EXPLANATORY MEMORANDUM TO

THE FLAVOURINGS IN FOOD REGULATIONS (NORTHERN IRELAND) 2010

2010 No. 414

1. Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency in Northern Ireland to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule is made under Articles 15(1)(a), (e) and (f) 16(2), 25(1)(a) and (b) and (3) and 47(2) of the Food Safety (Northern Ireland) Order 1991.

2. Purpose of the Rule

2.1 Although governed by harmonising European Directives, food flavourings and food ingredients with flavouring properties are inconsistently regulated across the EU. Differences also exist regarding the application of the maximum levels established in the legislation for certain biologically active principles[(1)](BAPs) which may be present in flavourings and food ingredients with flavouring properties. This rule enforces EU measures which introduce harmonised controls for the assessment and authorisation of flavourings and their source materials used in food. This provides a high level of consumer protection.

3. Legislative Background

3.1 The existing regulatory framework for food flavourings in the EU is established under Council Directive 88/388/EEC (which is completed by Directive 91/71/EEC). This Directive also provided for the adoption of a positive list of flavouring substances under Regulation (EC) 2232/96. In the interest of clarity and efficiency, this legislation has been replaced by EU Regulation 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring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.

3.2 There is an ongoing evaluation programme of the flavouring substances currently regulated under Regulation (EC) 2232/96; however it is intended that following the completion of the evaluation programme these substances will be transferred into a new Union List of flavouring substances and their source materials provided under Regulation 1334/2008.

3.3 EU Regulation 1334/2008 is directly applicable in the UK, for the most part as of 20th January 2011; however a Statutory Rule (SR) is required to enforce the Regulation and identify penalties for non-compliance. As such, this rule is being made to enforce, within Northern Ireland, the provisions of the new EU Regulation.

4. Parity or Replicatory Measure

4.1 This Rule applies to Northern Ireland only. Parallel legislation is being made in England, Scotland and Wales.

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(1) BAPs are substances of toxicological significance which occur naturally in certain herbs and spices and are an inherent part of their flavour.

5. European Convention on Human Rights

5.1 As this Rule is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Policy background

6.1 Flavourings can be individual substances or complex mixtures containing two dozen or more substances in order to give the desired flavour to food.

6.2 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.

6.3 Whilst harmonised controls do already exist, changes were required in order to maintain a high level of consumer protection and to ensure the free movement of safe and wholesome food and to take into account the new scientific and technological developments. 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. Additionally, the new EU Regulation confers powers on the Commission to update the Union List of flavouring substances and their source materials by the comitology route. Moreover, provisions in the Regulation provide additional safeguards on the use of flavourings for consumers, i.e. new labelling requirements for flavourings sold as such to consumers, additional requirements for the authorisation of flavourings derived from Genetically Modified Organisms (GMOs) and the move of BAP controls in food and drink to risked-based controls, where the maximum levels established are based on EFSA opinions, and will focus on the food or the food categories that contribute most to dietary intake.

6.4 In the interest of clarity and efficiency, current flavourings legislation has been replaced by Regulation 1334/2008.

7. Consultation

Within Government

7.1 District Councils will be responsible for enforcement of these measures and their coordinating body was consulted as part of the full public consultation on the Commission proposal and on the enforcement SR.

Public Consultation

7.2 In September 2006, the FSA launched a 12 week public consultation on the Commission's proposals for three new Regulations on Flavourings, Additives and Enzymes. Approximately 200 stakeholders were consulted and no responses were received in Northern Ireland. A proportion of these related to food additives and enzymes: consumer groups and industry were generally content with the flavourings proposal. A summary of specific responses can be found at **http://www.food.gov.uk/consultations/consulteng/2006/?completed=Yes.**

7.3 In July 2010, the FSA consulted publicly for 12 weeks on the rule to which this Memorandum relates. Approximately 200 stakeholders were consulted. One response was received in Northern Ireland.

8. Guidance

8.1 The Flavourings industry has produced guidance to this technical legislation. Government is producing guidance as to when products can be labelled as containing natural flavourings.

9. Equality Impact

9.1 These regulations will apply in equal measure to all Section 75 groups. It is not expected that any of these changes will impact differentially across any of the section 75 groups.

10. Impact

10.1 An Impact Assessment is attached to this memorandum. This Impact Assessment has been prepared by FSA colleagues in England but it is believed to be equally representative of the situation in Northern Ireland.

11. Regulating small business

11.1 The legislation applies to small businesses. The Trade Association that covers small businesses has not identified any significant impact on business emanating directly from Regulation 1334/2008.

