EXPLANATORY MEMORANDUM TO

THE FOOD ADDITIVES (ENGLAND) REGULATIONS 2009

2009 No. 3238

1. This explanatory memorandum has been prepared by The Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The instrument enforces Regulation 1333/2008 of the European Parliament and of the Council on food additives in relation to food additives which protects 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 amending Directive 2008/84 on purity criteria for additives other than sweeteners and colours.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 Current food additives legislation is complex and amendments are by co-decision of the European Council and Parliament. Regulation 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.

4.2 As indicated above, the instrument will also implement Directive 2009/10. By way of a transposition note, details are provided in the Annex to this Memorandum as to how that will be achieved.

5. Territorial Extent and Application

5.1 This instrument applies to England. Separate S.I.s will be established for Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

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

7. Policy background

- ***What is being done and why***

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

7.2 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 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 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.

- ***Consolidation***

7.3 The EC Directives mentioned in 4.1 above, on food additives, colours and sweeteners have been amended a number of times. In the interests of clarity and efficiency, Regulation (EC)1333/2008 will rationalise the current complex legislation by revoking and re-enacting certain (but not all) provisions of these three separate EC Directives in a single Regulation.

8. Consultation outcome

8.1 Within Government

We have consulted Defra, the Better Regulation Executive and the Small Business Service. Local Authorities will be responsible for enforcement of these measures and their coordinating body was consulted as part of the full public consultation on the Commission proposal and on the enforcement SI.

8.2 Public Consultation

In September 2006, the FSA launched a 12 week public consultation on the Commission's proposal for a new Additives Regulation. 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. A summary of specific responses can be found at **http://www.food.gov.uk/consultations/consulteng/2006/?completed=Yes.**

In July 2009, the FSA consulted publically for 12 weeks on the instrument to which this Memorandum relates. Approximately 450 stakeholders were consulted. Only one response was received: LACORS (Local Authority Co-ordinators of Regulatory Services) offered comments on the clarity of the SI and these have been considered when drafting the final SI. Whilst we have some sympathy with LACORs comments, there will inevitably be a degree of complexity in the SI during the transitional phase, whilst certain provisions of the current Directives remain applicable. This arises from the need to implement the transitional provisions. Simplification of the SI will be possible once the transitional provisions no longer apply.

9. Guidance

9.1 Much of the detailed controls on additives (levels of use and types of food where they can be used) are specified in Annexes to existing legislation which will not be altered until the first half of 2011. In the meantime, the Government is working with the European Commission, other Member States and Stakeholders to simplify and clarify the Annexes. In light of this work, the Government will consider whether further guidance is necessary in the first half of 2011.

10. Impact

10.1 An Impact Assessment is attached to this memorandum.

11. Regulating small business

11.1 The legislation applies to small businesses. Two small businesses have been identified and consulted. Neither identified any significant impact on business emanating directly from Regulation 1333/2008.

12. Monitoring & review

12.1 The policy will be reviewed by UK Government 5 years after the Additive Regulation comes into force. This will allow time for all of its provisions to apply and for any transitional periods to expire.

13. Contact

Glynis Griffiths at the Food Standards Agency. Tel: 020 7276 8556 or email: glynis.griffiths@foodstandards.gsi.gov.uk, can answer any queries regarding the instrument.

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, when the instrument to which this memorandum relates is signed, 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.

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	**Impact Assessment of a draft proposal for a Regulation of the European Parliament and of the Council on Food Additives**	
Stage: Final	**Version:** 9	**Date:** 23 November 2009

Related Publications: Additives Regulation 1333:http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2008:354:SOM:EN:HTML
European Commission Impact Assessment: http://ec.europa.eu/food/food/chemicalsafety/additives/ia425.pdf

Available to view or download at:

http://www.food.gov.uk/consultations/

Contact for enquiries: Glynis Griffiths **Telephone:** 020 7276 8556

What is the problem under consideration? Why is government intervention necessary?

Consumers need to be confident that their food is safe to eat and that they can make an informed choice about what they consume. Government intervention is required to: protect consumer health by ensuring that the only products put into foods for a technological purpose have been evaluated for safety; to allow consumers to make an informed choice about what they eat through affective labelling; and to facilitate trade.

Current food additives legislation is complex. Intervention will simplify and consolidate three separate EC Directives and introduce the shorter comitology route for amendments to the Annexes, together with various other provisions beneficial to consumers.

