

FOOD STANDARDS AGENCY CONSULTATION

Title: Enforcement of the European Parliament and Council Regulation on Food Flavourings

CONSULTATION SUMMARY PAGE

Date consultation launched:	Closing date for responses:
21 July 2010	14 October 2010

Who will this consultation be of most interest to?

Manufacturers of food flavourings; suppliers of herbs and spices and food manufacturers using these products; Enforcement Authorities.

What is the subject of this consultation?

Enforcement in England of the new and revised EU legislation controlling the use of flavourings in food.

What is the purpose of this consultation?

To offer stakeholders the opportunity to comment on the draft enforcement provisions for the new EU Regulation on food flavourings and the accompanying Impact Assessment (IA).

Responses to this consultation should be sent to:

Janet Eldridge
Food Composition and Labelling Division
FOOD STANDARDS AGENCY
Tel: 020 7276 8581
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Postal address:
Aviation House
125 Kingsway
London WC2B 6NH
Email: janet.eldridge@foodstandards.gsi.gov.uk

Is an Impact Assessment included with this consultation?

Yes

No See Annex A for reason.



Enforcement of the European Parliament and Council Regulation on Food Flavourings

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 EU-wide rules on food enzymes, together with a proposal for common authorisation procedures for all three.

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. Enforcement SIs are now in place for additives and enzymes (which applied from 20 January 2010). However, as the Regulation on flavourings applies 12 months later (20 January 2011), we are consulting on the enforcement provisions for this Regulation now.

The purpose of this written consultation is to seek stakeholders' views on:

- **The enforcement in England of the EU Regulation described in this document (a draft enforcement SI for England can be found at Annex D);**
- **The accompanying Impact Assessment at Annex C - this updates the Partial Regulatory Impact Assessment on the original Commission flavourings proposal.**

Separate, corresponding, SIs will be made in Scotland, Wales and Northern Ireland and will be consulted on separately.

Provisions

The enforcement provisions of EU Regulation 1334/2008 come into effect from 20 January 2011. However, some provisions of this EU Regulation applied from its point of entry into force (20 January 2009). Amendments to Annexes II to V are permitted under Article 22. However, foods that are lawfully placed on the market prior to 20 January 2011 that do not comply with Regulation 1334/2008 can be marketed until their date of minimum durability or use-by-date in accordance with Article 30.

Offences

Regulation 3(1) of the Flavourings in Food (England) Regulations 2010 makes it an offence to fail to comply with the specified provisions of the new EU Regulation. Regulation 3(2) sets out the provisions in Regulation 1334/2008 which are enforced by making it an offence to fail to comply with them. Regulation 3(2)(h) in particular is an enforcement measure on which we seek the views of consultees; it enforces Article 19(2) and (3) respectively of Regulation 1334/2008. Article 19(2) relates to an approved flavouring which is subsequently modified via different production methods or by using different starting materials, and will therefore require another evaluation. Article 19(3) requires food business operators to inform the Commission immediately of any new information that might affect the safety assessment of an approved flavouring.

Enforcement measures have not been applied to Article 19(1) however, where the Commission requests food business operators to supply them with information regarding the categories and levels for flavourings used in foods. In the event that a food business operator declines to

provide the Commission with the requested information, it may result in the suspension of the use of the flavouring in question because an appropriate review cannot be conducted – which we believe would in practice render Article 19(1) a self-enforcing measure. We welcome your views as to whether enforcement measures are/are not required for Article 19(1).

Consequential and other amendments

Article 29 of EU Regulation 1334/2008 amends the Food Labelling Directive, (Directive 2000/13/EC), and as a consequence, changes are also required to the UK Food Labelling Regulations. Principal changes achieved by EU Regulation 1334/2008 can be found at Annex A.

Options

Two options are being considered:

- **Do nothing**
- **Enforce the European Parliament and Council Regulation on Flavourings**

Recommended Option:

- **Enforce the European Parliament and Council Regulation on Flavourings**

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/consulteng/2006/addenzyme flavour>

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 Regulation on flavourings and this new consultation seeks your views on provisions for its enforcement in England. An Impact Assessment and draft England enforcement SI for the EC Regulation can be found at Annex C and D 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 the Impact Assessment at Annex C, we would particularly welcome contributions, with supporting evidence on:

Q1: the costs and benefits of the measures that need to be undertaken in order to comply with the monitoring requirements for BAPs.

Q2: the familiarisation costs, enforcement costs and costs of re-labelling.

We also welcome views on the assessment given in the Specific Impact Test Annex at the end of the Impact Assessment and on the draft enforcement SI at Annex D of this document.

For the draft Regulation at Annex D, we would welcome your views on:

Q1: should enforcement measures under Regulation 3(2)(h) extend to Article 19(1) of EU Regulation 1334/2008?

Q2: whether you agree that Article 19(1) is a self-enforcing measure.

Other relevant documents

European Parliament and Council Regulation on Flavourings

This can be accessed at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0034:0050:EN:PDF>

or hard copies can be provided on request.

RESPONSES

1. **Responses are required by close 14 October 2010.** 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 **Donna Griffith-Sackey**
Branch **Food Additives Branch**
Division **Food Composition and Labelling Division**

Enclosed

Annex A: Principal changes achieved by EU Regulation 1334/2008

Annex B: Standard Consultation Information

Annex C: Impact Assessment

Annex D: Statutory Instrument

Annex E: List of interested parties

Principal changes achieved by EU Regulation 1334/2008

Background

Flavourings have been traditionally used in food to impart odour and/or taste. Some are naturally present in foods or are formed during the preparation of food. Flavourings can be individual substances or complex mixtures of substances containing two dozen or more constituents in order to provide the desired flavour to food.

Some flavourings and food ingredients with flavouring properties (e.g. herbs and spices) contain biologically active principles (BAPs) which are not only an inherent part of the flavour but may also pose a small health risk to consumers. As these substances occur naturally, maximum levels have been established in order to restrict their presence in foods. Additionally, BAPs cannot be added as such to food.

The existing regulatory framework for food flavourings in the European Union (EU) was established under Council Directive 88/388/EEC (which is completed by Directive 91/71/EEC). Directive 88/388/EEC (the Flavourings Framework Directive) provides definitions for flavourings; restricts the addition and presence of BAPs in food and provides rules for the labelling of flavourings. This Directive also provides for the adoption of a positive list of chemically defined flavouring substances under Regulation (EC) No. 2232/96. These are substances with chemically defined structures which are derived from foods or other source materials. Flavouring substances from food origin are classified as 'natural' flavouring substances, whereas those that are chemically synthesised and chemically identical to substances found in nature are currently classified as 'nature identical'. Flavouring substances that are chemically synthesised and not found in nature are considered to be 'artificial'.

EU Regulation 1334/2008

Member States have implemented the Flavourings Framework Directive and the application of the maximum levels established for BAPs differently. It has therefore become necessary to create harmonised EU controls for flavourings which ensure a high level of consumer protection, enable the free movement of safe and wholesome food and to take into account the new scientific and technological developments.