12. Monitoring and review

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

13. Contact

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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 Assessmen (IA)
	IA No: FOODSA 0013
	Date: 08/11/10
	Stage: Final
	Source of intervention: EU
	Type of measure: Secondary legislation
	Contact for enquiries: Wendy Dixon 020 7276 8587 wendy.dixon@foodstandards.gsi.gov.uk

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

SELECT SIGNATORY Sign-off For final 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:... Date:.......................................

Summary: Analysis and Evidence Policy Option 2

Description:

Provide for the enforcement of the new EU Regulation in England

Price Base Year 2010	PV Base Year 2010	Time Period Years 6	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	High: N/A	Best Estimate: -£18.9

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	1	N/A	**Optional**
High	N/A		N/A	**Optional**
Best Estimate	£14.25m		£1.7m	**£23.7**

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

Total cost of policy option in England: £24.48m (constant price). Total cost in England to industry: £289k in one-off familiarisation costs; re-labelling costs of £13.94m; £10.23m in total on-going costs associated with monitoring levels of Biologically Active Principles. Total cost in England to enforcement bodies (LAs): £16k in one-off familiarisation costs.

Over a 6 year period the total equivalent annual cost of familiarisation and labelling is approximately £2.67m in England. This equates to an EAC of approximately £54k for industry familiarisation, £3k for enforcement bodies familiarisation and £2.62m for industry labelling costs in England.

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

Short-run costs associated with initial activity for enforcement providing advice in response to enquiries including enforcement action to progress compliance.
Some companies may decide to reformulate if they are looking to continue to compete in the market for 'natural flavourings'.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	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). Over 6 years this equates to a total benefit in England of £5.2m (constant price).

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 eqivalent 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 and 30 minutes per business will be required with a total cost in England to the whole industry of £289k.

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

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
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)?			Minimal[2]		
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 duties[3] Statutory Equality Duties Impact Test guidance	No	15
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	15
Small firms Small Firms Impact Test guidance	No	15
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	15

2 Minimal once food business operators adjust to the new legislation but it is recognised there may be an initial amount of work for enforcement officers in providing advice in response to queries.

3 Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once relevant sections of the Equality Act come into force. Statutory equality duties part of the Equality Act 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/addenzymeflavour
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(EAC)4	2.67	2.67	2.67	2.67	2.67	2.67				
Annual recurring cost	1.70	1.70	1.70	1.70	1.70	1.70				
Total annual costs	4.38	4.38	4.38	4.38	4.38	4.38				
Transition benefits	N/A	N/A	N/A	N/A	N/A	N/A				
Annual recurring benefits	0.87	0.87	0.87	0.87	0.87	0.87				
Total annual benefits	0.87	0.87	0.87	0.87	0.87	0.87				

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

Microsoft Office
Excel Worksheet

4 Equivalent Annual Cost – the profile shows the combined total EAC for LAs and industry in England: approximately £2,616,903

Problem under consideration

1. Food flavourings and food ingredients with flavouring properties are inconsistently regulated across the European Union (EU). This could lead to reduced consumer protection and create barriers to trade within the EU.

   Flavouring legislation has evolved over 20 years and there is scope for consolidation and simplification.

Reason for Intervention

2. 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[5] (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.

3. 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.

4. 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.

Policy objectives and intended effect

5. The intention of the Regulation is to ensure that up-to-date harmonised controls exist for flavourings as well as risked-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 indiscriminate BAP controls in food and drink to risked-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.

5 BAPs are substances of toxicological significance which occur naturally in certain herbs and spices and are an inherent part of their flavour.

- 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

6. 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 under current legislation may not be added as such to food.

7. 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

   - 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; and
   - It provides rules for the labelling of flavourings which are intended for sale as such to food manufacturers, flavour houses and to final consumers.

8. 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.

9. 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.

10. The FSA consulted in September 2006 on the UK negotiating position. More detail is given on page 12 and a link to this consultation is provided below.

    http://www.food.gov.uk/consultations/consulteng/2006/addenzymeflavour

11. 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 are being made 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

12. It is anticipated that 4,590 food manufacturing businesses in England will be directly affected by the new Regulation[6]. 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

Location/ Firm Size	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 – 10-19 employees; Small – 20-49 employees; Medium – 50-249 employees; Large –250 or more employees.

Cost and Benefits options

Benefits

6 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.

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

Option 2 –

13. 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 £25.197 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 £189**8**. 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 England**9**. Table 2 displays the annual benefits broken down by firm location and size.

