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FOOD STANDARDS AGENCY CONSULTATION

Title: Enforcement of European Parliament and Council Regulations on Additives and Enzymes

CONSULTATION SUMMARY PAGE

Date consultation launched:	Closing date for responses:
29 July 2009	21 October 2009

Who will this consultation be of most interest to?

Manufacturers of additives and enzymes and food manufacturers using these products; Enforcement Authorities.

What is the subject of this consultation?

Enforcement in England of new and revised EC legislation controlling the use of additives and enzymes in food.

What is the purpose of this consultation?

To offer stakeholders the opportunity to comment on draft enforcement provisions for the new EC Regulations on additives and enzymes.

Responses to this consultation should be sent to:

Name Clifford Gedling

Division/Branch Novel Food, Additives and Supplements Division

FOOD STANDARDS AGENCY

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Is an Impact Assessment included with this consultation?	Yes ☒	No ☐ See Annex A for reason.

INVESTOR IN PEOPLE

If you would prefer to receive future FSA consultations by e-mail, or if you no longer wish to receive information on this subject please notify the named person in this consultation.

POSITIVE ABOUT DISABLED PEOPLE

Enforcement of European Parliament and Council Regulations on Additives and Enzymes

DETAIL OF CONSULTATION

Introduction

In July 2006 the European Commission published proposals for European Parliament and Council Regulations aimed at clarifying and updating the existing legislation on food additives and flavourings and introducing new EC-wide rules on food enzymes, together with a proposal for common authorisation procedures for all three, based on scientific opinions from the European Food Safety Authority (EFSA).

As European Parliament and Council Regulations, they are directly applicable in the UK; however Statutory Instruments (SIs) are required to enforce them and to identify penalties for failure to comply. The Regulation on flavourings will, however, generally apply 12 months later than the Regulations on additives and enzymes and so enforcement provisions for this Regulation will be consulted on next year. The Regulation on a common authorisation procedure does not have any elements which require enforcement in the UK and so it is not part of this consultation.

The purpose of this written consultation is to seek stakeholders' views on enforcement in England of the EC Regulations described in this document. Impact Assessments and draft enforcement SIs for England can be found at Annexes B and C respectively. Separate, corresponding, SIs will be made in Scotland, Wales and Northern Ireland and will be consulted on separately.

EC Regulations

Food Additives

For additives, the new Regulation (1333/2008) aims to streamline the food additive approval system laid down in Directive 89/107/EEC and simplify the list of food additives and food additive uses set out in the Annexes to the three current Directives covering sweeteners, colours and "miscellaneous" additives. All four Directives will be repealed and most of the existing provisions incorporated into the new Regulation. The approval of new additives, and all changes to the existing legislation, are currently required to be made under the co-decision procedure, involving approval by the Council and European Parliament, which is time consuming. Under the new Regulation, changes to the EC positive list of food additives will be able to be made by comitology i.e. allowing the Commission to update and add to the list following majority Member State approval at Standing Committee and a right of scrutiny by the European Parliament. All approvals for new additives will be based on a safety evaluation carried out by EFSA. The Regulation also includes new harmonised EC provisions for additives used in other additives and a new EC requirement for the labelling of the 6 colours identified in the Southampton study as having a potentially adverse effect on children's behaviour. (identified in Annex V of the Regulation)**.** The Southampton study was commissioned by the Agency in 2004 in order to determine whether a link exists between certain food additives and hyperactivity/ Attention Deficit Hyperactivity Disorder (ADHD). The findings of this study were published in The Lancet in September 2007. The study was designed to show whether mixes of specific artificial colours (tartrazine (E102), ponceau 4 R (E124), sunset yellow (E110), carmoisine (E122), quinoline

yellow (E104) and allura red AC (E129), and the preservative sodium benzoate (E211), had any effect on children's behaviour.

Under Article 34 of Regulation 1333/2008, the Annexes and corresponding Articles in the existing food additives legislation (Directives 95/2/EC, 94/35/EC and 94/36/EC) are retained until the new lists of food additives in Annex II and III of 1333/2008 come into force (expected to be in June 2011). The draft SI therefore, whilst revoking the colours, sweeteners, miscellaneous additives and food additives labelling legislation, re-enacts certain provisions of the first three of those, pending, in most cases, the transfer to Annexes II and III of the new Regulation of the lists of approved additives but, in the case of the miscellaneous additives E1103 Invertase and E1105 Lysozyme, pending the date of application of the Community list of food enzymes provided for in Article 17 of Regulation (EC) No. 1332/2008 on food enzymes (it is not possible to give a date for this as EFSA has an open ended period to make its evaluations, however we anticipate application of the Community List in 2015). The draft also carries forward certain of the transitional provisions contained in the first three of those (regulations 7, 10 and 13), i.e. those which are relevant to the substantive provisions retained and which it appears to the Agency may still be of practical benefit.
Other provisions will not be re-enacted.

Consequential and other amendments

The draft makes certain consequential amendments to certain other domestic legislation in the light of the changes made by 1333/2008, and others will be added to take account of the repeal of Directive 89/107/EEC by Regulation 1333/2008. In addition, the opportunity will be taken to sweep up a consequential amendment required by the recent recast and codification of Directive 89/398/EEC on foods for particular nutritional uses. The new Directive (2009/39/EC) make no changes of substance but there is a need to update references to Directive 89/398/EEC.

The draft also updates a reference to Council Directive 88/344/EEC on extraction solvents in the Specified Sugar Products (England) Regulations 2003 to refer to the codified and recast version of that Directive (2009/32/EC) which again makes no changes of substance.

Finally, the draft gives effect to the new Directive (2009/10/EC) amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners. A separate consultation exercise will be carried out on the amendments introduced by Directive 2009/10/EC. As Directive 2009/10 includes EU purity criteria for magnesium carbonates, those national ones prescribed in the Miscellaneous Food Additives Regulations 1995 are redundant and have therefore not been carried forward in the new Regulations.

Offences

Regulation 14(1) makes it an offence to fail to comply with the re-enacted provisions. Similarly, the Schedule, as read with regulation 14(2), sets out provisions in Regulation 1333/2008 which are required to be enforced by making it an offence to fail to comply with them

Ambulatory provisions

The Schedules contained in the current English additives regulations have been replaced with references to the corresponding Annexes in the EU Directives (95/2, 94/35 and 94/36).
It is proposed to include provisions which make certain references to the relevant EC measures ambulatory. This means, where this power is used, that future amendments to the Annexes to the current EU Directives and to the Annexes to Regulation 1333/2008/EC, as well as to the purity criteria legislation will have effect automatically in English legislation **without the need**

for further consultation. We have also provided for references to the whole of Directive 2009/39/EC to be ambulatory. As these are technical amendments on which we will already have sought stakeholders' views during the process of EU negotiations, we believe it is appropriate and proportionate to make use of these ambulatory provisions. However, we do not intend to make any amendments to the Articles in Directive 1333/2008 ambulatory, since any such amendments are likely to be of significance and we believe that full consultation on these should be carried out before they come into effect in English law.

We would welcome comments from consultees as to whether they are content with our approach.

Additional points

An important change in Regulation 17 is the substitution of "shall" for "may". This means that a court will no longer have a discretion as to whether or not to order the destruction of non-compliant food. It may also be helpful to note that, in Regulation 11 (1), the slightly wider concept of "place on the market" has been substituted for "sale". In the same connection, there is a new definition of "placing on the market" which has the same meaning as that in EU general food law.

The Draft Food (Jelly Mini-Cups) (Emergency Control) (England) Regulations 2009

A separate draft Statutory Instrument is attached which gives effect to Article 33.1(k) of Regulation 1333/2008. That provision revokes EC Decision 2002/247/EC suspending the placing on the market and import of jelly confectionery which contains E425: Konjac (i) Konjac gum (ii) Konjac glucomammane and which is intended for human consumption. That Decision was implemented in England by S.I. 2002/931. In 2004 a related EC Decision was adopted, namely Decision 2004/374/EC suspending the placing on the market and import of jelly mini-cups containing certain named additives. That Decision was implemented by S.I. 2004/1151, which amended 2002/931 for that purpose. As the 2004 Decision has not yet been revoked, it is necessary to preserve on the statute book those elements of 2002/931 as amended which implement Decision 2004/374/EC (i.e. those relating to jelly mini-cups) and revoke those that implement Decision 2002/247/EC (i.e. those relating to konjac). Whilst the new SI includes updated enforcement provisions, please note that the *substantive* requirements relating to jelly mini-cups with which it is necessary to comply are not changing at all. When, as is proposed, the 2004 Decision is revoked, we will repeal the 2009 jelly mini-cup legislation.

Enzymes

For enzymes, EC-wide rules are laid down for their evaluation, approval and control of use in food. Currently, food enzymes used during the processing of foods but not active in the final product (processing aids) are not covered by detailed EC legislation, though they are subject to the general controls of Regulation (EC) 178/2002 as regards food safety. The new Regulation allows for the establishment of an EC positive list of all food enzymes used in food for a technological purpose based on favourable scientific opinions by EFSA.