The new flavourings Regulation - EU Regulation 1334/2008 - aims to establish a harmonised system for the assessment and authorisation of flavourings and their source materials used in food. It replaces and repeals Council Directive 88/388/EEC, Commission Directive 91/71/EEC and Regulation (EC) No. 2232/96. These have been implemented into national law by the Flavourings in Food Regulations 1992 as amended, which will be revoked.

Authorisation Procedure

As a first step towards the positive list of flavourings provided for under Regulation (EC) No. 2232/96 (positive lists already exist for additives), the Commission established an EU Register of chemically defined flavouring substances (approximately 2800) under Commission Decision 1999/217/EC. Whilst Regulation (EC) No. 2232/96 will be revoked, the EU Register of flavouring substances will form the basis of the new Union list provided for under Article 25. Prior to their transfer to the new Union list, these substances must be evaluated for their safety and be adopted. The safety evaluations are in progress and are scheduled to be completed by 31 December 2010; which coincides with the date of adoption specified in Article 27 of the Regulation.

Use and Marketing

Under the existing regime, flavouring preparations are not included on the EU Register as these are considered to be natural (usually derived from food sources), and therefore do not require an evaluation prior to use. This will also apply to the Union list under the new Regulation. However, for flavouring preparations (and other types of flavourings) that are derived from non-food sources, these will require an evaluation in accordance with Article 9; and only those substances on the list will be able to be placed on the market as specified in Article 10. This provision will apply from June 2012, 18 months after the application of the Union list under Article 30 at the end of December 2010.

The new EU Regulation also introduces provisions that permit changes to the Union list established under Article 10 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 and the Council of Ministers.

Definitions

In addition, revised definitions have been introduced for flavourings which were categorised as natural, nature identical and artificial under Directive 88/388/EEC. The definition of nature-identical flavourings has been removed as it was thought to create confusion for consumers. For the term 'natural', specific requirements have been established under Article 16. The use of this term previously applied to flavourings derived solely or almost solely from an appropriate source material (e.g. food, vegetable or animal sources). Article 29 modifies the Food Labelling Directive to apply the same principles to foods containing flavourings.

Other flavourings which need to be described on food labels are smoke flavourings which impart a smoky flavour to the food as per Article 29.

Biologically Active Principles (BAPs)

Provisions already exist under Directive 88/388/EEC which prohibits their direct addition to food. Article 6 of the new Regulation incorporates this prohibition to ensure that the maximum permitted levels established are not exceeded due to the use of flavourings and food ingredients with flavouring properties in Annex IIIB to the Regulation. The maximum levels established for these substances are based on opinions produced by the European Food Safety Authority (EFSA), and will focus on the food or food categories that contribute most to dietary intake.

A derogation from these controls has been obtained by the UK for the substances safrole, methyl eugenol and estragol, where their presence in compound foods is due to the use of herbs and spices (whether fresh, dried or frozen) and not from the use of added flavourings. This derogation will enable restaurants and sandwich makers to better comply with the legislation. Additionally, Article 6 introduces risk-based controls for BAPs and Article 20 requires Member States to establish systems to monitor their presence in foods.

Annex II sets out the list of traditional food preparation processes which are important in deciding whether a flavouring may be considered a natural flavouring substance or a flavouring preparation (see Article 3). Annex III provides the list of BAPs that should not be added to food and the maximum permitted levels in certain compound foods. Annex IV lists the source materials to which restrictions apply when used in the production of flavourings and food ingredients with flavouring properties. Finally, Annex V sets out the conditions for the

production of thermal process flavourings and the maximum levels of certain substances used in their production.

Standard Consultation Information

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/worddocs/dataprotection.doc> 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 E. 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 from that Code should be included in each consultation and they are listed below:

The Seven Consultation Criteria

Criterion 1 — When to consult

Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2 — Duration of consultation exercises

Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 — Clarity of scope and impact

Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 — Accessibility of consultation exercises

Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 — The burden of consultation

Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6 Responsiveness of consultation exercises

Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 Capacity to consult

Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

10. Criterion 2 states that *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 Assessment 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 1B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

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.

Title: Impact Assessment of a New Regulation of the European Parliament and of the Council on Food Flavourings Lead department or agency: Food Standards Agency Other departments or agencies:	Impact Assessment (IA)
	IA No: 016
	Date: 16/07/2010
	Stage: Consultation
	Source of intervention: EU
	Type of measure: Secondary legislation
Contact for enquiries: Donna Griffith-Sackey - 020 7276 8581 James Ridsdale – 020 7276 8559	

Summary: Intervention and Options

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

Food flavourings and food ingredients with flavouring properties are inconsistently regulated across the European Union (EU). Differences between these controls could lead to reduced consumer protection, and create barriers to trade between member states. In addition, flavouring legislation has evolved over 20 years and there is scope for consolidation and simplification.

Government intervention is necessary to protect consumer health by ensuring that food flavourings have been evaluated for safety; and by addressing the asymmetries to allow consumers to make an informed choice about what they eat through effective labelling; and to facilitate trade.

What are the policy objectives and the intended effects?

Policy objectives and intended effects are to ensure that up-to-date harmonised controls exist for flavourings; to provide a high level of protection for the consumer with regard to food flavourings and to improve trade between Member States.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

- 1) Do nothing. Flavourings would continue to be regulated subject to the current provisions.
- 2) Provide for the enforcement of the new EU Regulation in England.

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

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed 01/2016
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	No

Chief Executive's 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 Chief Executive:  Date: 19/7/10

Summary: Analysis and Evidence

Policy Option 2

Description:

Price Base Year 2009	PV Base Year 2009	Time Period Years 5	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	High: N/A	Best Estimate: - £18.8

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	N/A	Optional
High	N/A	N/A	Optional
Best Estimate	£14.2m	£1.7m	£23.6m

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

Annual cost: Monitoring levels of Biologically Active Principles (BAPs) by Herb and Spice Industry in England (£1.7m)

One-off cost: familiarisation cost in England to industry (£231k) and enforcement bodies (£16k) and re-labelling cost to industry (£13.9m)

Other key non-monetised costs by 'main affected groups'

None identified

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	N/A	Optional
High	N/A	N/A	Optional
Best Estimate	N/A	£0.87m	£4.8m

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

Annual Benefit: Saving to food manufacturers in England from simplification of legislation (£0.87m).

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

Enhanced consumer protection.

Additional consumer information regarding natural flavourings.

Improve and facilitate trade between member states.

Key assumptions/sensitivities/risks

Discount rate (%) 3.5%

We estimate that the changes being made are likely to save an organisation the time equivalent of one person-day per year with total savings in England for the whole industry in the order of £0.87 million per year. We estimate that a one-off familiarisation time of 2 hours per organisation will be required with a total cost in England to the whole industry of £231k.

