EXECUTIVE NOTE

THE FOOD ADDITIVES (SCOTLAND) REGULATIONS 2009
SSI/2009/436

Description

The above instrument was made under the powers in 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, and paragraph 1A of Schedule 2 to the European Communities Act 1972. The instrument is subject to negative resolution procedure and does not amend primary legislation.

Policy Objective

This instrument, which extends to Scotland only, 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.

Legislative Background

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.

The EC Regulation is directly applicable across the UK, however a Scottish Statutory Instrument (S.S.I.) is required to enforce the Regulation and identify penalties for non-compliance.

Policy Background

The key aspects are:

- 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 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

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

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 1333/2008.

- Member States are required to implement by 20 January 2010.

Consultation

In September 2006, FSAS issued a 12 week consultation notifying stakeholders on the Commission's proposal for a new Additives Regulation which were part of the proposed EU Regulations on food additives, food flavourings and food enzymes. Approximately 235 stakeholders were consulted on these proposals and the summary of this consultation can be found at: http://www.food.gov.uk/multimedia/pdfs/improveagentscotenz.pdf

In July 2009, FSAS issued a 12 week consultation on the new food additives SSI. Approximately 235 stakeholders were consulted and FSAS received one comment in support of the Regulation from a Local Authority Environmental Health Officer. A summary of comments received are given within the Regulatory Impact Assessment in **Annex 2.**

Other Administrations

Similar Regulations will apply in England, Wales and Northern Ireland.

Impact

The Food Standards Agency Scotland fully consulted all stakeholders on the proposed Regulation. In Scotland there are no producers of food colours or of food additives. Other comments from manufacturers of colours and food additives and ingredients received from across the UK are summarised in **Annex 2.**

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Food Standards Agency Scotland
9 December 2009

ANNEX 2

FINAL REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

1.1 Regulation of the European Parliament and of the Council on Food Additives.

2. PURPOSE AND INTENDED EFFECT

Objective

2.1 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), Directive 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 that food additives which fall within the scope of the Genetically Modified (GM) Food and Feed Regulation (1829/2003) are also authorised under that Regulation prior to authorisation under this Regulation.

- To introduce controls over the use of all additives used in other additives and in enzymes preparations**,** 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 Southampton study should carry additional label information that consumption may have an adverse effect on activity and attention in children.

3. Background

3.1 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.

3.2 Provisions and procedures for drawing up harmonised European Community controls on food additives were introduced in Directive 89/107/EEC. 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. These will eventually be incorporated into a single Commission Regulation.

All permitted additives are required to be assessed for safety by the EFSA (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.

3.3 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. FSA Scotland consulted in September 2006 on the UK negotiating position and by November 2008 the Regulation was adopted by Council and came into force on 20 January 2009.

3.4 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 Scotland through a Scottish Statutory Instrument. Separate SIs are required for England, Wales and Northern Ireland.

Rationale for Government Intervention

3.5 In order to maintain a high level of consumer protection and to ensure the free movement of safe and wholesome food, EC wide legislation has been established for food additives. However, current additives legislation is complex. Three separate EC Directives on ‘’miscellaneous’’ additives, colours and sweeteners contain annexes which list permitted additives/additive uses. The lengthy EC co-decision procedure, involving agreement by the Council and EP applies when changes are made to Annexes.

3.6 Government intervention is necessary to simplify and consolidate these Directives and introduce the shorter comitology route for amendments to the Annexes together with various other provisions.

Devolution

3.7 The EC Regulation is directly applicable in the UK. However, a Scottish Statutory Instrument (SSI) is required to enforce the Regulation and identify penalties for non-compliance. This Regulation will apply only to Scotland; separate SIs will be established for England, Wales and Northern Ireland.

4. CONSULTATION

In Government

4.1 Government departments including the Scottish Government DG Health were kept informed of progress made in negotiations relating to the European Regulations through regular progress reports. No adverse comments were received.

Public Consultation

4.2 FSA Scotland has consulted with all of its stakeholders with an interest in food additives including industry, trade bodies and enforcement bodies (Local Authorities) and other government departments during negotiations with the European Commission and other EU Member States. In 2005, 2006 and 2007, FSA Scotland issued several interested party letters on early food additives proposals.

Results of Consultation

FSA Scotland

4.3 In September 2006, FSAS issued a 12 week consultation notifying stakeholders of the proposed EU Regulations on food additives, food flavourings and food enzymes. Approximately 235 stakeholders were consulted on these proposals. This consultation can be found at: http://www.food.gov.uk/multimedia/pdfs/improveagentscotenz.pdf

4.4 Two responses were received in Scotland. Both were from Scottish local authorities who welcomed a simplified food additives legislation creating a single instrument for authorisation and use of additives.