Two options are being considered:

- **Do nothing**
- **Enforce the European Parliament and Council Regulations on additives and enzymes.**

Recommended Option:

- **Enforce the European Parliament and Council Regulations on food additives and enzymes.**

Consultation Process

The FSA launched a 12-week consultation on the original Commission proposals in September 2006. Approximately 450 stakeholders were consulted across the UK and the proposals received general support with issues being raised on specific points. A summary of the 22 replies can be found at: **http://www.food.gov.uk/consultations/conslteng/2006/?completed=Yes**

Responses helped inform the UK negotiating position and further contact was maintained with a number of industry and consumer groups during Council negotiations. The UK supports the new Regulations on additives and enzymes and this new consultation seeks your views on provisions for their enforcement in England. Impact Assessments and draft England enforcement SIs for each EC Regulation can be found at Annexes B and C of this consultation document.

After this consultation closes, the FSA will reflect on your responses before deciding how to proceed.

Questions asked in this consultation.

For each of the Impact Assessments at Annex B, we would particularly welcome contributions on:

Q1: the costs and benefits of the given options
Q2: administrative burden costs

We also welcome views on the assessments given in each of the Specific Impact Test Annexes at the end of each Impact Assessment and on the draft enforcement SIs at Annex C of this document.

Other relevant documents

European Parliament and Council Regulations on:

- Additives
- Enzymes

These can be accessed at:
http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2008:354:SOM:EN:HTML

or hard copies can be provided on request.

RESPONSES

Responses are required by close 21 October 2009. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

Name	**James Ridsdale (Food Enzymes)**
	Glynis Griffiths (Food Additives)
Branch	**Additives Branch**
Division	**Novel Food, Additives and Supplements Division**

Enclosed

Annex A: Standard Consultation Information

Annex B: Impact Assessments

Annex C: Statutory Instruments

Annex D: List of interested parties

Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at **http://www.food.gov.uk/multimedia/pdfs/dataprotection.pdf** Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex D. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. A Welsh version of the consultation package can be found at www.food.gov.uk

7. Please contact us for alternative versions of the consultation documents in Braille, other languages or audiocassette.

8. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.

9. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: **http://www.berr.gov.uk/files/file47158.pdf** The Consultation Criteria are available at **http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44458.html**

10. Criterion 2 of HM Government Code of Practice on Consultation states *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible*.

11. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. Please see the Impact Assessments at Annex B.

12. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 2C, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 0207 276 8630.

Comments on the consultation process itself

13. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at **http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc**

14. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at **http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc** The questionnaire can also be used to update us about your existing contact details.

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	**Impact Assessment of a Regulation of the European Parliament and of the Council on Enzymes**	
Stage: Consultation	**Version:** 5	**Date:** 23 July 2009

Related Publications: Enzymes Regulation: 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: Dr James Ridsdale **Telephone:** 020 7276 8559

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

Food enzymes (other than those used as food additives) are not currently regulated across the EU or are regulated as processing aids under the legislation of the different Member States. Differences between these controls, whilst not necessarily preventing a high level of consumer protection, may create conditions of unequal and unfair competition, and hinder the free movement of goods across the European Community.

What are the policy objectives and the intended effects?

Policy objectives: To protect the consumer with regard to food enzymes and to improve trade between EC Member States.

Intended effects: Harmonised controls for enzymes whether used as food additives or as processing aids in the production of foodstuffs and a high level of consumer protection.

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

1) Do nothing. Food enzymes (other than those used as food additves) would continue to be regulated subject to the different regimes of the various Member States.

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 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, within 1 year of the Community List of Approved Enzymes coming into force. It is not possible at this stage to put a date to the review as EFSA have an undetermined period to assess all enzyme submissions, but we anticipate approximately 2015.

Ministerial/CEO Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister/Chief Executive*:

.....Date:

* for Impact Assessments undertaken by non-ministerial departments/agencies and NOT being considered by Parliament

Summary: Analysis & Evidence

Policy Option: 2	Description: Acceptance and Enforcement of the Enzymes Regulation

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ 10,000	1
Average Annual Cost (excluding one-off)	
£ 0	

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

Costs of time spent on familiarisation with legislation by affected businesses and enforcement authorities.

Total Cost (PV) **£ 10,000**

Other **key non-monetised costs** by 'main affected groups' Administrative cost of providing a dossier to the Commission on any new scientific or technical information which might affect the assessment of the safety of the food enzyme. An additional cost of £9 per dossier is estimated. The expected frequency is not known, but it is expected to be a contingent and rare requirement.

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ 0	
Average Annual Benefit (excluding one-off)	
£ 0	

Description and scale of **key monetised benefits** by 'main affected groups' None quantified

Total Benefit (PV) **£ 0**

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

Harmonised controls across EC will make trade simpler.

Benefits to international trade from being able to offer an "EU Approved" product.

Key Assumptions/Sensitivities/Risks

Price Base Year 2008	Time Period Years 5	**Net Benefit Range** (NPV) **£ -10,000**	**NET BENEFIT** (NPV Best estimate) **£ -10,000**

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?				£ Negligable
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

Food enzymes (other than those used as food additives) are not currently regulated across the EU or are regulated as processing aids under the legislation of the different Member States. Whilst the current non-harmonised controls do not necessarily prevent a high level of consumer protection, consumers are not currently benefiting from the assurance given by a single Community-wide authorisation procedure. Without harmonised controls, manufacturers need to be aware of (and comply with) all of the different controls in the Member States with which they wish to trade, creating conditions of unequal and unfair competition and hindering the free movement of goods across the European Community.

The new Regulation applies equally to all food enzymes across the European Community, whether used as food additives or used as processing aids in the production of foodstuffs, to ensure consistency across the Community, as well as a high level of protection of human health and protection of consumers' interests.

Intended effect

The goal is to ensure that harmonised Community controls exist for all food enzymes (including those used as processing aids in the production of foodstuffs). The Regulation will not apply however to enzymes used exclusively as processing aids in the production of food additives, flavourings and novel foods for which corresponding Regulations exist. It does not extend to enzymes intended to be ingested as foods in themselves e.g. as supplements or dietary aids.

The intention is for the Regulation to establish the authorisation of food enzymes and not food enzyme preparations (by which is meant a formulated product consisting of one or more enzymes along with other additives or food ingredients).

The key objectives of the measure are as follows:

- To introduce general criteria and safety requirements for the use of food enzymes.
- To introduce a positive Community list of authorised enzymes, including their specifications and conditions of permitted uses in foods.
- To introduce provisions for the labelling of enzymes and enzyme preparations used or intended for use in food.
- To require that enzymes which fall within the scope of the GM food and feed Regulation (1829/2003) are also authorised under that Regulation prior to authorisation under this Regulation.

Background

Enzymes are substances (usually proteins) that catalyse (i.e. increase the rate of) chemical reactions. As such, they can be useful in the production of food, achieving results which might be too time consuming or expensive by other methods. The proposal to establish Community procedures for the safety assessment, authorisation and labelling of enzymes used or intended for use in food was announced by the European Commission in a White Paper on Food Safety published on 12 January 2000.

Currently, the scope of Directive 89/107/EEC (the Food Additives Framework Directive) only covers enzymes used as food additives and only two enzymes are authorised under this Directive (E1103 Invertase and E1105 Lysozyme).

There are also different levels of regulation of enzymes used as processing aids in different Member States. France and Denmark already have national controls and other Member States would be likely to introduce them if there were no EC harmonising measures.

The UK has negotiated in Council during the development of these provisions and supports the published Regulation. As an EC Regulation, it is directly applicable in the UK; however a Statutory Instrument (S.I.) is required to enforce the Regulation and identify penalties for non-conformance. Separate S.I.s will be established for Scotland, Wales and Northern Ireland.

Options

Option 1 – Do nothing. Food enzymes (other than those used as food additives) would continue to be regulated subject to the different regimes of the various Member States.

Option 2 – Accept the proposed new Enzymes Regulation 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 introduces a harmonised EC market for the supply of food enzymes so industry has to gain only a single EU authorisation. Industry has also indicated that being able to offer an "EU approved" product is likely to be a positive selling point in international markets.

Consumers benefit from greater assurance as to the safety in use of authorised food enzymes and this is underpinned by the requirement for enzyme users to supply to the Commission any new safety information which might affect the risk assessment, as well as that for users to supply usage information upon request**.**

The proposal will benefit manufacturers of food enzymes as they will have access to an EC harmonised market based upon an EU authorisation of their products.

The UK is not left out of step with the EC and so is not vulnerable to infraction proceedings.

Costs

Option 1 – Under this option, the current legislation would remain in place, so there are no incremental costs to this option.

Option 2 – The UK industry is small (probably fewer than 10 companies) and is focused on producing food enzyme preparations. We expect that large companies based in other countries will seek authorisations for food enzymes themselves (which will in any case be generic). We have discussed with UK industry whether this will involve additional expense which may be passed down to formulators of food enzymes. We do not think this will be the case because a significant number of the 200-400 food enzymes are already approved in at least one Member State (we estimate a minimum of 170) and for others data has already been generated either for corporate governance reasons or to comply with legislation in other markets (such as Japan).

In the few cases where UK companies do produce enzymes, industry has told us that these either replicate enzymes for which larger companies will be seeking authorisation or their trade with other countries means that the required data have already been generated. Industry also commented that new costs may be partly offset by not having to gain separate authorisations from both France and Denmark.

Consultations suggest the effect on enforcement authorities will be minor and that the proposed Regulation does not have an impact on race equality or sustainability.