Impact on admin burden (AB) (£m):		Impact on policy cost savings (£m):		In scope Yes/No
New AB:	AB savings:	Policy cost savings:	Net:	

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			20/01/2011		
Which organisation(s) will enforce the policy?			Local Authorities/PHAs		
What is the annual change in enforcement cost (£m)?			Negligible		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded: N/A	Non-traded: N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			Costs: N/A	Benefits: N/A	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	Micro	< 20	Small	Medium	Large
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Does your policy option/proposal have an impact on...?	Impact	Page ref within IA
Statutory equality duties¹ Statutory Equality Duties Impact Test guidance	No	13
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	13
Small firms Small Firms Impact Test guidance	No	13
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	No	13

¹ Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) - Notes

References

No.	Legislation or publication
1	Public consultation http://www.food.gov.uk/consultations/consulteng/2006/addenzyme flavour
2	European Commission Impact Assessment http://ec.europa.eu/food/food/chemicalsafety/additives/ia425.pdf

Evidence Base

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y ₀	Y ₁	Y ₂	Y ₃	Y ₄	Y ₅	Y ₆	Y ₇	Y ₈	Y ₉
Transition costs	£14.19	N/A	N/A	N/A	N/A	N/A				
Annual recurring cost	£1.70	£1.65	£1.59	£1.54	£1.49	£1.43				
Total annual costs	£15.90	£1.65	£1.59	£1.54	£1.49	£1.43				
Transition benefits	N/A	N/A	N/A	N/A	N/A	N/A				
Annual recurring benefits	£0.87	£0.84	£0.81	£0.78	£0.76	£0.73				
Total annual benefits	£0.87	£0.84	£0.81	£0.78	£0.76	£0.73				

* For non-monetised benefits please see summary pages and main evidence base section



Microsoft Office
Excel Worksheet

Evidence Base (for summary sheets)

Reason for Intervention

The regulation of flavourings and food ingredients with flavouring properties across the European Union (EU) differs between Member States. Differences also exist regarding the application of maximum levels of certain biologically active principles (BAPs) which may be present in flavourings and food ingredients with flavouring properties. These inconsistencies have created the need for uniform EU controls which ensure the free movement of safe and wholesome food, and to take into account the new scientific and technological developments for flavourings.

In the interest of clarity and efficiency, current flavourings legislation has been replaced by Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 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.

Regulation 1334/2008 offers simplification of the existing flavourings legislation, and clarifies the role of the European Food Safety Authority (EFSA) in the evaluation of flavourings and their source materials. Moreover, provisions in the new Regulation provide additional safeguards on the use of flavourings for consumers, i.e. new labelling requirements for flavourings sold as such to consumers.

Intended effect

The intention of the Regulation is to ensure that up-to-date harmonised controls exist for flavourings as well as risk-based maximum levels for BAPs which may be present in foods. As regards the maximum levels of BAPs, a derogation has been established for herbs and spices used in compound foods (whether fresh, dried or frozen) where the presence of the BAPs safrole, estragol or methyleugenol arise from the use of the herbs and spices and not from the use of added flavourings.

The key objectives of the EU measure are:

- To create a single instrument for the evaluation and authorisation of certain flavourings, food ingredients with flavouring properties, their source materials and their conditions of use in or on foods.
- To provide for the creation of an EU list of flavourings and their source materials.
- To confer on the Commission powers to update the list of flavourings.
- To formalise the role of the European Food Safety Authority (EFSA) for the risk assessment of flavourings.
- To move from BAP controls in food and drink to risk-based controls. The maximum levels established for these substances will be based on EFSA opinions and will focus on the food or the food categories that contribute most to dietary intake.
- To introduce provisions for the labelling of flavourings sold as such to food manufacturers or to the final consumer, and for the responsibilities of food business operators in respect of these products.
- To require the authorisation under Regulation 1829/2003 on genetically modified (GM) food and feed of new flavourings which consist of, contain, or are produced from a genetically modified organism (GMO). Flavourings which require evaluation under Regulations 1829/2003 and 1334/2008 will be evaluated simultaneously. Flavourings which are included on the positive list but produced from a different GM source approved under Regulation 1829/2003 will not require re-evaluation under Regulation 1334/2008.

Background

Flavourings have been traditionally used to impart odour and/or taste to food. Some are naturally present in foods or are formed during the preparation of food. The flavourings added to food can be individual substances or complex mixtures of substances containing two dozen or more constituents in order to provide the desired flavour to food. However, all flavourings, and each constituent of a flavouring blend must be safe under General Food Law (Regulation EC 178/2002). BAPs are naturally occurring components of flavourings and food ingredients with flavouring properties (such as herbs and spices). These substances raise toxicological concern and therefore should not be added as such to food.

The decision to update existing legislation on flavourings was announced by the European Commission in a White Paper on Food Safety published on 12 January 2000 (which can be accessed via the weblink below).

http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf

Council Directive 88/388/EEC (the Flavourings Framework Directive) established the general framework for food flavourings in the European Union. This Directive establishes the general principles applicable to flavourings for use in foods:

- It provides definitions for flavourings, flavouring substances, flavouring preparations, process flavourings and smoke flavourings;
- It restricts the addition and the presence of certain toxicologically relevant substances (biologically active principles) in flavourings and / or foods to which flavouring preparations and food ingredients with flavouring properties have been added;
- It provides rules for the labelling of flavourings which are intended for sale as such to food manufacturers, flavour houses and to final consumers.

Directive 88/388/EEC also provides for the adoption of more specific provisions on flavouring sources, flavouring substances, process flavourings, smoke flavourings and production methods (to be applied to additives, solvents and processing aids used for the production of flavourings). The following legislation has been adopted under the provisions set out in Directive 88/388/EEC:

- A procedure for the establishment of a positive list of flavouring substances for use in and on foods has been adopted as European Parliament and Council Regulation (EC) No. 2232/96. The positive list must be adopted by 31st December 2010.
- Regulation (EC) No. 2065/2003 of the European Parliament and Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods.
- Commission Regulation (EC) No. 627/2006 of 21 April 2006 implementing Regulation (EC) No. 2065/2003 of the European Parliament and of the Council as regards quality criteria for validated analytical methods for sampling, identification and characterisation of primary smoke products.

In August 2006, the Commission published a proposal for a new Regulation on flavourings, as part of the Food Improvement Agents Package of Regulations which also:

- introduced updated controls on food additives;
- introduced controls for the first time on food enzymes; and
- a common procedure for authorising new flavourings, additives and enzymes.

The FSA consulted in September 2006 on the UK negotiating position. More detail is given on page 10 and a link to this consultation is provided below.

<http://www.food.gov.uk/consultations/consulteng/2006/addenzyme flavour>

In November 2008 the Regulation was adopted by Council and it came into force on 20th January 2009. It generally applies from 20 January 2011. As an EU 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-compliance. Separate S.I.s will be established for Scotland, Wales and Northern Ireland.

Options

Option 1 – Do nothing. Flavourings would continue to be regulated subject to the current provisions.