Table 2 – Annual savings to food manufacturing businesses

Location/ Firm Size	Micro	<20	Small	Medium	Large	Total	Total Rounded
England	£540,143	£114,909	£101,734	£79,777	£30,740	£867,303	£867,000
Wales	£40,599	£8,637	£7,647	£5,996	£2,311	£65,189	£65,000
Scotland	£75,903	£16,147	£14,296	£11,211	£4,320	£121,876	£122,000
NI	£40,599	£8,637	£7,647	£5,996	£2,311	£65,189	£65,000
UK	**£697,244**	**£148,330**	**£131,324**	**£102,980**	**£39,681**	**£1,119,558**	**£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

14. 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.

15. The food manufacturing industry may choose to move to the use of liquid flavouring extracts made from herbs and spices to control the levels of BAPs. 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.

16. 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 levels. The UK considered these proposed controls would have been disproportionate to the risk and therefore secured a derogation for safrole, methyleugenol and estragol. Nutmeg and mace naturally contain safrole and methyleugenol is naturally present in nutmeg and tarragon. Tarragon and basil are natural sources of estragol.

17. To comply with BAP limits in compound foods, manufacturers and caterers may choose to rely on the herb and spice supply industry to monitor levels in incoming batches. Previous

7 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)
8 £25.194 * 7.5 = £188.955
9 £188.955* 4,590 = £867,303

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.

18. Assuming industry adopted the approach of widely testing batches, the total cost to the UK herb and spice industry is estimated to be £2.2**10** 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 size**11**

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

Labelling of natural flavourings

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

20. 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 product**12**.

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

21. 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 by multiplying the number of products by the upper and lower bounds of the cost per product respectively (£1,500 and £3,000).

22. 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 takes effect. It is also likely that in anticipation of the forthcoming legislation these re-labelled products will display

10 Based on calculations provided by the Seasoning and Spice Association (SSA)
11 £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).
12 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

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.

23. We therefore assume that 33% (1/3) of the applicable products will be re-labelled before the legislation applies and that about 67% (2/3) of all products will require re-labelling when the legislation takes effect 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. The Food and Drink Federation agreed with these labelling cost estimates. 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

Location/ Firm Size	Micro	<20	Small	Medium	Large	Total	Total Rounded
England	£8,684,301	£1,847,473	£1,635,661	£1,282,641	£494,228	£13,944,304	£13,944,000
Wales	£652,742	£138,862	£122,942	£96,408	£37,148	£1,048,101	£1,048,000
Scotland	£1,220,343	£259,612	£229,848	£180,240	£69,450	£1,959,494	£1,959,000
NI	£652,742	£138,862	£122,942	£96,408	£37,148	£1,048,101	£1,048,000
UK	**£11,210,127**	**£2,384,810**	**£2,111,392**	**£1,655,696**	**£637,975**	**£18,000,000**	**£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 – 10-19 employees; Small – 20-49 employees; Medium – 50-249 employees; Large – 250 or more employees.

Equivalent Annual Costs (EAC)

24. In order for 'one-off' transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula**13**. Under Standard HMT Green book guidance a discount rate of 3.5% is used.

25. A total one-off cost to industry in England is an estimated £13,944,304. This yields an EAC of approximately £2,616,903 in England over 6 years. Table displays the EAC for industry by country.

Table 6 – Equivalent Annual Cost (EAC) for Industry by location

Location	Industry Labelling EAC
UK	£3,378,028
England	£2,616,903
Wales	£196,695
Scotland	£367,735
NI	£196,695

Familiarisation cost

Industry

26. There will be a one-off cost to businesses for reading and familiarising themselves with the new Regulation. It is anticipated that on average it will take one hour per business to read and familiarise and a further one hour disseminating to key staff within the organisation. Feedback from industry stakeholders indicated that familiarisation and dissemination time might be greater. We have increased the average to 2 hours 30 minutes**14**.

27. There are 4,590 food manufacturers in England which could be directly affected by the Regulation. A wage rate of £25.19**15** has been applied for a manager of an organisation

13 The equivalent annual cost formula is as follows: EAC=PVC/A, where A =[1-1/(1+r)^t]/r, where PVC is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.
14 One stakeholder indicated some businesses estimated they may require approx. 150 hours in clarifying the requirements of the legislation and disseminating this to all relevant staff within their business. The revised figure of 2 1/2 hours is an average over 4,590 companies from micro to large.
15 Wage rate obtained from the Annual Survey of Household Earnings (2009)

who reads the document, which is multiplied by the number of businesses and the reading time, two and a half hours, to give a one off familiarisation cost to industry in England of £289,101. Table 7 displays the one off familiarisation cost to industry broken down by region and firm size.