Both businesses and Local Authorities / Port Health Authorities will be required to familiarise themselves with the legislation, which incurs an estimated one-off time cost of approximately £10,000[1]

[1] 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), Environmental Health Officers £14.94 (£19.42 including overheads) (source: Annual Survey of Household Earnings (2008)); time required 1 hour per organisation; 10 affected businesses, 469 local authorities and approximately 40 Port Health Authorities requiring separate familiarisation time.

Summary of costs and benefits – Option 2

Change	Benefit	Cost
Evaluation of enzymes	Ensures consumer protection.	£10K one-off familiarisation costs to businesses and Local Authorities / Port Health Authorities. No other costs to UK as it is expected that evaluations will be sought by major manufacturers who are not UK based.
Harmonisation of EU market	Facilitates trade across EU	£0

Q1. We particularly welcome comments and supporting evidence on the costs and benefits of the given options

Administrative Burden Costs

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

The first IO is a requirement for producers or users of food enzymes, when requested, to inform the European Commission of the actual use of a food enzyme. EC food law (Regulation 178/2002) already requires a comprehensive system of traceability between food businesses, so the main cost of the new IO is likely to be the actual provision of information to the Commission. We expect this to be co-ordinated through the relevant European trade organisations and so we see the cost for UK business as being negligible.

The IO second requires a producer or user of a food enzyme to inform the European Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the food enzyme. 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 these new IOs are justifiable for the benefit of consumer protection which they bring.

Summary of Administrative Burden Costs

Change	Benefit	Cost
Requirement to provide new safety data	Ensures consumer protection	£9 per occasion (expected to be rare)
Requirement to provide usage data	Ensures consumption does not exceed acceptable safety limits	£0 to UK industry.

Q2. We particularly welcome comments and supporting evidence on administrative burden costs

Consultation (refers to the formal consultation on the Commission's original proposal, and informal consultations during Council discussions on the proposal).

i) Within government

We have consulted Defra, the Better Regulation Executive and 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 early proposals.

ii) Public 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). Approximately 450 stakeholders were consulted and a summary of the 22 responses can be found at **http://wwwfood.go.uk/consultations/consulteng/2006/?completed=Yes**

Only a small number of the 22 responses related to the Enzymes proposal, however consumers welcomed enhanced controls on Food Enzymes. Industry welcomed the benefits from a harmonised EC market.

Enforcement

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

Simplification

Controls on food enzymes across the EC will be harmonised making sales across the EU simpler.

Implementation and Review

The new Regulation came into force on 20 January 2009; however 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, within 1 year of the Community List for Enzymes of coming into force. It is not possible to put a date to this at this time as EFSA have an undetermined time period to evaluate food enzymes, but is estimated to be approximately 2014.

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

Food Enzymes Market

The large majority of the world enzyme market, though based in the EU, is outside of the UK. In 2004 the world enzymes market was worth 760 million US dollars (over £412 million). The two dominant forces in the international enzymes market are Novozymes and Danisco, which acquired the Genencor International business in 2005, bringing its share of the total enzymes market from 2% to 20%. DSM of the Netherlands takes third place in the international market.

In the EU, manufacturers use between 200 and 400 generic enzymes and several thousand trade names (i.e. enzyme preparations). In the UK, there is not a substantial manufacturing industry. Instead, the market consists of a number of medium sized and smaller producers/blenders of which there are a very small number in the UK.

After consultation with UK manufacturers, we are satisfied that the new Regulation is unlikely to limit the number or range of UK suppliers, either directly or indirectly or to limit the ability or incentive for UK industry to compete.

This is due to the fact that authorisations will be generic as opposed to applicant specific. Authorisations will also be made largely of individual enzymes, not enzyme preparations. Where safety data does not already exist, it is expected that larger, non-UK, manufacturers will provide it and UK companies will be able to benefit.

Small Firms Impact Test

The enzymes industry is very specialised and initial soundings with industry, including small firms, on earlier draft proposals identified a number of concerns that were communicated to the Commission by industry representatives. These concerns have largely been addressed in the new Regulation (see Annex C).

Our discussions with a small firms representative in this sector suggest that, with long implementation periods, reformulation and re-labelling will not have an immediate significant cost impact, as changes can be gradually introduced when product packaging becomes due to be reprinted and formulations reviewed. Many concerns regarding cost depended on the level of authorisation required by the legislation. These concerns have been largely addressed now that the European Commission has confirmed that authorisation will generally be for food enzymes themselves (and not for formulated products).

Sustainable development

Economic impacts have been taken into account through cost/benefit analysis. The new Enzyme Regulations should have a positive social impact by ensuring consumer safety. It is written into the new Regulation (Recital 6) that the approval of enzymes 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.

Impact Assessment, Enzymes

Appendix

Options

Options considered during discussion of the proposal:

- That EFSA should evaluate food enzymes as opposed to food enzyme preparations.

The Commission proposal of July 2006 did not specify the level at which EFSA should evaluate enzyme applications and a number of possibilities were considered. For example manufacturer specific approvals, generic approvals, approval of enzyme preparations (formulated product consisting of one or more enzymes along with other additives or food ingredients). The UK recognised that any criteria must be effective, but also proportionate and saw the best way forward as being generic approvals of individual enzymes. Our view was supported by the majority of Member States and the Commission and taken on board by EFSA. EFSA do, however, retain the option to make individual approvals more specific if they feel that it is justified on safety grounds.

- Oppose broadening the proposal to include all processing aids.

Initial consultation revealed some interest for all processing aids being caught by the scope of the legislation. As well as considering the merits of controlling processing aids, the UK thought carefully about broadening the scope of the Regulation. We came to the conclusion that doing this would introduce a very significant change to the proposal and that this should not be considered without first undertaking an impact assessment.

- Support targeted risk-based monitoring as opposed to a 10-yearly re-authorisation.

Early drafts of the Commission proposal included a commitment to review enzyme authorisations every ten years, and we considered carefully whether or not this should be retained. However, other obligations on industry, within the proposal, to notify the Commission of new information which may effect the risk assessment for an additive, coupled with monitoring by Member States, permit a more targeted risk based approach.

- Oppose a requirement for complete removal of all enzyme residues from the final food.

The Commission's proposal did not call for complete removal of all enzyme residues, however some of the groups we consulted and some Member States were in favour of this. We considered this carefully and came to the conclusion that removal of all enzyme residues, when used as processing aids, would in many cases be technically un-achievable. At the very least, it

would be a significant change for the food industry and its impact would need to be considered carefully.

- Propose that food enzymes caught by both the new Enzyme Regulation and also Regulation (EC) No 1829/2003 on genetically modified organisms should be assessed by EFSA at the same time

We felt that the double authorisation under enzymes and GM legislation was likely to be required for a minority of enzymes but that it was important that consumers could be re-assured that an enzyme had been assessed for safety under both legislative frameworks. However, we supported a system where industry could make a single application to EFSA, who would evaluate the dossier in accordance with both sets of legislative requirements.

During the course of discussions it emerged that it was more correct from a legal point of view, to retain separate assessments. However the European Parliament insisted that the Commission make a written commitment to ensure that when this situation arose, assessments would run in parallel. EFSA confirmed that this was workable.

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: Consultation	**Version:** 7	**Date:** 23 July 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, 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.

Ministerial/CEO Sign-off For SELECT STAGE Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister/Chief Executive*:

.....Date:

* for Impact Assessments undertaken by non-ministerial departments/agencies and NOT being considered by Parliament

Summary: Analysis & Evidence

Policy Option: 2	Description: Enforcement of the Additives Regulation

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ 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	
One-off	**Yrs**
£ 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?				£ Negligable	
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 authority 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[1] with total savings in the order of £1.23 million per year.

[1] 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. Whilst large organisations may have more products and

- 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.[2]

[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)); 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.

Q1. We particularly welcome contributions on the costs and benefits of the given options. Please quantify any costs and benefits in as much detail as possible.

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.

Q2. We particularly welcome contributions on administrative burden costs

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Consultation (refers to the formal consultation on the Commission's original proposal, and informal consultations during Council discussions on the proposal)

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 Flavouring Regulation (as well as the rest of the FIAP). 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.

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, within 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

Only 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 contact in the company pointed out that the food colours industry was a very difficult one to be in at the moment. There are small margins of profit to be made and the major supermarkets that control the majority of the general food market regularly put pressure on colours manufacturers to reduce their costs. The colours industry is regarded as a battle of risk versus reward and the more 'hoops' they have to go through, the less the reward is. (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.

No further comments related directly to small firms were received in response to public consultation.

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.

S T A T U T O R Y I N S T R U M E N T S

2009 No.

FOOD, ENGLAND

The Food (Jelly Mini-Cups) (Emergency Control) (England) Regulations 2009

Made - - - -	*2009*
Laid before Parliament	*2009*
Coming into force - -	*20th January 2010*

The Secretary of State makes the following Regulations in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972(**a**).

The Secretary of State, has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to food (including drink)(**b**).

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(**c**), there has been open and transparent public consultation during the preparation and evaluation of the following Regulations.

Title, commencement and application

1.—(1) These Regulations may be cited as the Food (Jelly Mini-Cups) (Emergency Control) (England) Regulations 2009 and come into force on 20th January 2010.

(2) These Regulations apply in relation to England only.