Option 2 – Provide for the enforcement of the new EU Regulation in England.

Costs and benefits of options

Sectors and groups affected

The Regulation will affect:

- manufacturers of food flavourings as a result of the new labelling requirements when selling flavourings to food manufacturers and to final consumers;
- suppliers of herbs and spices due to the new requirements for monitoring BAPs and the risk - control measures that need to be in place;
- manufacturers of seasonings and condiments due to the new labelling requirements for natural flavourings and smoke flavourings which impart a smoky flavour to the food;
- food manufacturing companies (e.g. manufacturers of drinks, snacks, confectionery and prepared meals and dishes) for the reasons mentioned above; and
- enforcement authorities and food manufacturers will also need to familiarise themselves with the new Regulation.

Food manufacturers

It is anticipated that 4,590 food manufacturing businesses in England will be directly affected by the new Regulation². Only food manufacturers will incur costs and benefits as a result of the Regulation. Table 1 displays the number of food manufacturing businesses directly affected by the Regulation broken down by region and size of business, based on the number of employees.

Table 1 – Food manufacturers affected by the new enforcement regulations

	Micro	<20	Small	Medium	Large	Total
England	2,859	608	538	422	163	4,590
Wales	215	46	40	32	12	345
Scotland	402	85	76	59	23	645
NI	215	46	40	32	12	345
UK*	3,690	785	695	545	210	5,925

* Totals may not sum due to rounding

Note: Sizes are defined by number of employees per premises as follows: Micro – less than 10 employees; < 20 – 10-20 employees; Small – 20-49 employees; Medium – 50-249 employees; Large – more than 250 employees.

² The Inter Departmental Business Register (IDBR) can be accessed via the Office of National Statistics. <http://www.statistics.gov.uk/idbr/idbr.asp>; Figures are the sum of premises listed under SIC code 10 'Manufacture of Food Products'. However, SIC code 10.91 'Manufacture of prepared feeds for farm animals' and SIC code 10.92 'Manufacture of prepared pet foods' have been excluded.

Cost and Benefits options

Benefits

Option 1 – Do nothing. Current legislation would remain in place. There are therefore no incremental benefits to this option.

Option 2 – This option will benefit the food manufacturing industry because of the consolidation and simplification of this legislation. We estimate that the changes being made are likely to save an organisation the time equivalent of one person-day per year. To quantify the savings an hourly rate of £25.19³ has been applied to a production manager which is multiplied by the time equivalent of one person-day per year per organisation, 7.5 hours. This equates to an annual cost saving per food manufacturing business of £189⁴. When the saving per business is applied to 4,590 food manufacturing businesses, it equates to a total annual cost saving to food manufacturers of £0.87 million in England⁵. Table 2 displays the annual benefits broken down by firm location and size.

Table 2 – Annual savings to food manufacturing businesses

	Micro	<20	Small	Medium	Large	Total
England	£540,143	£114,909	£101,734	£79,777	£30,740	£867,303
Wales	£40,599	£8,637	£7,647	£5,996	£2,311	£65,189
Scotland	£75,903	£16,147	£14,296	£11,211	£4,320	£121,876
NI	£40,599	£8,637	£7,647	£5,996	£2,311	£65,189
UK	£697,244	£148,330	£131,324	£102,980	£39,681	£1,119,558
Rounded	£700,000	£150,000	£130,000	£100,000	£40,000	£1,120,000

This option also ensures that the UK is not out of step with the EU and so is not vulnerable to infraction proceedings.

Costs

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

Option 2 – There are new controls establishing maximum levels of BAPs in certain foods and new labelling requirements for natural flavourings and smoke flavourings which impart a smoky flavour to the food.

BAPs from Herbs and Spices

The new legislation establishes risk-based controls for biologically active principles (BAPs) where the maximum levels set for certain BAPs will focus on the food categories that provide the greatest risk.

In practice, the food manufacturing industry may well choose to move to the use of liquid flavouring extracts made from herbs and spices because the levels of BAPs will be more easily controlled. Controls on BAPs in flavouring extracts already exist under current legislation, so compliance in this fashion would involve minimal new costs associated with scientific and technical updating of the list of substances to be monitored.

In the catering industry the same solution is possible for large suppliers of pre-packed food/ready meals. However in restaurants where food is prepared on the premises and fresh herbs and spices are used it would have been extremely difficult for them to ensure compliance because of natural variability of BAP

³ Wage rate obtained from The Annual Survey of Household Earnings (2009) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of a 'Production manager' is used (£19.38 plus 30% overheads)

⁴ £25.194 * 7.5 = £188.955

⁵ £188.955 * 4,590 = £867,303

levels. The UK considered these proposed controls would have been disproportionate to the risk and therefore secured a derogation for safrole, methyleugenol and estragol.

To comply with BAP limits in compound foods, manufacturers and caterers might choose to rely on the herb and spice supply industry to monitor levels in incoming batches. Previous information from the herb and spice industry in 2007 indicates that in order for a small to medium sized enterprise (SME) to comply with controls on maximum levels for BAPs, they would need to test on average, 266 batches of herbs and spices and 45 batches of oleoresins per year. As an alternative, the herb and spice industry has told us that they are in the process of gathering data to identify the typical levels of BAPs in herbs and spices. Seasoning and condiment manufacturers would rely largely on data from their herb and spice suppliers but industry has told us that additional administrative and other costs would be approximately £20k to £30k per annum.

Assuming industry adopted the approach of widely testing batches, the total cost to the UK herb and spice industry is estimated to be £2.2⁶ million per annum. However, if industry works to typical values the total cost per annum could be significantly less. Table 3 displays the cost to the herb and spice industry broken down by region and firm size:

Table 3 – Cost of BAP limits by region and firm size⁷

	Micro	<20	Small	Medium	Large	Total
England	£1,061,415	£225,802	£199,914	£156,767	£60,406	£1,704,304
Wales	£79,780	£16,972	£15,026	£11,783	£4,540	£128,101
Scotland	£149,153	£31,730	£28,093	£22,029	£8,488	£239,494
NI	£79,780	£16,972	£15,026	£11,783	£4,540	£128,101
UK	£1,370,127	£291,477	£258,059	£202,363	£77,975	£2,200,000
Rounded	£1,370,000	£291,000	£258,000	£202,000	£78,000	£2,200,000

Labelling of natural flavourings

New provisions will require prescribed terms to be used when referring to flavourings as ‘natural’ in the ingredients list.

Information on the frequency at which businesses re-label products in this category is limited, however 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 £1,500 to £3,000 per product⁸.

Table 4 – Labelling cost estimates in the range of £1,500 to £3,000

No. of products	Lower bound	Best estimate Mid-point	Upper bound
If all 12,000 re-labelled	£18,000,000	£27,000,000	£36,000,000
If 2/3 of total i.e. 8,000 re-labelled	£12,000,000	£18,000,000	£24,000,000

Estimates of the total cost of re-labelling are detailed in the table above. Discussions between the Agency and stakeholders have indicated that the number of products currently labelled as containing natural flavourings is estimated at 12,000. The lower and upper bounds of the total costs are calculated

⁶ Based on calculations provided by the Seasoning and Spice Association (SSA)

⁷ £2.2m total BAP cost has been apportioned across devolved administrations using the percentage breakdown by region and size of business for food manufacturers (IDBR).