4.5 In July 2009, FSAS issued a 12 week consultation on the new food additives SSI and approximately 235 stakeholders were consulted. FSAS received one comment from a Local Authority Environmental Health Officer who was generally supportive of the Regulation.

FSA England

4.6 FSA England consulted over the same period and received 22 comments from stakeholders. These comments have been taken into consideration and are available at: http://wwwfood.go.uk/consultations/consulteng/2006/?completed=Yes

5. OPTIONS

5.1 **Option 1 Do nothing**

Food additives would continue to be regulated subject to current provisions

5.2 **Option 2 Make appropriate domestic Regulations**

Accept the EC Regulation as drafted and provide for its enforcement in Scotland

Benefits

5.3 **Option 1 –** Under this option, the current legislation would remain in place, with which industry and enforcement authorities are familiar.

5.4 **Option 2 –** This option would benefit the:-

- 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 UK organisation one person-day per year[2] with total savings in the order of £1.23 million per year.

- 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

5.5 **Option 1** – There would be no new direct costs to industry

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

5.7 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 (e.g. preservatives) in their own right.

5.8 FSA has no indication from industry of the magnitude of additional costs arising from the new requirement for the additional labelling information regarding the 6 Southampton study colours. Whilst the FSA is working with industry to achieve a voluntary withdrawal of these colours from all food and drink by the end of 2009, FSA understands that there are around 1000 products on the UK market which still contain these colours. Any companies whose products still contain these colours will need to make appropriate labelling changes.

[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.

5.9 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

5.10 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.

5.11 It is thought that the one-off costs incurred by businesses and local authorities from the 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	Savings for industry –	0

[3] Wage rates (2008) for Science and Technology professionals - £23.18 p/h, wage rates (2008) for Public Service Administrative Professionals - £27.16 p/h (source: Annual Survey of Household Earnings (2008); time required 3 hrs, 7,195 UK food manufacturing companies (source: Inter-Departmental Business Register 2008) and 469 UK local authorities.

comitology	likely to be in the region of hundreds of thousands of pounds for each new additive.	
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.

6. **Administrative Burden Costs**

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

6.2 The first 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 an 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.

6.3 The second 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.FSA Scotland considers the cost of these new information obligations is justified because of the continued consumer protection they bring.

7. **Impact on Government Departments**

FSA Scotland has consulted with the Scottish Government DG Health, among others, which was kept informed of progress in negotiations relating to the European Directive through regular progress reports. No adverse comments were received.

8. **Small Firms Impact Test**

8.1 As far as the FSA Scotland is aware there are no producers of food colours or of food additives in Scotland.

8.2 FSA in England identified two SMEs, both manufacturers of colours that 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 have not been emanating from 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.

8.3 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. Legal Aid

The Additives Regulations do not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications.

10. 'Test Run' of Business Forms

There are no forms associated with this piece of legislation.

11 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.

12. Enforcement, Sanctions and Monitoring

Enforcement

Local Authorities will be responsible for enforcement of these measures and have been consulted as part of the public consultation on early proposed Regulations. The impact on the public sector is believed to be minimal. There will also be ongoing and unchanged administration costs to food authorities for monitoring and enforcing the new Regulations.

13. Sanctions

The criminal sanctions within the Additives Regulation would apply in the case of prosecution against those in breach of the new Regulations. This is currently a fine not exceeding level 5 on the standard scale.

14. Simplification

The existing EC harmonised legislation will be simplified allowing for a faster approval system for new food additives. The annexes of permitted additives will be restructured making it easier to see which additives are permitted within the food categories. The Regulation is directly applicable in Member States.

15. Monitoring

In the UK this will be reviewed within 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.

16. Implementation and Delivery Plan

The new Regulation came into force on 20 January 2009, however some provisions apply after this date. It will be implemented across the UK by secondary legislation which will include enforcement provisions in Scotland. Separate but parallel legislation will be required for England, Wales and Northern Ireland.

17. Post Implementation Review

The Agency will continue to consult with Local Authorities, industry and other stakeholders to evaluate the effectiveness of and experience with the legislation. In accordance with the Scottish Government's Business Competitiveness Division**,** guidelines, this RIA will be reviewed, as appropriate, in order to establish that it is "fit for purpose" therefore not adding any additional burdens to businesses. In line with Scottish Government's guidance, FSA Scotland will review the continued effectiveness of this Regulation through the use of a Review Regulatory Impact Assessment that will be completed within 10 years.

18. Summary and Recommendation

18.1 Two options have been identified either 1) the legislation remains the same or 2) the Regulation is implemented into Scots law which will ensure that the UK is in line with the rest of the EC.

18.2 **Option 2 is the preferred option** which would ensure that Scotland is in line with the rest of the UK. Industry can continue to benefit from the uniform safety measures and free trade across the European Community. It will simplify legislation and allow for a faster approval system for food additives and will include additional safeguards for consumers.

19. Declaration and Publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed ……..

Date ……..

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