Interpretation

2.—(1) In these Regulations—

"the Act" means the Food Safety Act 1990(**d**) and, save where otherwise indicated, any expression used both in these Regulations and in the Act has the same meaning as in the Act;

"commercial operation" does not include exporting;

"the Commission Decision" means Commission Decision 2004/374/EC suspending the placing on the market and import of jelly mini-cups containing the food additives E400, E401,

(**a**) 1972 c.68.
(**b**) S.I. 2003/2901.
(**c**) OJ No. L31, 1.2.2002, as last amended by Commission Regulation (EC) No. 2002/2008 amending Regulation (EC) No. 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority (OJ No. L60, 5.3.2008, p.17).
(**d**) 1990 c.16.

E402, E403, E404, E405, E406, E407, E407a, E410, E412, E413, E414, E415, E417 and/or 418(**a**);

"controlled jelly mini-cups" means any jelly mini-cups which contain any of the relevant food additives and which are intended for human consumption;

"food authority" has the meaning that it bears by virtue of section 5(1) of the Act, except that it does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and Middle Temple); and

"the relevant food additives" means the food additives E400: alginic acid; E401: sodium alginate; E402: potassium alginate; E403: ammonium alginate; E404: calcium alginate; E405: propane 1,2-diol alginate; E406: agar; E407: carrageenan; E407a: processed euchema seaweed; E410: locust bean gum; E412: guar gum; E413: tragacanth; E414: acacia gum; E415: xanthan gum; E417: tara gum and E418: gellan gum.

(2) Any term used both in these Regulations and in the Commission Decision has the same meaning as in the Commission Decision.

(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(**b**), to a port health authority;

(b) by an order under section 6 of the Public Health Act 1936(**c**), 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(**d**), to a single authority for a metropolitan county,

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

Prohibitions

3.—(1) No person shall carry out any commercial operation with respect to any controlled jelly mini-cups.

(2) For the purposes of paragraph (1), any jelly mini-cups which contain any of the relevant food additives shall be presumed until the contrary is proved to be controlled jelly mini-cups.

(3) No person shall use any of the relevant food additives in the manufacture of any jelly mini-cups which are intended for human consumption.

(4) For the purposes of paragraph (3), any jelly mini-cups shall be presumed until the contrary is proved to be intended for human consumption.

(5) Any person who knowingly contravenes paragraph (1) or (3) shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale, to imprisonment for a term not exceeding three months or to both.

Enforcement

4.—(1) Each food authority shall enforce and execute these Regulations within its area.

(2) For the purposes of enabling a food authority to carry out its duty of executing and enforcing these Regulations, an authorised officer of that authority shall be subject to the same obligations as regards the procurement of samples under section 29 of the Act as are imposed on an authorised officer of an enforcement authority by regulations 6 to 8 of the Food Safety (Sampling and Qualifications) Regulations 1990(**e**) (in these Regulations referred to as "the 1990 Regulations"), with the modification that any reference in those Regulations to section 29 of the Act shall be

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(**a**) OJ No. L118, 23.4.2004, p.70.
(**b**) 1984 c.22; section 7(3)(d) was substituted by paragraph 27 of Schedule 3 to the Food Safety Act 1990.
(**c**) 1936 c. 49; section 6 is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.
(**d**) 1985 c. 51; paragraph 15(6) was amended by paragraph 31(b) of Schedule 3 to the Food Safety Act 1990.
(**e**) S.I. 1990/2463, to which there are amendments not relevant to these Regulations.

deemed to be a reference to that section as applied for the purposes of these Regulations by regulation 5(5).

(3) Each food authority shall give such assistance and information to the Secretary of State and the Food Standards Agency as they may reasonably request in connection with the execution and enforcement of these Regulations.

Application etc. of various provisions of the Act

5.—(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 shall be construed for the purposes of these Regulations 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(**a**)), with the further modifications that—

(i) subsections (2) to (4) shall apply in relation to an offence under regulation 3(1) and (3) as they apply to an offence under regulation 14 or 15, and

(ii) in relation to an offence under regulation 3(1), the references to "sale" in subsection (4)(b) are deemed to include references to the carrying out of any commercial operation.

(d) section 30 (analysis etc. of samples) with the further modifications that—

(i) the reference to "section 29 above" in subsection (1) shall be deemed to be a reference to that section as applied by regulation 5(5), and

(ii) in the definition of "sample" in subsection (9) the reference to "regulations under section 31 below" shall be deemed to be a reference to regulation 4(2);

(e) section 32 (powers of entry), with the further modification that in subsection (1) the reference to "an enforcement authority" shall be deemed to be a reference to a food authority;

(f) section 33(1) (obstruction etc. of officers);

(g) section 33(2), with the further modification that the reference to "any such requirement as is mentioned in subsection (1)(b) above" shall be deemed to be a reference to any such requirement as is mentioned in section 33(1)(b) as applied by sub–paragraph (f);

(h) section 35(1) (punishment of offences)(**b**), in so far as it relates to offences under section 33(1) as applied by sub–paragraph (f);

(i) section 35(2) and (3)(**c**), in so far as it relates to offences under section 33(2) as applied by sub–paragraph (g);

(j) section 36 (offences by bodies corporate);

(k) section 36A (offences by Scottish partnerships)(**d**); and

(l) section 44 (protection of officers acting in good faith).

(2) Subject to paragraph (3), section 9 of the Act (inspection and seizure of suspected food) applies for the purposes of these Regulations as if it read as follows—

"**9.**—(1) An authorised officer of a food authority may at all reasonable times inspect any jelly mini-cups which—

(a) have been sold or are offered or exposed for sale; or

(**a**) Section 21 was amended by S.I. 2004/3279.
(**b**) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c.44), Schedule 26, paragraph 42, from a date to be appointed.
(**c**) Section 35(3) was amended by S.I. 2004/3279.
(**d**) Section 36A was inserted by the Food Standards Act 1999 (1999 c.28), Schedule 5, paragraph 16.

(b) are in the possession of, or have been deposited with or consigned to, any person for the purpose of sale or of preparation for sale.

(2) Subsections (3) to (8) apply where, whether or not on an inspection carried out under subsection (1), it appears to an authorised officer that—

(a) any person has carried out commercial operations with respect to controlled jelly mini-cups, in contravention of regulation 3(1) of the Food (Jelly Mini-Cups) (Emergency Control) (England) Regulations 2009; or

(b) any person has used any of the relevant food additives in the manufacture of any jelly mini-cups which are intended for human consumption, in contravention of regulation 3(3) of those Regulations.

(3) The authorised officer may either—

(a) give notice to the person in charge of the jelly mini-cups that, until the notice is withdrawn, the jelly mini-cups or any specified quantity of them—

(i) are not to be used for human consumption, and

(ii) either are not to be removed or are not to be removed except to some place specified in the notice; or

(b) seize the jelly mini-cups and remove them in order to have them dealt with by a justice of the peace;

and any person who knowingly contravenes the requirements of a notice under sub-paragraph (a) shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(4) Where the authorised officer exercises the powers conferred by subsection (3)(a) that officer shall, as soon as is reasonably practicable and in any event within 21 days, determine whether or not he or she is satisfied that there has been no contravention of regulation 3(1) or (3) of the Food (Jelly Mini-Cups) (Emergency Control) (England) Regulations 2009 in relation to the jelly mini-cups and—

(a) if he or she is so satisfied, shall forthwith withdraw the notice; and

(b) if he or she is not so satisfied, shall seize the jelly mini-cups and remove them in order to have them dealt with by a justice of the peace.

(5) Where an authorised officer exercises the powers conferred by subsection (3)(b) or (4)(b), he shall inform the person in charge of the jelly mini-cups of his intention to have them dealt with by a justice of the peace and –

(a) any person who under regulation 3(5) of the Food (Jelly Mini-Cups) (Emergency Control) (England) Regulations 2009 might be liable to a prosecution in respect of the jelly mini-cups shall, if he attends before the justice of the peace by whom the jelly mini-cups fall to be dealt with, be entitled to be heard and to call witnesses; and

(b) that justice of the peace may, but need not, be a member of the court before which any person is proceeded against for an offence consisting of a contravention of regulation 3(1) or (3) of the Food (Jelly Mini-Cups) (Emergency Control) (England) Regulations 2009 in relation to those jelly mini-cups.

(6) If it appears to a justice of the peace, on the basis of such evidence as the justice of the peace considers appropriate in the circumstances, that any person has contravened regulation 3(1) or (3) of the Food (Jelly Mini-Cups) (Emergency Control) (England) Regulations 2009 in relation to any jelly mini-cups falling to be dealt with by the justice of the peace under this section, the justice of the peace shall condemn the jelly mini-cups and order—

(a) the jelly mini-cups to be destroyed or to be so disposed of as to prevent them from being used for human consumption; and

(b) any expenses reasonably incurred in connection with the destruction or disposal to be defrayed by the owner of the jelly mini-cups.

(7) If a notice under subsection (3)(a) is withdrawn, or the justice of the peace by whom any jelly mini-cups fall to be dealt with under this section refuses to condemn them, the food authority shall compensate the owner of the jelly mini-cups for any depreciation in their value resulting from the action taken by the authorised officer.

(8) Any disputed question as to the right to or the amount of any compensation payable under subsection (7) shall be determined by arbitration.