⁸ These figures are based on Agency consultations with stakeholders for the Recommendations on Saturated Fat Impact Assessment – <http://www.food.gov.uk/multimedia/pdfs/satfatimpactassessment.pdf>

by multiplying the number of products by the upper and lower bounds of the cost per product respectively (£1500 and £3000).

Assuming a 3 year re-labelling cycle, it is likely that some products will be re-labelled as part of the re-labelling cycle before January 2011 when the legislation comes into force. It is also likely that in anticipation of the forthcoming legislation these re-labelled products will display information relating to the new natural flavouring provisions. As this would be part of the standard re-labelling cycle the associated costs are not a result of the new legislation.

We therefore assume that 33% (1/3) of the applicable products will be re-labelled before legislation comes into force and that about 67% (2/3) of all products will require re-labelling when the legislation comes into force which will not be within the usual re-labelling cycle. 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 £13.9 million in England. Table 5 displays the labelling costs to industry broken down by location and firm size.

Table 5 – Labelling costs broken down by region and firm size

	Micro	<20	Small	Medium	Large	Total
England	£8,684,301	£1,847,473	£1,635,661	£1,282,641	£494,228	£13,944,304
Wales	£652,742	£138,862	£122,942	£96,408	£37,148	£1,048,101
Scotland	£1,220,343	£259,612	£229,848	£180,240	£69,450	£1,959,494
NI	£652,742	£138,862	£122,942	£96,408	£37,148	£1,048,101
UK*	£11,210,127	£2,384,810	£2,111,392	£1,655,696	£637,975	£18,000,000
Rounded	£11,210,000	£2,385,000	£2,111,000	£1,656,000	£638,000	£18,000,000

* Totals may not sum due to rounding

Note: Sizes are defined by number of employees per premises as follows: Micro – less than 10 employees; < 20 – 10-20 employees; Small – 20-49 employees; Medium – 50-249 employees; Large – more than 250 employees.

Q. The Agency welcomes opinions, preferably with an evidence backing, regarding the assumptions used for the calculations for labelling costs.

Familiarisation cost

Industry

There will be a small one-off cost to businesses for reading and familiarising themselves with the new Regulation. We have estimated that a business will invest one hour reading and familiarising themselves with the Regulation. In addition, we have estimated that each person uses a further hour for dissemination to key staff within the organisation, meaning a total of two hours.

There are 4,950 food manufacturers in England which could be directly affected by the Regulation. A wage rate of £25.19⁹ has been applied for a manager of an organisation who reads the document, which is multiplied by the number of businesses and the reading time to give a familiarisation cost to industry broken down by region and firm size.

⁹ Wage rate obtained from the Annual Survey of Household Earnings (2009) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=5313>). Median hourly wage of a 'Production manager' is used £19.38 plus 30% overheads).

Table 6 – Familiarisation cost to food manufacturers

	Micro	<20	Small	Medium	Large	Total
England	£144,038	£30,642	£27,129	£21,274	£8,197	£231,281
Wales	£10,826	£2,303	£2,039	£1,599	£616	£17,384
Scotland	£20,241	£4,306	£3,812	£2,989	£1,152	£32,500
NI	£10,826	£2,303	£2,039	£1,599	£616	£17,384
UK	£185,932	£39,555	£35,020	£27,461	£10,581	£298,549
Rounded	£190,000	£40,000	£40,000	£30,000	£10,000	£300,000

Local Authorities

It is anticipated that Local Authorities (LA) will also need to read and familiarise themselves with the new Regulation. The familiarisation cost per LA is calculated by multiplying the reading time, 2 hours, by the wage rate applied to an Environmental Health Officer of £20.70¹⁰. To quantify the overall familiarisation cost to enforcement authorities, we multiply the familiarisation cost per LA by the number of LAs in England, 389, which gives a one-off familiarisation cost to LAs in England of £16,101¹¹. Table 7 displays the familiarisation cost and the number of LAs per country.

Table 7 – Number of Local Authorities and familiarisation cost per country

Location	Number of LA's	Familiarisation cost
England	389	£16,101
Wales	22	£911
Scotland	32	£1,325
NI	26	£1,076
UK	469	£19,413
Rounded		£20,000

Q. The Agency welcomes opinions, preferably with an evidence backing, regarding the assumptions used for the calculations for familiarisation costs.

Administrative Burden Costs

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

The first IO is a requirement for producers or users of food flavourings, when requested, to inform the Commission of the actual use of the flavouring i.e. the categories of food in which it is used, and the levels.

The Regulation specifies (Article 20) that detailed rules for collection of information from industry will be adopted in accordance with comitology so there will be an opportunity to build in a proportionate, risk based approach during comitology discussions. We also note that, whilst the new proposal formalises the Commission's power to request this information, in practice it will be able to request this data whether or not the new proposal is adopted. This is because if there is concern about exposure to a particular flavouring, the Commission will act to control exposure unless appropriate usage information is submitted. Therefore, we do not anticipate any new incremental costs.

The second IO requires a producer or user of a food flavouring to inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the

¹⁰ Wage rate obtained from the Annual Survey of Household Earnings (2009) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=5313>). Median hourly wage of an Environmental Health Officer is used £15.92 plus 30% overheads).

¹¹ 41.39 * 389 = £16,101

flavouring. 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 therefore consider that any additional costs of these new requirements will be minimal.

Enforcement Costs

Local authorities are responsible for enforcement of current legislation on flavourings. In consulting LACORS to determine the costs involved in the enforcement of the UK Regulations, we were advised that any additional costs of enforcing these provisions will be minimal.

Summary view of the options

Overall we support the Regulation in updating the existing legislation to protect consumers from the toxicological effects of BAPs themselves, and in a proportionate way by specifying the most important food categories contributing to consumer exposure. Option 1 would not provide these benefits.

Q. 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.

Q. We particularly welcome contributions 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 with DEFRA, the Better Regulation Executive and the Enterprise Directorate of the Department of Business, Innovation and Skills. Local Authorities will be responsible for enforcement of these measures and LACORS was consulted as part of the full public consultation on earlier proposals.

ii) Public consultation

In September 2006 the FSA launched a 12 week public consultation on the Commission's proposal for new EU Regulations on flavourings (as well as additives and enzymes). Approximately 450 stakeholders were consulted and a summary of the 22 results can be found at:

<http://www.food.gov.uk/consultations/consulteng/2006/?completed=Yes>

Consumer representatives welcomed the review of the legislation. Concerns were raised in relation to the information provided to consumers on the nature and source of flavourings used in foods. They wished to see clear, transparent criteria by which authorisation decisions would be made and the UK was successful in securing agreement that the time period allotted to the Commission to draft authorisation decisions should include a period of public consultation. They were in favour of a ten year review of all flavourings, however, we felt that the agreed on-going evaluation would provide a more focused risk-based solution which is proportionate and allows action to be taken sooner, if concerns arise.