What are the policy objectives and the intended effects?

Policy objectives include the creation of a single instrument for principles for authorisation and use of additives; the introduction of comitology to update the list of permitted additives; new requirements for the authorisation of GMO additives; new controls over the use of additives used in additives, and new labelling requirements for six specific food colours which were the subject of a study by Southampton University to investigate their effect on hyperactivity in children.

Intended effects include simplifed legislation, a faster approval system for food additives, and a number of additional safeguards for consumers.

What policy options have been considered? Please justify any preferred option.

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.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

In the UK, after 5 years of the Additives Regulation coming into force. This will allow time for all of its provisions to apply and for any transitional periods to expire.

Ministerial Sign-off For Final Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister:

Gillian Merron.....Date: **7th December 2009**

Summary: Analysis & Evidence

Policy Option: 2	Description: Enforcement of the Additives Regulation

COSTS

ANNUAL COSTS	Yrs
One-off (Transition)	
£ 1.3 million	1
Average Annual Cost (excluding one-off)	
£ 0	

Description and scale of **key monetised costs** by 'main affected groups' One off cost of re-labelling to industry (approximately £830,000), and one off familiarisation cost to industry and enforcement bodies (£0.5 million).

Total Cost (PV) **£ 1.3 million**

Other **key non-monetised costs** by 'main affected groups'. Non identified

BENEFITS

ANNUAL BENEFITS	Yrs
One-off	
£ 0	5
Average Annual Benefit (excluding one-off)	
£ 1.23 million	

Description and scale of **key monetised benefits** by 'main affected groups'

Total saving to industry from simplification of legislation (£1.23m per annum).

Total Benefit (PV) **£ 5.7 million**

Other **key non-monetised benefits** by 'main affected groups'

Additional consumer protection and potential savings to industry from reduced time taken to approve new additives or new use of additives.

Key Assumptions/Sensitivities/Risks

We estimate that the changes being made are likely to save an organisation one person-day per year with total savings for the whole industry in the order of £1.23 million per year. We estimate that a one-off familiarisation time of 3 hrs per organisation will be required with a total cost to the whole industry of £0.5 million.

Price Base Year 2008	Time Period Years 5	**Net Benefit Range** (NPV) **£ 4.4 million**	**NET BENEFIT** (NPV Best estimate) **£ 4.4 million**

What is the geographic coverage of the policy/option?				UK	
On what date will the policy be implemented?				January 2010	
Which organisation(s) will enforce the policy?				Local Authorities/PHAs	
What is the total annual cost of enforcement for these organisations?				£ Negligible	
Does enforcement comply with Hampton principles?				Yes	
Will implementation go beyond minimum EU requirements?				No	
What is the value of the proposed offsetting measure per year?				£ N/A	
What is the value of changes in greenhouse gas emissions?				£ N/A	
Will the proposal have a significant impact on competition?				No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large	
Are any of these organisations exempt?	No	No	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** £ N/A

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Evidence Base (for summary sheets)

Reason for Intervention

Consumers need to be confident that their food is safe to eat and that they can make an informed choice about what they consume. Government intervention is required to: protect consumer health by ensuring that the only products put into foods for a technological purpose have been evaluated for safety; to allow consumers to make an informed choice about what they eat through affective labelling; and to facilitate trade.

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. The new Regulation offers rationalisation of the current complex legislation, which has been subject to numerous amendments, and permits the "fast track" of amendments to the positive list of food additives, which the Food Standards Agency supports as beneficial both for industry and consumers. Moreover provisions in the new Regulation provide additional safeguards on additive use for consumers i.e. controls on the use of additives in additives, additional requirements for the authorisation of additives derived from Genetically Modified Organisms (GMOs), and the compulsory labelling of six colours were identified by the study carried out by Southampton University, as 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.

Intended effect

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 (S.I.) 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 S.I. (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 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 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.*

Background

The decision to update existing Community legislation on additives was announced by the European Commission in a white paper on food safety published on 12 January 2000.