(9) For the purposes of –

(a) subsection (2)(a), any jelly mini-cups which contain any of the relevant food additives shall be presumed until the contrary is proved to be controlled jelly mini-cups; and

(b) subsection (2)(b), any jelly mini-cups shall be presumed until the contrary is proved to be intended for human consumption.".

(3) The expressions "food authority", "jelly mini-cups", "controlled jelly mini-cups", "the relevant food additives" and "for human consumption", which are used in section 9 of the Act in so far as it applies for the purposes of these Regulations by virtue of paragraph (2), shall, for those purposes, bear the meanings that those expressions respectively bear in these Regulations.

(4) Section 2 of the Act (extended meaning of "sale" etc) shall apply in relation to section 9 of the Act in so far as it applies for the purposes of these Regulations by virtue of paragraph (2).

(5) Section 29 of the Act (procurement of samples) shall apply for the purposes of these Regulations with the modifications that—

(a) for the words "an enforcement authority" there shall be substituted the words "a food authority";

(b) for subsection (b)(ii) there shall be substituted the following provision—

"(ii) is found by him on or in any premises which he is authorised to enter pursuant to section 32 as applied for the purposes of the Food (Jelly Mini-Cups) (Emergency Control) (England) Regulations 2009 by regulation 5(1)(d) of those Regulations;";

(c) subsection (c) shall be omitted; and

(d) for the words "any of the provisions of this Act or of regulations or orders made under it" in subsection (d) there shall be substituted the words "the Food (Jelly mini-cups) (Emergency Control) (England) Regulations 2009".

(6) Regulation 9(1) of the 1990 Regulations shall apply for the purposes of these Regulations as if it read as follows—

"(1) Where a sample procured under section 29 of the Act as applied by regulation 5(5) of the Food (Jelly Mini-Cups) (Emergency Control) (England) Regulations 2009 has been analysed or examined pursuant to regulation 4(3)(b) of those Regulations, the owner shall be entitled on request to be supplied with a copy of the certificate of analysis or examination by the authority which, by virtue of regulation 4(1) of those Regulations, has the duty of enforcing them.".

Revocation

6. The Food (Jelly Confectionery) (Emergency Control) (England) Regulations 2002(**a**) are revoked.

Signed by authority of the Secretary of State for Health

Name
Parliamentary Under Secretary of State
Department of Health

Date

(**a**) S.I. 2002/931, amended by S.I. 2004/1151.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply in relation to England only, implement Commission Decision 2004/374/EC suspending the placing on the market and import of jelly mini-cups containing the food additives E400, E401, E402, E403, E404, E405, E406, E407, E407a, E410, E412, E413, E414, E415, E417 and/or E418 (OJ No. L118, 23.4.2004, p.70).

These Regulations—

(a) prohibit—

(i) the carrying out of commercial operations with regard to jelly mini-cups which contain any of the food additives E400, E401, E402, E403, E404, E405, E406, E407, E407a, E410, E412, E413, E414, E415, E417 or E418 and which are intended for human consumption, and

(ii) the use of any such additive in the manufacture of any jelly mini-cups which are intended for human consumption (*regulation 3*);

(b) provide for their enforcement (*regulation 4*);

(c) apply, with modifications, certain provisions of the Food Safety Act 1990 (1990 c.16)(*regulation 5*); and

(d) revoke the Food (Jelly Confectionery) (Emergency Control) (England) Regulations 2002 (S.I. 2002/931, amended by S.I. 2004/1151)(*regulation 6*).

A full impact assessment has not been produced for this instrument as no impact on the private or voluntary sectors is foreseen.

S T A T U T O R Y I N S T R U M E N T S

2009 No. 0000

FOOD, ENGLAND

The Food Additives (England) Regulations 2009

Made - - - -	*2009*
Laid before Parliament	*2009*
Coming into force - -	*20th January 2010*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(a) and (e), 17(1) and (2), 26(1)(a) and (b), (2)(e) and (3), and 48(1) of the Food Safety Act 1990(**a**), and now vested in him(**b**), and paragraph 1A of Schedule 2 to the European Communities Act 1972(**c**).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for any reference to—

(a) an Annex to a Community instrument that is specified in regulation 2(6) to be construed as a reference to that Annex as amended from time to time; and

(b) the Directive that is specified in regulation 2(7) to be construed as a reference to that Directive as amended from time to time.

In accordance with section 48(4A) of that Act, he has 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(**d**), there

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(**a**) 1990 c. 16; section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28) "the 1999 Act". Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999Act and S.I. 2004/2990.

(**b**) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Functions of "the Ministers" so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.

(**c**) 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006 c.51).

(**d**) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Commission Regulation (EC) No. 2002/2008 amending Regulation (EC) No. 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority (OJ No. L60, 5.3.2008, p.17).

has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Title, application and commencement

1. These Regulations may be cited as the Food Additives (England) Regulations 2009, apply in relation to England only and come into force on 20th January 2010.

Interpretation

2.—(1) In these Regulations —

"acid" means any substance which increases the acidity of a food and/or imparts a sour taste to it;

"acidity regulator" means any substance which alters or controls the acidity or alkalinity of a food;

"the Act" means the Food Safety Act 1990;

"anti-caking agent" means any substance which reduces the tendency of individual particles of a food to adhere to each other;

"anti-foaming agent" means any substance which prevents or reduces foaming;

"antioxidant" 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" means any substance which contributes to the volume of a food without contributing significantly to its available energy value;

"carrier" and "carrier solvent" have the meanings respectively given to them in Directive 95/2;

"colour" has the meaning given to it in Directive 94/36;

"Directive 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(**a**);

"Directive 94/35" means European Parliament and Council Directive 94/35/EC on sweeteners for use in foodstuffs(**b**);

"Directive 94/36" means European Parliament and Council Directive 94/36/EC on colours for use in foodstuffs(**c**);

"Directive 95/2" means European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners(**d**);

"Directive 08/60" means Commission Directive 2008/60/EC laying down specific purity criteria concerning sweeteners for use in foodstuffs(**e**);

"Directive 08/84" means Commission Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners(**f**);

(**a**) OJ No. L184, 15.7.1988, p.61, as last amended by Commission Directive 91/71/EEC completing 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 (OJ No. L42, 15.2.1991, p.25).

(**b**) 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).

(**c**) OJ No. L237, 10.9.1994, p.13.

(**d**) 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.

(**e**) OJ No. L158, 18.6.2008, p.1.

(**f**) 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).

"Directive 08/128" means Commission Directive 2008/128/EC laying down specific purity criteria concerning colours for use in foodstuffs(**a**);

"Directive 09/39" means Directive 2009/39/EC of the European Parliament and of the Council on foodstuffs for particular nutritional uses (recast)(**b**);

"emulsifier" 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;

"emulsifying salt" 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" 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" means any substance which enhances the existing taste and/or odour of a food;

"flavouring" has the meaning that it bears in Article 1.2 of Directive 88/388;

"flour treatment agent" means a substance added to flour or dough to improve its baking quality, but does not include any emulsifier;

"foaming agent" means any substance which makes it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid food;

"food" 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"—

(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 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(**c**),

(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 amylolitic 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 glumatic acid, glycine, cysteine and cystine and their salts) having no additive function,

(viii) caseinates and casein, and

(ix) inulin;

(**a**) OJ No. L6, 10.1.2009, p.20.
(**b**) OJ No. L124, 20.05.2009, p.21.
(**c**) OJ No. L330, 5.12.1998, p.32.

"food authority", subject to paragraph (3), has the meaning that it bears by virtue of section 5(1) of the Act, except that it does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and Middle Temple);

"food for infants or young children" 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" means any substance which gives a food texture through the formation of a gel;

"glazing agent" 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" 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" means children under the age of one year;

"miscellaneous additive" 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" 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" 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" 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" 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" 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" 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" means any substance which prolongs the shelf-life of a food by protecting it against deterioration caused by micro-organisms;

"processing aid" 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" means any gas, other than air, which expels a food from a container;

"purity criteria", 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" means any substance or combination of substances which liberates gas and thereby increases the volume of a dough or a batter;

"Regulation 1333/2008" means Regulation (EC) No.1333/2008 of the European Parliament and of the Council on food additives(**a**);

"relevant food additive" means any miscellaneous additive, colour or sweetener, or an enzyme which is not acting as a processing aid;

"sell" includes possess for sale, and offer, expose or advertise for sale, and "sale" and "sold" shall be construed accordingly;

"sequestrant" means any substance which forms a chemical complex with metallic ions;

"specified permitted colour" means any permitted colour other than—

(d) E123 Amaranth;

(e) E127 Erythrosine;

(f) E128 Red 2G;

(g) E154 Brown FK;

(h) E160b Annatto, bixin, norbixin;

(i) E161g Canthaxanthin;

(j) E173 Aluminium; and

(k) E180 Litholrubine BK;

"specified Regulation 1333/2008 provision" 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 the Schedule;

"stabiliser" has the meaning given to it in Directive 95/2;

"sweetener" means any food additive which is used or intended to be used—

(l) to impart a sweet taste to food; or

(m) as a table-top sweetener;

"thickener" means any substance which increases the viscosity of a food; and

"young children" 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(**b**), to a port health authority;

(b) by an order under section 6 of the Public Health Act 1936(**c**), 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(**d**), to a single authority for a metropolitan county,

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

(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

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(**a**) OJ No. L354, 31.12.2008, p.16.
(**b**) 1984 c.22; section 7(3)(d) was substituted by paragraph 27 of Schedule 3 to the Food Safety Act 1990 (1990 c.16).
(**c**) 1936 c.49; section 6 is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.
(**d**) 1985 c.51; paragraph 15(6) was amended by paragraph 31(b) of Schedule 3 to the Food Safety Act 1990.