Industry generally welcomed the proposals which will simplify existing legislation. However the Seasoning and Spice Association raised concerns over the proportionality, practicality and enforceability of the controls on BAPs in compound foods where these BAPs were present due to the use of fresh or dried herbs and spices. The controls would introduce difficulties with respect to sampling and testing in order to ensure compliance, caused by the large natural variability of levels in the source product. We have provided costings for these points in the costs section of this IA.

The enforcement authorities welcomed the proposed simplification of the legislation.

These results fed in to UK Government's negotiating position, and we continued to communicate with stakeholders throughout the negotiation process (see Annex 3).

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 provisions of the new Regulation to monitor and review the consumption and use of flavourings and to report their findings to the European Commission.

Simplification

The previous legislation was spread across a number of provisions and had been amended several times. By putting it into a single measure it will be less onerous on business to follow. The new measures will also harmonise controls across member states.

Implementation and Review

The new Regulation came into force on 20 January 2009, and will apply from 20th January 2011. It will be enforced in England by secondary legislation. It will be enforced in Scotland, Wales and Northern Ireland by similar but separate legislation. The new Regulation will be reviewed in the UK 5 years after coming into force (2016). This will allow time for all of its provisions to apply and for transitional periods to expire.

Annexes

Annex 1: Post Implementation Review (PIR) Plan

<p>Basis of the review:</p> <p>1. The FSA's rolling simplification programme, which aims to reduce the regulatory burdens on businesses while maintaining consumer protection.</p>
<p>Review objective:</p> <p>1. Check to see how food businesses are complying with the requirements set out in the legislation. 2. Assess the effectiveness of the derogation secured for fresh herbs and spices. 3. Review the legislation in light of the new EU Food information Regulation as regards the new labelling requirements for natural flavourings.</p>
<p>Review approach and rationale:</p> <p>1. Re-evaluate the estimated costs and benefits by undertaking: a. Discussions with industry, trade organisations and enforcement bodies to establish ease of complying with the new provisions regarding BAPs monitoring and labelling requirement, and, where possible, a best estimate of cost savings/time saved. b. Discussions with consumer organisations to determine the ease with which consumers can identify the nature and source of flavourings used in foods.</p>
<p>Baseline:</p> <p>1. The current baseline is given in option 1 (i.e. do nothing – existing legislation remains). 2. The baseline for a review will be the success of the measures outlined in option 2 (i.e. consolidation and simplification of the existing legislation).</p>
<p>Success criteria:</p> <p>1. Positive feedback of cost and time savings made by food businesses can be used as an indication of policy success. 2. Positive feedback from consumers and consumer organisations will also be considered in assessing whether the policy has been successful (e.g. understanding of the food labels). 3. Another measure of success could also be the ease of interpretation of the legislation by both enforcement officers and food businesses.</p>
<p>Monitoring information arrangements:</p> <p>1. Monitoring to be carried out via routine meetings and discussions as well as through other feedback and enquiries from consumers, trade organisations and enforcement bodies.</p> <p>These exchanges with stakeholders will help to identify positive and negative lessons learnt, as well as identify areas for future development.</p>
<p>Reasons for not planning a PIR:</p> <p>N/A.</p>

Annex 2: Specific Impact Tests

Competition Assessment

Application of the competition filter test indicated that the impact on competition is likely to be small. Although the UK flavouring market is concentrated, with 10 companies controlling 85% of sales (the rest of the market being made up of small manufacturers / distributors) there is no reason to believe the proposal would affect some firms disproportionately, and modify the structure of the market.

Small Firms Impact Test

Earlier drafts of the EU Regulation have received comments from industry, including small businesses and many of their views and suggestions have been incorporated into the final Regulation (see Annex 3). In order to determine the impact on small flavouring businesses we have spoken to the British Essence Manufacturers Association (BEMA) who represent UK flavouring producers/distributors (including small flavouring companies). No significant impact on small firms was raised during the consultation.

We considered that the setting of BAP limits, stemming from the use of herbs and spices for compound foods, would have a disproportionate impact for small restaurants and catering businesses preparing food on site. The derogation achieved by the UK for safrole, methyleugenol and estragol will go a long way towards addressing this.

Sustainable Development

Impacts under all three pillars of sustainable development (economic, social and environmental) have been and continue to be considered in the preparation of this Impact Assessment.

Option 2 is the relatively more sustainable option because of the positive social impacts it offers to consumers. They are afforded a high level of protection due to the evaluations required for certain flavourings prior to use as well as the risk-control measures to be established for BAPs, which will focus on the food or food categories that contribute most to dietary intake. Additionally, consumers will be able to identify the nature and source of the flavourings used in foods.

Food businesses and enforcement bodies will benefit from the simplification and consolidation of the existing legislation, as it makes it easier to comply and enforce respectively. Negative impacts have been minimised for food businesses (e.g. restaurants and sandwich shops) using herbs and spices in compound foods by the UK securing the derogation for safrole, methyleugenol and estragol.

Some negative environmental and social impacts have been identified due to the re-labelling of products using natural or smoke flavourings which impart a smoky flavour to food. Labels/packaging that do not comply with the new legislation will have to be disposed of and so will be a wasted resource and new labels/packaging will need to be printed, resulting in unnecessary carbon emissions and increased costs. However, as the printing of new labels is due to the change in legislation, these costs will reduce with subsequent label printing cycles.

Statutory Equality Duties

The EU Regulation does not have an impact on race, gender or disability equality.

Annex 3: UK Government's negotiating position on Flavourings - UK Options / Achievements

Fresh and dried herbs and spices

Whilst existing flavourings legislation placed controls on BAPs in flavourings, the new Flavourings Regulation makes explicit that the limits will also apply to food flavoured with certain herbs and spices. The UK considers that compliance with these maximum limits will be challenging because of natural variation in the content of these substances in herbs and spices. However, data which demonstrates for some herbs and spices, that consumption is of no toxicological concern, are not sufficiently robust to make a risk management decision on excluding all BAPs present in food through the use of herbs and spices.

Throughout negotiations, the UK remained concerned by the potential impact the proposal might have on food served in restaurants, as chefs would be interested in producing a meal with the appropriate flavour and would not have the facilities to monitor compliance with maximum limits. To this end, the UK was successful in securing an exemption from controls on the substances methyl eugenol, safrol and estragol where their presence in food is due solely to the use of herbs and spices (these BAPs occur in many of the commonly used herbs and spices). This will be of particular benefit to food producers making meals from scratch with basic ingredients, such as restaurant chefs.