Provisions and procedures for drawing up harmonised European Community controls on food additives were introduced in Directive 89/107/EEC (the food additives "framework" Directive). The three European Parliament and Council Directives on "miscellaneous" additives, colours and sweeteners were adopted under the provisions of Directive 89/107/EEC in 1994/95. All three Directives set out in their Annexes positive lists of approved additives, and in most cases specify the foods in which they can be used and the maximum level of use. In addition, Commission Directives 2008/128/EC, 2008/60/EC and 2008/84/EC have been introduced which set out purity criteria (specifications) for colours, sweeteners, and miscellaneous additives respectively and replace (also respectively) Commission Directives 94/45/EC, 95/31/EC and 96/77/EC. These will eventually be incorporated into a single Commission Regulation. All permitted additives are required to be assessed for safety by the European Food Safety Authority (or its predecessor, the Scientific Committee on Food (SCF)). Amendments to the lists of permitted additives, or to their conditions of use, are adopted following the lengthy co-decision procedure, involving agreement by the Council and European Parliament before the legislation is finalised. However, provisions are included in all three Directives to permit issues of interpretation to be resolved by Standing Committee. Directive 95/2/EC has been amended on six previous occasions and Directive 94/35/EC on three occasions. Directive 94/36/EC has not been amended.

This new measure aims to update and simplify the current legislative position.

In August 2006, the Commission published a proposal for a new Regulation on Additives as part of the Food Improvement Agents package which also introduced updated controls on food flavourings, controls for the first time on food enzymes, and a common authorisation procedure for authorising new additives, flavourings and enzymes. The Food Standards Agency consulted in September 2006 on the UK negotiating position. In November 2008 the Regulation was adopted by Council and came into force on 20th January 2009. It generally applies from 20 January 2010 although 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 in additives, of additives in enzymes and of carriers in nutrients will apply from 1 January 2011. The new Regulation applies directly in Member States but requires enforcement in the UK through a Statutory Instrument. Separate SIs are required for England, Scotland, Wales and Northern Ireland.

Options

Option 1 – Do nothing. Food additives would continue to be regulated subject to current provisions.

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

Costs and benefits of options

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.

[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.

- 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
- consumers and industry by making clear the authorisation route for additives which fall within scope of Regulation 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 (£)	
Number 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]

[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.

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

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 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.

Consultation

i) Within government

DEFRA was consulted because of its responsibility for food industry matters. The former Department of Business, Enterprise and Regulatory Reform (now the Department of Business, Innovation and Skills) was consulted because this is a single market measure that will impact on trade within the EC and with third countries, and the Better Regulation Executive was consulted concerning this regulatory impact assessment. In addition, the Small Business Service has been consulted on the issue of the impact of the additives legislation on small businesses.

ii) Public consultation

In September 2006 the FSA launched a 12 week public consultation on the Commission's proposal for the new Additives Regulation (as well as the rest of the Food Improvement Agents Package). Approximately 450

stakeholders were consulted across the UK and a summary of the 22 results can be found at **http://www.food.gov.uk/consultations/consulteng/2006/?completed=Yes**. These results fed in to UK Government's negotiating position.

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 this IA.)

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 additives. Approximately 450 stakeholders were consulted. One response (Local Authority Co-ordinators of Regulatory Services – LACORS) was directly relevant to the food additives SI. Comments were provided on the text of the SI and these have been considered when drafting the final SI.

Enforcement

Enforcement of the England Regulations will continue to be the responsibility of Local Authority Trading Standards or Environmental Health Departments.

As in existing provisions, Member States are obliged under the new Regulation to monitor and review the consumption and use of food additives and to report their findings to the European Commission.

Simplification

- the existing EC harmonised legislation will be simplified;
- decisions on new additives will be made faster; and
- the annexes of permitted additives will be re-structured so it is easier to see which are permitted in any given category of food. The Regulation is directly applicable in Member States.

Implementation and Review

The new Regulation came into force on 20 January 2009, although some provisions will apply after this date. It will be implemented in the UK by secondary legislation which will include enforcement provisions. Separate but parallel legislation will be 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.

Specific Impact Tests: Checklist

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	Yes
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Annexes

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.

Small Firms Impact Test

Two SMEs, 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 IA 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.

Sustainable development

Economic impacts have been taken into account through cost / benefit analysis. The new Additives Regulations should have a positive social impact by maintaining protection of consumer safety. It is written into the new Regulation (Recital 7) that the approval of additives should take into account societal, economic, traditional, ethical and environmental factors.

Race equality issues

The proposed Regulation does not have an impact on race equality.

Gender equality issues

The proposed Regulation does not have an impact on gender equality.

Disability equality issues

The proposed Regulation does not have an impact on disability equality.