 February. It therefore goes beyond what is required to implement the Directive.

10. The Food Standards Agency considers that this earlier implementation is justified, given that it does not consider that the requirements of the amending Directive are particularly onerous, that it is considered that those affected by those requirements are likely already to be in a position to comply with them and that implementation is only 24 days sooner than the latest possible date for implementation.

11. Implementation is not effected by a specific implementing provision in the instrument. Rather it is achieved by virtue of the definitions referred to above, and

in particular the definition of “purity criteria” referred to in paragraph 5 of this Annex – read in conjunction with section 20A of the Interpretation Act 1978.

12. Under section 20A, a reference in subordinate legislation to a Community instrument has effect, unless the contrary intention is shown, as a reference to that instrument as amended at the date the subordinate legislation making the reference is signed.

13. Consequently, the reference to Directive 2008/84/EC in the definition of “purity criteria” referred to in paragraph 5 of this Annex should be read as a reference to that Directive as amended by Directive 2009/10/EC.