Targeted risk-based monitoring

Early drafts of the Commission proposal included a commitment to review flavouring authorisations every ten years. The UK considered carefully whether or not this should be retained. However other obligations on Industry within this Regulation, to notify the Commission of new information which may affect the risk assessment of an additive, coupled with monitoring by Member States, permit a more targeted risk based approach. The UK was successful in putting forward this argument, and the risk based approach was included in the Regulation.

Labelling of natural flavourings

The new Regulation prescribes terms to be used when labelling flavourings as natural. These require that the source of the natural flavouring is identified; however the particular term to be used varies depending on the composition of the flavouring. These terms are also to be used in the ingredients list of foods sold to the final consumer. Businesses have told us that the length of these phrases makes correct labelling of some products difficult, particularly where a packet may contain products of different flavours leading to several of the prescribed terms being listed.

The UK pressed for the option of using the term 'natural flavourings', as an alternative to the longer terms prescribed, however this was not supported by sufficient Member States to be included in the final Regulation.

STATUTORY INSTRUMENTS

2010 No. 0000

FOOD, ENGLAND

The Flavourings in Food (England) Regulations 2010

Made - - - - 2010

Laid before Parliament 2010

Coming into force - - [20th January 2011]

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)(a) and (b) and (3) and 48(1) of the Food Safety Act 1990(a) and now vested in him(b).

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(c), there 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 Flavourings in Food (England) Regulations 2010, apply in relation to England only and come into force on [20th January 2011].

Interpretation

2.—(1) In 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, S.I. 2004/2990 and S.I. 2004/3279.
 - (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 subsequently 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) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Commission Regulation (EC) No. 596/2009 of the European Parliament and of the Council adopting a number of instruments subject to the procedure referred to in Article 251 of the treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adoption to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p14).

“the Act” means the Food Safety Act 1990;

“the EU Regulation” means 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(a);

“authorised officer” means any person who is authorised in writing, either generally or specifically, by a food authority or as the case may be a port health authority to act in matters arising under these Regulations;

“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 EU Regulation has the same meaning in these Regulations as it bears in the EU Regulation.

(3) Any reference in regulation 3 to a numbered Article is a reference to the Article so numbered in the EU Regulation.

Offences and penalties

3.—(1) A person who contravenes or fails to comply with any of the EU provisions specified in paragraph (2) as read with the transitional arrangements contained in Article 30 is guilty of an offence.

(2) The EU provisions are —

- (a) Article 4 (general conditions of use of flavourings or food ingredients with flavouring properties);
- (b) Article 5 (prohibition of non-compliant flavourings or non-compliant food);
- (c) Article 6(1) and (2) (restrictions on the presence of certain substances);
- (d) Article 7 (restrictions on the use of certain source materials);
- (e) Article 10 (restriction relating to the Community list of flavourings and source materials);
- (f) Article 14(1) (labelling of flavourings not intended for sale to the final consumer);
- (g) Article 17 (labelling of flavourings intended for sale to the final consumer); and
- (h) Article 19(2) and (3) (reporting obligations on food business operators).

(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.

Enforcement authorities

4. It is 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 EU Regulation.

(a) OJ No. L.354, 31.12.2008, p.34.

(b) 1984 c. 22.

Application of various sections of the Food Safety Act 1990

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 of it 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)(a) with the modification that —
 - (i) subsections (2) to (4) shall apply in relation to an offence of contravening regulation 3(2)(a) to (g) 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)(b), in so far as it relates to offences under section 33(1) as applied by paragraph (3)(b);
- (e) section 35(2) and (3)(c), 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); and
- (g) 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 the EU Regulation.

(3) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act is to be construed as including a reference to the EU 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 etc. of officers);
- (c) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” is deemed to be a reference to any such requirement as is mentioned in that subsection as applied by sub-paragraph (b); and
- (d) section 44 (protection of officers acting in good faith).

(4) Section 34 of the Act (time limit for prosecutions) applies to offences under 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 shall 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.

Amendments to the Food Labelling Regulations 1996

7.—(1) The Food Labelling Regulations 1996(a) are amended in accordance with paragraphs (2) and (3).

(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.

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

(a) for the definition of “the additives regulations” substitute the following —

““the additives regulations” means the Food Additives (England) Regulations 2009, Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives and 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;”;

(b) for the definition of “flavouring” substitute the following —

“the noun “flavouring” bears the same meaning as “flavourings” as defined in Article 3(2)(a) of Regulation 1334/2008;”;

(c) the definitions of “flavouring preparation”, “flavouring substance”, “process flavouring” and “smoke flavouring” are omitted.

(3) In regulation 14 (names of ingredients) —

(a) for paragraph (5) substitute the following —

“(5) Subject to paragraph (5A) and to regulation 34B, where an ingredient being a flavouring is added to or used in a food it shall be identified by either —

(a) the word “flavouring” or, where more than one such ingredient is used, “flavourings”, or

(b) a more specific name or description of the flavouring; or

(c) the expression “smoke flavouring(s)” or “smoke flavouring(s) from (*insert name of food or food category or source*)” if the flavouring component contains smoke flavouring as defined by Article 3(2)(f) of Regulation 1334/2008 and imparts a smoky flavour to the food.”;

(b) for paragraph (6) substitute the following —

“(6) The word “natural” to describe an ingredient being a flavouring may only be used in accordance with Article 16 of Regulation 1334/2008.”; and

(c) paragraphs (7) and (8) are omitted.

Revocation

8. The Flavourings in Food Regulations 1992(b) are revoked in so far as they apply in relation to England.

Signed by authority of the Secretary of State for Health

Minister's name
Parliamentary Under-Secretary of State
Department of Health

Date 2010

(a) S.I. 1996/1499. Regulation 14(5) was previously amended by S.I. 2003/2647 and S.I. 2004/2824. Regulation 34B was amended by S.I. 2005/2057 and S.I. 2008/1188.

(b) S.I. 1992/1971.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. To be completed after consultation