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 a Community instrument that is specified in paragraph (6) is a reference to that Annex as amended from time to time,

(6) The Community instruments are Directive 94/35, Directive 94/36, Directive 95/2, Directive 08/60, Directive 08/84, Directive 08/128 and Regulation 1333/2008.

(7) The Directive is Directive 09/39.

Use of colours in or on food

3.—(1) No person shall use in or on any food any colour other than a permitted colour.

(2) No person shall 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 shall 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 shall 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 shall 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(**a**) or any other marking required on any meat product, other than the permitted colours—

(**a**) 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

(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 shall use any colour for—

(a) the decorative colouring of eggshells, or

(b) the stamping of eggshells (as provided for in Regulation (EEC) No. 1274/91 introducing detailed rules for implementing Council Regulation (EEC) No. 1907/90 on certain marketing standards for eggs) (**a**),

other than a permitted colour.

Sale of colours and food containing colours

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

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

(3) No person shall sell any food having in it 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 6, it shall be 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 1st April 2005; and

(b) the matter constituting the offence would not have constituted an offence under the Colours in Food Regulations 1995(**b**) as they stood immediately before the coming into force of the Colours in Food (Amendment)(England) Regulations 2005(**c**).

Use of miscellaneous additives

8.—(1) No person shall 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 shall 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 shall 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

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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).

(**a**) OJ No. L121, 16.5.1991, p.11, as last amended by Commission Regulation (EC) No. 326/2003 correcting Regulation (EEC) No. 1274/91 introducing detailed rules for implementing Council Regulation (EEC) No.1907/90 on certain marketing standards for eggs (OJ No. L47, 21.2.2003, p.31).

(**b**) S.I. 1995/3124, amended by S.I. 2000/481, S.I. 2001/3442, S.I. 2002/1923, S.I. 2003/1563, S.I. 2003/1564, S.I. 2005/519, S.I. 2005/2626, S.I. 2007/453, S.I. 2008/85 and S.I. 2009/891.

(**c**) S.I. 2005/519.

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 shall 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 shall 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 shall 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 shall 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 shall 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 shall sell any miscellaneous additive for use in or on food unless that additive is a permitted miscellaneous additive.

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

(4) No person shall 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 shall 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 shall be a defence for the accused to show—

(a) that the miscellaneous additive concerned is E431-E436 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 1st 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 1st April 2005,

and that the matter constituting the offence would not have constituted an offence under the Miscellaneous Food Additives Regulations 1995(**a**) had the amendments made to them by regulation 3 of the Miscellaneous Food Additives (Amendment) (England) Regulations 2004(**b**) 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 shall be a defence to prove that—

(a) the food additive, food or flavouring concerned was placed on the market or labelled before 27th 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) (England) Regulations 2005(**c**) 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 shall be a defence to prove that—

(a) the food additive or food concerned was placed on the market or labelled before 15th 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) (England) Regulations 2007(**d**) 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 shall 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 shall use any sweetener in or on any food except a permitted sweetener that—

(a) is used in or on 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

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

Sale of food containing sweeteners

12. No person shall sell any food having in it 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 shall be a defence to prove that—

(**a**) S.I. 1995/3187, amended by S.I. 1997/1413, S.I. 1999/1136, S.I. 2000/3323, S.I. 2001/60, S.I. 2001/2294, S.I. 2001/3442. S.I. 2001/3775, S.I. 2002/379, S.I. 2003/1008, S.I. 2003/1563, S.I. 2003/1564, S.I. 2003/1596, S.I. 2003/1659, S.I. 2003/2243, S.I. 2003/3120, S.I. 2003/3295, S.I. 2004/2601, S.I. 2005/1099, S.I. 2005/2626, S.I. 2007/1778, S.I. 2008/42 and S.I. 2009/891.
(**b**) S.I. 2004/2601.
(**c**) S.I. 2005/1099.
(**d**) S.I. 2007/1778.

(a) the act constituting the offence was committed before 29th 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 29th July 2005; and

(c) the act constituting the offence would not have constituted an offence under the Sweeteners in Food Regulations 1995(**a**) 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) (England) Regulations 2004(**b**) 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 arrangements 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 1st 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 1st 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 20th 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 20th 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.

Enforcement

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

Application of various sections of the Food Safety Act 1990

16. The following provisions of the Act shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be 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);

(**a**) S.I. 1995/3123, amended by S.I. 1996/1477, S.I. 1997/814, S.I. 1999/982, S.I. 2001/2294, S.I. 2002/379, S.I. 2003/1182, S.I. 2004/3348, S.I. 2005/2626 , S.I. 2007/1778 and S.I. 2009/891.

(**b**) S.I. 2004/3348.

(c) section 21 (defence of due diligence)(**a**) with the modification that—

(i) subsections (2) to (4) shall 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)(**b**), in so far as it relates to offences under section 33(1) as applied by paragraph (3)(b);

(g) section 35(2) and (3)(**c**), 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)(**d**).

(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 shall 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) shall apply to offences under these Regulation as it applies to offences punishable under section 35(2) of the Act.

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 shall 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(**e**) in regulation 3 (exemptions), for sub-paragraph (d) of paragraph (1), in so far as that provision applies to England, 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 (England) Regulations 2009 in compliance with the provisions of those Regulations.".

(**a**) Section 21 was amended by S.I. 2004/3279.
(**b**) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c.44), Schedule 26, para 42, from a date to be appointed.
(**c**) Section 35(3) was amended by S.I. 2004/3279.
(**d**) Section 36A was inserted by the 1999 Act, Schedule 5, paragraph 16.
(**e**) S.I. 1966/1073, amended by S.I. 1982/1727, S.I. 1985/67, S.I. 1990/2486, S.I. 1991/1426, S.I. 1992/2597, S.I. 1995/3187, S.I. 2001/3775 and S.I. 2005/2626.

(2) In the Fruit Juices and Fruit Nectars (England) Regulations 2003(**a**), 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 (England) Regulations 2003(**b**) for note 1 to Schedule 1 (partly or wholly dehydrated preserved milk products and their reserved descriptions) there is substituted the following note—

> "Any designated product may contain any substance permitted pursuant to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives and any vitamin.".

(4) In the Meat Products (England) Regulations 2003(**c**), 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 by 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.(**d**)".

(5) In the Jam and Similar Products (England) Regulations 2003(**e**)—

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

> ""permitted sweetener" means any sweetener in so far as its use is permitted in the specified jam or similar product by the Food Additives (England) 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 (England) Regulations 2003

19. In Note 7 to the table in Schedule 1 to the Specified Sugar Products (England) Regulations 2003(**f**), for the expression "Council Directive 88/344/EEC" there is substituted "Directive 2009/32/EC of the European Parliament and of the Council(**g**)".

Revocations

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

(a) the Food Additives Labelling Regulations 1992(**h**);

(**a**) S.I. 2003/1564, amended by S.I. 2005/2626.
(**b**) S.I. 2003/1596, amended by S.I. 2004/2145, S.I. 2005/2626, S.I. 2006/14 and S.I. 2008/85.
(**c**) S.I. 2003/2075, amended by S.I. 2005/2626 and S.I. 2008/517.
(**d**) OJ No. L354, 31.12.2008, p. 34.
(**e**) S.I. 2003/3120, amended by S.I. 2005/2626.
(**f**) S.I. 2003/1563, amended by S.I. 2005/2626.
(**g**) OJ No. L141, 6.6.2009, p.3.
(**h**) S.I. 1992/1978, amended by S.I. 1995/3123, S.I. 1995/3124, S.I. 1995/3187, S.I. 1996/1499, S.I. 1999/1136, S.I. 2001/2294, S.I. 2001/3442, S.I. 2001/3775, S.I. 2002/379 and S.I. 2005/2626.

(b) the Sweeteners in Food Regulations 1995;

(c) the Colours in Food Regulations 1995; and

(d) the Miscellaneous Food Additives Regulations 1995.

Signed by authority of the Secretary of State for Health

Minister's name
Minister of State
Department of Health

Date

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 *quantum satis* 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 for 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 for 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.

Provision of Regulation 1333/2008	*Subject – matter*
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 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)	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 by weight of the total.
Article 22.3 (as read with Article 22.4 and 5)	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 .

Provision of Regulation 1333/2008	*Subject – matter*
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)

S T A T U T O R Y I N S T R U M E N T S

2009 No. 0000

FOOD

The Food Enzymes Regulations 2009

Made - - - -	*2009*
Laid before Parliament	*2009*
Coming into force - -	*20th January 2010*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(a), (e) and (f), 17(2), 26(1) and (3), and 48(1) of the Food Safety Act 1990(**a**), (the 1990 Act) and now vested in him(**b**).

In accordance with section 48(4A) of the 1990 Act, he has had regard to relevant advice given by the Food Standards Agency.