Table 7 – Familiarisation cost to food manufacturers

Location/ Firm Size	Micro	<20	Small	Medium	Large	Total	Total Rounded
England	£180,048	£38,303	£33,911	£26,592	£10,247	£289,101	£289,000
Wales	£13,533	£2,879	£2,549	£1,999	£770	£21,730	£22,000
Scotland	£25,301	£5,382	£4,765	£3,737	£1,440	£40,625	£41,000
NI	£13,533	£2,879	£2,549	£1,999	£770	£21,730	£22,000
UK	**£232,415**	**£49,443**	**£43,775**	**£34,327**	**£13,227**	**£373,186**	**£373,000**

Equivalent Annual Costs (EAC)

28. As per one off labelling costs we equivalently annualise the one off familiarisation costs for industry. The total one-off familiarisation cost for industry in England is £289,101. This yields an EAC of approximately £54,255 in England over 6 years. Table 8 displays the EAC for industry by country.

Table 8 – Equivalent Annual Cost (EAC) for Industry by location

Location	Industry Familiarisation EAC
UK	£70,035
England	£54,255
Wales	£4,078
Scotland	£7,624
NI	£4,078

Reformulation costs

29. The Flavourings Regulation does not require companies to label products as containing natural flavourings, but does introduce more stringent requirements when a company does want to so identify a product. These changes may encourage some companies to reformulate some of their product lines if they are looking to continue to compete in the market for 'natural flavourings'. However, we are unable to accurately estimate and quantify this potential cost.

Local Authorities

30. 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 Enforcement Officer of £20.70[16]. 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 £16,101[17]. Table 9 displays the familiarisation cost and the number of LAs per country.

Table 9 – Number of Local Authorities and familiarisation cost per country

(http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=5313). Median hourly wage of a 'Production manager' is used £19.38 plus 30% overheads).

16 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).

17 41.39 * 389 = £16,101

Location	Number of LA's	Familiarisation cost	Rounded familiarisation cost
England	389	£16,101	£16,100
Wales	22	£911	£900
Scotland	32	£1,325	£1,300
NI	26	£1,076	£1,100
UK	**469**	**£19,413**	£19,400

Equivalent Annual Costs (EAC)

31. As with familiarisation costs and labelling costs for industry we equivalently annualise the one off familiarisation costs for enforcement authorities. The total one off familiarisation cost for enforcement bodies in England is £16,101. This yields an EAC of approximately £3,022 in England over 6 years. Table 10 displays the EAC for Enforcement Authorities by country.

Table 10 – Equivalent Annual Cost (EAC) for enforcement authorities by country

Location	Enforcement Authorities EAC
UK	£3,643
England	£3,022
Wales	£171
Scotland	£249
NI	£202

Administrative Burden Costs

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

33. 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.

34. 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.

35. 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 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.

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

Enforcement Costs

37. 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. In the most recent consultation (on putting in place national enforcement provisions), there was some feedback from Trading Standards that in the short term there could be significant enforcement action to progress compliance, whilst accepting the additional long term enforcement costs will be negligible. These one-off costs were not quantified.

Summary view of the options

38. 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. The Regulation will also ensure consistency in the legislation regarding flavourings in the EU which will help UK businesses. Option 1 would not provide these benefits.

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

i) Within government

39. 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

40. 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

41. 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.

42. 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.

43. The enforcement authorities welcomed the proposed simplification of the legislation.

44. These results were fed in to the UK Government's negotiating position, and we continued to communicate with stakeholders throughout the negotiation process (see Annex 3). In July 2010 the FSA consulted publicly for 12 weeks on the enforcement provisions. The consultation and a summary of responses can be found at:

    http://www.food.gov.uk/consultations/consulteng/2010/enforcementfoodflavouringseng .

Enforcement

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

46. 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

47. 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

48. 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 the date of application (i.e. in 2016). This will allow time for all of its provisions to apply (some are not triggered until the EU list of authorised flavourings has been adopted) and for transitional periods to expire.

Annexes

Annex 1: Post Implementation Review (PIR) Plan

Basis of the review: 1. The FSA's rolling simplification programme, which aims to reduce the regulatory burdens on businesses while maintaing consumer protection.
Review objective: 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.
Review approach and rationale: 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.
Baseline: 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).
Success criteria: 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.
Monitoring information arrangements: 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. 2. These exchanges with stakeholders will help to identify positive and negative lessons learnt, as well as identify areas for future development.
Reasons for not planning a PIR: N/A.

Annex 2: Specific Impact Tests

Competition Assessment

48. 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

49. 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.

50. 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

51. 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.

52. 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.

53. 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.

54. 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

55. 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.

56. 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

57. 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

58. 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.

59. 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.