FLAVOURINGS CONSULTATION - LIST OF CONSULTEES

A F Suter Ltd	British Cheese Board
A H Allen & Partners	British Dietetic Association
A. H. Allen Ltd	British Essence Manufacturers Association
Action Against Allergy	British Frozen Food Federation
Advertising Association	British Hospitality Association
AEA Technology	British Meat Processors Association
Alcontrol Laboratories Group	British Retail Consortium
Allied Bakeries Ltd	British Soft Drinks Association Ltd
Allied Technical Centre	British Specialist Nutrition Association
Alltech (UK) Ltd	Britvic plc
Alpro UK Ltd	Brunel Healthcare Manufacturing Ltd
Ambersil Ltd	Brunner Mond & Company Ltd
Arla Foods UK	Burson-Marsteller
Arthur Branwell & Co Ltd	Bush Boake Allen
Artisan Foods	Buzz 2000 Ltd
Asda Stores Limited	Cadbury plc
Asia Food Products Ltd	Cadbury Schweppes plc
Association for the International Promotion of Gum	CAFIA
Association of Cereal Food Manufacturers	Cambridge Health Plan Ltd
Association of Convenience Stores	CAMedica Consulting
Association of Port Health Authorities	Campden BRI
Association of Public Analysts	Cantox Health Sciences International
Association of Public Analysts of Scotland	Cargill
Bakery Working Group of Soil Association	Centre for Pregnancy Nutrition
Barentz BV	Cereal Partners UK
Basildon Chemical Co Ltd	Chartered Institute of Environmental Health Chemistry & Industry Magazine
Belfast Trust	Cherry Valley Farms Ltd
Bernard Matthews Farms Ltd	Chilled Food Association Ltd
Berry Ottaway and Associates Limited	Christan Hanson UK Ltd
Bespoke Foods Ltd	CIPCEL (Comité International de la Pellicule Cellulosique)
Birds Eye Iglo Group Ltd	CMS Cameron McKenna LLP
Birmingham City Council Trading Standards	Coca-Cola European Union Group
Birmingham City Laboratories	Coca-Cola Great Britain & Ireland
BMMA	Committee of the EU
Boehringer Ingelheim Limited	Consultant, ELC
Booker Ltd	Consumer Council for Northern Ireland
Botanix	Consumer Focus
Bottle Green Drinks Company	Consumer Focus Scotland
Bowmans Milling Ltd	Consumer Focus Wales
Braes Group Ltd	Co-operative Group
Brent Council	County Confectionery
Brent Environmental Health Authority	Covington and Burling LLP
Brewing Research International	Cullinane Associates Ltd
Bristol City Council	Cultor Food Science
Bristol City Council Scientific Services	Dairy Crest Group plc
British Beer and Pub Association	Danisco Ingredients UK Ltd
British Caramel Manufacturers Association	Dawn Foods (UK) Ltd
	DBC Foodservice

Decision News Media
Department for Children, Schools and Families
Department of Health (Hong Kong)
Dera Food Technology UK Ltd
Derbyshire Trading Standards Office
DSM Food Specialities
Durham County Council
East End Foods plc
Edlong Flavours, Edlong Co Ltd
Edme Ltd
Eggar & Co Chemicals Ltd
Euro Food Marketing
EuroChemLink Ltd
Eurofins Laboratories Ltd
European Snacks Association / SNACMA
Exova (UK) Ltd
F I Data Services
Farmhouse Cheesemakers Ltd
Federation of Bakers
Federation of Women's Institutes in Northern Ireland
FIPRA International Ltd
Firmenich UK Ltd
Flavour Craft
Food Additives and Ingredients Association
Food and Drink Federation
Food and Environment Research Agency
Food Commission UK Ltd
Food Ethics Council
Food Industry Environmental Network LLC
Food Law Monthly
FoodChain Europe Ltd
FR Benson & Partners Ltd
Franz Zentis GmbH & Co
Friends of the Earth
Frutarom UK Ltd
Geest Industries Plc
Gerber Juice Company Ltd
Gin & Vodka Association
Glasgow Scientific Services
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
Hertfordshire Trading Council
Holland & Barrett Retail Limited
Huntington Life Sciences
Hyperactive Childrens Support Group
Hyperama
Ice Cream Alliance
Icefresh Foods Limited
Iceland Foods Limited
Institute of Food Science and Technology
Institute of Grocery Distribution
International Life Sciences Institute (ILSI)
International Pectin Producers' Association
International Speciality Products
J Ralph Blanchfield Consultancy
J Sainsbury plc
Japanese Embassy
Kapajo.com
Keller & Heckman LLP
Kellogg Europe Trading Limited
Kent County Council
Kent Scientific Services
Keylink Ltd
Kimpton Brothers Ltd
Kraeber (UK) Ltd
KTC (Edibles) Ltd
Laboratory of the Government Chemist
Laurens Patisseries
Leatherhead Food International
Leicester City
LGC Limited
Lidl UK GmbH
London Borough of Bexley
London Borough of Ealing Council
London Borough of Greenwich
London Port Health Authority
Lycored Ltd
Margaret Anderson & Associates
Marinalg International
Marks and Spencer plc
Marlin Chemicals Ltd, Industrial Waxes Division
Mars UK Limited
Masonline Ltd
Mastertaste
McCormick (UK) Ltd
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	The Food Commission
National Farmers' Union	The National Association of Cider Makers
National Federation of Women's Institutes	Thorntons plc
National Starch & Food Innovation	TMC Ventures Inc.
Nestle UK Limited	Townswomens Guild
Neville Craddock Associates	Turkish Embassy
Nutragen Ltd	Unilever plc
Omya UK Limited, Technical Centre	United Distillers & Vintners Brand Technical Centre
Overseal Natural	United Kingdom Vineyards Association
P & B (Foods) Ltd	University College Chester
Pattinson Scientific Services	University of Nottingham
PepsiCo UK & Ireland	University of Reading
PQ Corporation	University of Sussex
Premier Foods Ltd	Vegetarian Economy and Green Agriculture
Princes Soft Drinks	Ventress Technical Ltd
Procter & Gamble UK and Ireland	Verner Wheelock Associates Limited
Provision Trade Federation	Vitrition UK Ltd
R.Twining and Company Limited	Wales Assembly for Women
Reading Scientific Services Ltd	Warwickshire County Council
Regulatory Solutions	West Yorkshire Joint Services
Rhodia Ltd	Westler Foods Ltd
Roderic Establishment	Which?
Royal Environmental Health Institute of Scotland	Whitehouse Consultancy Ltd
Royal Society for Public Health	Whitworths Foods Group Ltd
S. Black Ltd	William Blythe & Co Ltd
Salt Association	Wimpy UK
Scotch Whisky Association	Wine and Spirit Trade Association
Scotch Whisky Research Institute	Witwood Food Products Ltd
Sea Fish Industry Authority	Worcestershire Scientific Services
Seed Crushers & Oil Producers Association	Worldwide Fruit Ltd
Seed Crusher's and Oil Processor's Association	Zeelandia Ltd
Sensient Flavours	Dr Ed Komorowski
SHS International Limited	Mr Brian Taylor
Society of Independent Brewers (SIBA)	Dr Richard Moody
Soda Club Ltd	Dr Andrew Smith
Soil Association	Dr F Sullivan
Somerset (1 1 9)	Mr John Stevens
Somerset County Council	Ashley Roberts
Southampton City Council	Dr Nancy Zeman
SPP Ingredients	Lionel Stanbrook
Superdrug Stores Plc	Dr Richard Burt
Surrey County Council	Mr Paul Anthony Taylor
Surrey Trading Standards, Mid Surrey Area Office	Mr Edward Langridge
Sustain	The Co-operative Group
Sweet and Maxwell London	Local Government Regulation
Tate & Lyle plc	Weetabix Ltd
Tazaki Foods Ltd	Toms Confectionery Ltd
Tesco Stores plc	Direct Food Ingredients Ltd
Tetley Group Ltd	Asda Stores Ltd
	St Ivel Ltd