In so far as these Regulations cannot be made under the powers in the 1990 Act cited above, the Secretary of State makes these Regulations as a Minister designated(**c**) for the purposes of section 2(2) of the European Communities Act 1972(**d**) in relation to measures relating to the description of, and other requirements relating to, spirit drinks.

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(**e**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

(**a**) 1990 c. 16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), "the 1999 Act". Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act and S.I. 2004/2990.

(**b**) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 (1999 c. 28). Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.

(**c**) S.I. 1989/1327, to which there are amendments not relevant to these Regulations.

(**d**) 1972 c.68.

(**e**) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Commission Regulation (EC) No. 202/2008 amending Regulation (EC) No. 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority (OJ No. L60, 5.3.2008, p.17).

Title, commencement and extent

1.—(1) These Regulations may be cited as the Food Enzymes Regulations 2009 and come into force on 20th January 2010.

(2) Regulations 1 and 12 extend to the United Kingdom and regulations 2 to 11 apply in relation to England only.

Interpretation

2.—(1) In these Regulations —

"the Act" means the Food Safety Act 1990;

"the EC Regulation" means Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97(**a**);

"food authority" does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple) nor a port health authority;

"port health authority" means —

(a) in relation to the London port health district (within the meaning given to that phrase for the purposes of the Public Health (Control of Disease) Act 1984(**b**) by section 7(1) of that Act), the Common Council of the City of London; and

(b) in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984, a port health authority for that district constituted by order under section 2(4) of that Act.

(2) Any other expression used in these Regulations and in the EC Regulation has the same meaning in these Regulations as it bears in the EC Regulation.

(3) Unless indicated otherwise, any reference to a numbered Article is a reference to the Article so numbered in the EC Regulation.

Offences, penalties and savings

3.—(1) A person who contravenes or fails to comply with any of the Community provisions specified in paragraph (2) as read with the transitional arrangements contained in Article 18 and Article 24 is guilty of an offence.

(2) The Community provisions mentioned in paragraph (1) are —

(a) Article 4 (restriction on placing on the market and use of food enzymes not on Community list);

(b) Article 5 (prohibition on placing on the market of non-compliant food enzymes or foods containing such enzymes);

(c) Article 10(1) (requirements for labelling of food enzymes and preparations not intended for sale to the final consumer);

(d) Article 12(1) (requirements for labelling of food enzymes and preparations intended for sale to the final consumer);

(e) Article 14(1) and (2) (requirement to provide specified information to the Commission).

(3) Anyone convicted of an offence under paragraph (1) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(**a**) OJ No. L.354, 31.12.2008, p.7.
(**b**) 1984 c. 22.

Enforcement and competent authorities

4. It shall be the duty of each food authority within its area and each port health authority within its district to execute and enforce these Regulations and the EC Regulation.

Application of various sections of the Food Safety Act 1990

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

(a) section 20 (offences due to fault of another person);

(b) section 21 (defence of due diligence),with the modification that —

(i) subsections (2) to (4) shall apply in relation to an offence under regulation 3(1) as they apply in relation to an offence under section 14 or 15, and

(ii) in subsection (4) the references to "sale" are deemed to include references to "placing on the market";

(c) section 30(8) (which relates to documentary evidence);

(d) section 35(1) (punishment of offences), in so far as it relates to offences under section 33(1) as applied by paragraph (3)(b);

(e) section 35(2) and (3), in so far as it relates to offences under section 33(2) as applied by paragraph (3)(c);

(f) section 36 (offences by bodies corporate);

(g) section 36A (offences by Scottish partnerships).

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

(3) The following provisions of the Act shall 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 the EC Regulation 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 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);

(d) section 44 (protection of officers acting in good faith).

(4) Section 34 of the Act (time limit for prosecutions) applies to offences under regulation 3 as it applies to offences punishable under section 35(2) of the Act.

Condemnation of Food

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

Amendment of the Food Labelling Regulations

7.—(1) The Food Labelling Regulations 1996(**a**) are amended in accordance with paragraphs (2) to (4).

(2) In regulation 2(1) (interpretation) —

(a) following the definition of "follow-on formula" insert the following definition —

> ""food enzyme" has the meaning that it bears in Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes(**b**);"; and

(b) in the definition of "ingredient", after the expression "any additive" insert the expression ", any food enzyme".

(3) In regulation 14 (names of ingredients) after paragraph (9) insert the following as paragraph (9A) —

> "(9A) a food enzyme other than one referred to in regulation 17(b) or (c) shall be identified by the appropriate category in Schedule 4 followed by the specific name of that enzyme.".

(4) In regulation 17 (ingredients which need not be named) —

(a) in paragraphs (b) and (c) in each case after the expression "any additive" insert "or food enzyme"; and

(b) in paragraph (d) after the expression "an additive" insert "or food enzyme".

Amendment of the Caseins and Caseinates Regulations 1985

8. In the Schedule to the Caseins and Caseinates Regulations 1985(**c**), in column 2 of Part II (technological adjuvants and bacterial cultures) after the expressions "rennet" and "other milk-coagulating enzymes" in each case add the expression "meeting the requirements of Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes".

Amendment of the Fruit Juices and Fruit Nectars (England) Regulations 2003

9. In Schedule 4 (permitted treatments and additional substances) to the Fruit Juices and Fruit Nectars (England) Regulations 2003(**d**), after the expressions "Pectolytic enzymes", "Proteolytic enzymes" and "Amylolytic enzymes" in paragraphs 4, 5 and 6 respectively in each case add the expression "meeting the requirements of Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes".

Amendment of the Novel Food and Novel Food Ingredients Regulations 1997

10. In regulation 2(1) (interpretation) of the Novel Foods and Novel Food Ingredients Regulations 1997(**e**), for the definition of "Regulation (EC) No 258/97" substitute the following definition —

> ""Regulation (EC) No 258/97" means Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and food ingredients(**f**) as last amended by Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes;".

(**a**) S.I. 1996/1499, as amended by S.I. 2004/2824. There are other amending S.I.s but none is relevant to this instrument.
(**b**) OJ No. L354, 31.12.2008, p.7.
(**c**) S.I. 1985/2026, as amended by S.I. 1989/2321, S.I. 1990/2486, S.I. 1991/1476, S.I. 1992/2596 and S.I. 2005/2626.
(**d**) S.I. 2003/1564, as amended by S.I. 2005/2626.
(**e**) S.I. 1997/1335, as amended by S.I. 1999/1756, S.I. 1999/3182, S.I. 2000/253, S.I. 2000/768 and S.I. 2004/2335.
(**f**) OJ No. L43, 14.2.1997, p.1, as amended by Regulations (EC) No 1829/2003 (OJ No. L268, 18.10.2003, p.1), No 1882/2003 (OJ No. L284, 31.10.2003, p.1) and No 1332/2008 (OJ No. L354, 31.12.2008, p.7).

Amendment of the Spirit Drinks Regulations 2008

11. In the table in Part 2 of Schedule 2 to the Spirit Drinks Regulations 2008(**a**), at the end of the entry in column 2 that appears opposite the entry "Article 9(9)" in column 1, add the words "as last amended by Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes".

Signed by authority of the Secretary of State for Health

Minister's name
Minister of State
Date 2009 Department of Health

(**a**) S.I. 2008/3206.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. To be completed after consultation.

Annex D

A F Suter Ltd
A H Allen & Partners
Abbott Laboratories Ltd , Medical Division
Action Against Allergy
Additives Survivors Network
Advertising Association
AEA Technology
AFP Consultants Ltd
Agricoat Natureseal Ltd
Ajinomoto Switzerland AG
Alcontrol Laboratories
Allied Bakeries Ltd
Allied Technical Centre
Alltech (UK) Ltd
Alpro UK Ltd
Amano Enzyme Co Ltd
Ambersil Ltd
Applied Chemicals
Arthur Branwell & Co Ltd
Artisan Foods
Asda Stores Limited
Asia Food Products Ltd
Askeys Ltd
Association for the International Promotion of Gum
Association of Cereal Food Manufacturers
Association of Convenience Stores
Association of Malt Products Manufacturers
Association of Port Health Authorities
Association of Public Analysts
Astor-Stag Ltd
Augustus Oils Ltd
B R & M Holmes (Butchers)
Bakery Working Group of Soil Association
Barbour Index Plc
Barentz BV
Barry Atwood
Basildon Chemical Co Ltd
Bernard Matthews Farms Ltd
Berry Ottawayand Associates Limited
Bespoke Foods Ltd
Biocatalysts Ltd
Bioresco
Biozyme Laboratories Ltd
Birds Eye Group
Birmingham City Council Trading Standards
Birmingham City Laboratories
Blagden Chemicals Ltd
BMMA
BOC Gases
Bodycote Law Labs
Boehringer Ingelheim Limited
Booker Ltd
Botanix

Bottle Green Drinks Company
Bowmans Milling Ltd
BRAES Group Ltd
Brent Council
Brent Environmental Health Authority
Brewing Research International
Bristol City Council
British Aerosol Manufacturers Association
British Caramel Manufacturers Association
British Cheese Board
British Dietetic Association
British Essence Manufacturers Association
British Frozen Food Federation
British Hospitality Association
British Lubricants Federation Ltd
British Meat Processors Association
British Medical Association
British Plastics Federation
British Retail Consortium
British Soft Drinks Association Ltd
British Starch Industry Association
British Sugar Plc
British Wax Refining Co Ltd
Britsnail Marketing Co-op c/o New Dawn Products
Britvic plc
Bromley Central Library
Brunel Healthcare Manufacturing Ltd
Brunner Mond & Company Ltd
Burson Marsteller
Bush Boake Allen
Business In Sport and Leisure
Buzz 2000 Ltd
C I P C E L
Cabot Carbon Limited
Cadbury plc
Cadbury Schweppes plc
CAFIA
Cambridge Health Plan Ltd
CAMedica
Campden BRI
Cantox Health Sciences International
Cargill
Cargill Flavor Systems/Duckworth Group
Castrol International
Centre for Pregnancy Nutrition
Cereal Partners UK
Chance & Hunt
Charcuterie Continental Ltd
Chartered Institute of Environmental Health
Chemistry & Industry Magazine
Cherry Valley Farms Ltd
Chilled Food Association Ltd
Christan Hanson UK Ltd
Ciba Speciality Chemicals Water Treatments Ltd

Clifford Chance
CMS Cameron McKenna
Coca-Cola Great Britain & Ireland
Coca-Cola Group Europe
Colorcon Ltd
Committee of the EU
Confederation of Paper Industries
Consensus Action on Salt and Health
Consumer Focus
Cosmetic Toiletry and Perfumery Association
Council For Nutrition & Therapy
County Confectionery
Covington and Burling LLP
Cullinane Associates Ltd
Cultor Food Science
Custom Pharmaceuticals Limited
Dairy Crest Group PLC
Dairy UK Ltd
Dalgety Ltd/Spillers Foods Ltd
Danisco Ingredients Ltd
Dawn Foods (UK) Ltd
DBC Foodservice
Department of Health (Hong Kong)
Dera Food Technology UK Ltd
Derbyshire Trading Standards Office
Devon County Council
Diabetes UK
Direct Food Ingredients Ltd
DSM Food Specialities
Durham County Council
East End Foods plc
Edlong Flavours, Edlong Co Ltd
Edme Ltd
Egger & Co Chemicals Ltd
Elanco Animal Health
ELC
ERCOTS
Ernest Jackson & Co Ltd
Euro Food Marketing
EuroChemLink Ltd
Eurofins Laboratories Ltd
European Catering Association (Great Britain)
European Public Policy Advisors
European Research into Consumer Affairs
European Snacks Association / SNACMA
F I Data Services
F R Benson & Partners Ltd
Farmhouse Cheesemakers Ltd
Federation of Bakers
Federation of Women's Institutes in Northern Irela
FERA
Fibrisol
FIPRA International Ltd
Firmenich UK Ltd

Flavour Craft
Flexible Packaging Association
Food & Drink Federation
Food Additives and Ingredients Association
Food Club/Masonline ltd
Food Commission UK Ltd
Food Ethics Council
Food Industry Environmental Network LLC
Food Law Monthly
Food Science Australia
Foodaware
FoodChain Europe Ltd
FoodNavigator.com
FRAME
Friends of the Earth
Frozen and Chilled Potato Processors Association
Frutarom (UK) Ltd
FS Crisps Ltd
Fuji Oil Co Ltd
Geest Industries Plc
Gell Systems
Gerber Juice Company Ltd
Gin & Vodka Association
Givaudan UK Ltd
Glasgow Scientific Services
Glass Associates Ltd
GNT UK Limited
Good Relations Ltd
Goodman Fielder Limited
Greencell Ltd
Greenpeace UK
Griffith Laboratories UK Ltd
Halal Food Authority
Hampshire County Council
Haribo Dunhills (Pontefract) plc
Haringey Council
Hays Albion Chemicals Group
Hazelwood Preserves Ltd
Healan Ingredients Ltd
Health Food Manufacturers' Association
Health Promotion Agency for Northern Ireland
Herbalife (U K) Limited
Hermes Sweeteners Ltd
Hertfordshire County Council
Holland & Barrett Retail Limited
Huntington Life Sciences
Hyperactive Childrens Support Group
Hyperama
Ice Cream Alliance
Ice Fresh Foods LTD
Iceland Foods PLC
ICI Plc Chemicals & Polymers Group
Imarco Food Ingredients Ltd
Infant and Dietetic Foods Association

Innovia Films Ltd
Institute of Food Science and Technology
Institute of Grocery Distribution
Institute of Trading Standards
International Life Sciences Institute (ILSI)
International Pectin Producers' Association
International Speciality Products
International Sweeteners Association
Inveresk Research Group
ISP Alginates
J Ralph Blanchfield Consultancy
J Sainsbury plc
James Finlay Ltd
Japanese Embassy
John Russell Associates
Kapajo.com
KB Food Research Services
Keller & Heckman LLP
Kellogg Europe Trading Limited
Kent Scientific Services
Kerry Ingredients Europe
Keylink Ltd
Kimpton Brothers Ltd
Kingfisher Colours Ltd
Knoll Pharma Chemicals
Kraeber (UK) Ltd
KTC (Edibles) Ltd
Laboratory of the Government Chemist
Laurens Patisseries
Lawcode
Leatherhead Food International
Leicester City Council
Lidl UK GmbH
Local Authorities Co-ordinators of Regulatory Services
London Borough of Ealing Council
London Borough of Greenwich
London Port Health Authority
LP Gas Association
Lycored ltd
Map Technologies
Margaret Anderson & Associates
Marinalg International
Marks & Spencer Plc
Marlin Chemicals Ltd, Industrial Waxes Division
Marlow Foods Ltd
Mars UK Limited
Mastertaste
McCormick (UK) Ltd
Metal Packaging Manufacturers Assoc
Mitsubishi Kagaku Foods Corp of Japan
Morelands Ltd/MH Foods ltd
Muller Dairy (UK) Limited
National Association of British and Irish Millers
National Association of Master Bakers

National Childbirth Trust
National Consumer Federation
National Council of Women of Great Britain
National Farmers Union
National Federation Of Women's Institutes
National Office of Animal Health
National Society for Phenylketonuria
National Starch & Food Innovation
Nestle Confectionery (UK)
Neville Craddock Associates
Nutragen Ltd
Omya UK Limited, Technical Centre
Overseal Natural
Oxford Chemicals Ltd
P & B (Foods) Ltd
Packaging & Industrial Films Association (PIFA)
Pattinson Scientific Services
PepsiCo UK
Phytone Ltd
Pic-A-Chic Ltd
Pinset & Co Solicitors
Potato Marketing Board
Poth Hille & Company Ltd
Poultmass (Trading) Ltd
PQ Corporation
Premier Foods Ltd
Princes Soft Drinks
Procter & Gamble UK and Ireland
Proprietary Association of Great Britain
Provision Trade Federation
Public Projection Department
R Twining and Co Ltd
Reading Scientific Services Ltd
Regulatory Solutions
RHM Technology Ltd
Rhodia Ltd
Rocol
Roderic Establishment
ROHA Caleb UK Ltd
Ross Biosciences
Rowland Company
Royal Collage of Midwives
Royal College of Physicians
Royal Pharmaceutical Society of Great Britain
Royal Society for the Promotion of Health
Royal Society of Chemistry
Rusk Manufacturers Association
S. Black Ltd
Salt Association
Sandwell Information Service
Savannah Products Ltd
SCM Chemicals Ltd
Scotch Whisky Research Institute
SEAFISH

Seed Crushers & Oil Producers Association
Selective Services Ltd
Sensient Flavours
Sensient Food Colours UK
Seven Seas Ltd
Shell UK
SHS International Limited
Society of Dyers & Colourists
Society of the Chemical Industry
Soda Club Ltd
Soil Association
Solmedia Ltd
Somerfield Stores Limited
Somerset County Council
Soup and Gravy Manufacturers Association
South West Water
Southampton City Council
SPP Ingredients
St Ivel Ltd
Sugarflair
Sun-bee Co
Superdrug Stores Plc
Supreme Salt Company Ltd
Surrey County Council
Surrey Trading Standards
Sustain
Sweet and Maxwell London
Tate & Lyle plc
Tazaki Foods Ltd
Tesco Stores plc
Tetley Group Ltd
The Association of the British Pharmaceutical Industries
The Consumer Policy Institute
The Co-operative Group
The Food Commission
The Sugar Bureau
The Whitehouse Consultancy
Thorntons plc
TMC Ventures Inc.
Toms Confectionery Ltd
Tonka UK Ltd
Townswomens Guild
Tradspec Consultancy
Tranfood Meat Company Ltd
Turkish Embassy
Unilever plc
United Distillers & Vintners Brand Technical Centre
University College Chester
University of Nottingham
University of Reading
University of Sussex
Vegetarian Economy and Green Agriculture
Ventress Technical Ltd
Verner Wheelock Associates Limited

Vitrition UK Ltd
Warner Lambert Confectionary
Warwickshire County Council
Weetabix Limited
West Yorkshire Joint Services
Westler Foods Ltd
Which?
Whitworths Foods Group Ltd
William Blythe & Co Ltd
William Ransom & Son Plc
Wimpy UK
Wine and Spirit Trade Association
Witwood Food Products Ltd
Worcestershire Scientific Services
Worldwide Fruit Ltd
Xyrex Ltd
Zeelandia Ltd
Zeneca