EXECUTIVE NOTE

THE FLAVOURINGS IN FOOD (SCOTLAND) REGULATIONS 2010

SSI 2010/439

Description

The above instrument was made under the powers in 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([1]). The instrument is subject to negative resolution procedure and does not amend primary legislation.

Policy Objective

This instrument, which extends to Scotland only, enforces Regulation 1334/2008 of the European Parliament and of the Council on food flavourings. 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[2] (BAPs) which may be present in flavourings and food ingredients with flavouring properties. This instrument 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.

Legislative Background

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 In the interest of clarity and efficiency, this legislation has been replaced by EU Regulation 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring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.

There is an ongoing evaluation programme of the flavouring substances currently regulated under Regulation (EC) 2232/96; however it is intended that following the

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([1])1990 c.16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990; sections 16(1), 17(2) and 48(1) were amended by paragraph 8 of Schedule 5 to the Food Standards Act 1999 (c.28); section 17(2) was also amended by paragraph 12 of Schedule 5 to the 1999 Act; section 26(3) was amended by Schedule 6 to the 1999 Act; section 48(4) is disapplied in respect of these Regulations by virtue of section 48(4C) which was inserted by S.I. 2004/2990; by virtue of section 40(2) of the 1999 Act, amendments made by Schedule 5 to that Act are to be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46). The functions of the Secretary of State, in so far as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. In so far as not so transferred, and in so far as relating to food (including drink) including the primary production of food, relevant functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849).

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

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.

EU Regulation 1334/2008 is directly applicable across the UK, however a Scottish Statutory Instrument (S.S.I.) is required to enforce the Regulation and identify penalties for non-compliance.

Policy Background

The key aspects are:

- 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,confer on the Commission powers to update the list of flavourings and 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.
- 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.
- Member States are required to implement by 20 January 2010.

Consultation

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

In July 2010, FSA Scotland issued a 12 week consultation on the enforcement food flavourings SSI. Approximately 235 stakeholders were consulted and FSA Scotland received one comment in support of the Regulations from an International Association. These comments are summarised within the Business and Regulatory Impact Assessment.

Other Administrations

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

Impact

Details of costs and benefits to stakeholders are provided in the Business and Regulatory Impact Assessment.

Contact

Claire Moni at the Food Standards Agency Scotland (Telephone 01224 285158)
(email: claire.moni@foodstandards.gsi.gov.uk

Food Standards Agency Scotland
6 December 2010

Final Business and Regulatory Impact Assessment

1. Title of Proposal

Enforcement of EC Regulation 1334/2008 on Food Flavourings

2. Purpose and Intended Effect

- **Objective**

2.1 The 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.

2.2 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 Biologically Active Principles 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.

2.3 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) [1] 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.

[1] 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**

2.4 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.

2.5 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 web link below).

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

2.6 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.

2.7 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.

2.8 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.

2.9 The FSA in Scotland consulted in September 2006 on the UK negotiating position. More details on the consultation are given on page 4 and at: http://www.food.gov.uk/consultations/consultscot/2006/improveagentscot

In November 2008 the Regulation was adopted by Council and it came into force on the 20 January 2009. It generally applies from the 20 January 2011. As an EU Regulation it is directly applicable in Scotland and across the UK however a Scottish Statutory Instrument (SSI) is required to enforce the Regulation and identify penalties for non – compliance. Separate S.I.s are being made for England, Wales and Northern Ireland.

- **Rationale for Government Intervention**

2.10 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.

3. Consultation

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

- **Within Government**

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

- **Public Consultation**

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

- **Business**

Industry was included in the public consultation and interested party letters as mentioned above. The industry stakeholders vary from small to medium sized companies with a specific interest in food additives. Many small flavouring producers and distributors across the UK are represented by the British Essence Manufacturers Association (BEMA). Further details on the consultation with industry are provided below.

Results of Consultation

3.1 FSA Scotland

In September 2006, FSA in Scotland issued a 12 week consultation notifying stakeholders of the proposed EU Regulations on food additives, food flavourings and food enzymes. Approximately 235 stakeholders were consulted on these proposals. One response was received from a Scottish local authority who welcomed the Regulations as providing clearer definitions and supported the use of the term 'natural' flavouring. This comment has been taken into consideration and was fed in to the UK Government's negotiating position. No comments were received from businesses in Scotland. This consultation can be found at;
http://www.food.gov.uk/consultations/consultscot/2006/improveagentscot

3.2 Separate consultations also took place in FSA in Wales and FSA in Northern Ireland but no comments were received.

3.3 In July 2010, FSA in Scotland consulted publicly for 12 weeks on the enforcement provisions for the Regulation on flavourings in Scotland. FSA in Scotland received one comment from International Aloe Science Council (IASC). This comment was also sent to FSA in England and is summarised in UK wide summary table available at the link below.

FSA England

3.4 The FSA in England, in September 2006 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

3.5 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.

3.6 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. The FSA has provided costings relevant to all the regions of the UK and these are discussed in pages 8-15. The enforcement authorities welcomed the proposed simplification of the legislation.

UK Wide

3.7 Responses helped inform the UK negotiating position and we continued to communicate with stakeholders throughout the negotiating process (see page 19). 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 .

4. Options

4.1 Option 1 – Do nothing Doing nothing would mean that enforcement of the Regulation would not be provided for in Scotland and the UK would be in

breach of its EU obligations. This could lead to us open to infraction proceedings by the European Commission.

4.2 **Option 2- Make appropriate domestic enforcement Regulations.** Provide for the enforcement of the Flavourings Regulation in Scotland. The option fully meets the UK Government's commitment to fulfil its EU obligations. Under Treaty obligations we are required to give effect in the UK to the enforcement provisions of the Regulation. The UK was involved with the Commission and other Member States throughout the negotiations that developed the Regulation and we support its adoption.

5. Sectors and groups affected

5.1 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 food,
- food manufacturing companies (e.g. manufacturers of drinks, snacks, confectionery and prepared meals/dishes) for the reasons mentioned above, and
- enforcement authorities and food manufacturers will also need to familiarise themselves with the new Regulation.

6. Benefits

6.1 **Options 1-** Under this option, the current legislation would remain and with which both industry and enforcement authorities are familiar. There are therefore no incremental benefits to this option.

6.2 **Option 2-** Make appropriate domestic Regulations for the enforcement of the Flavourings Regulation.

6.3 This option introduces a harmonised EC market for the supply of food flavourings as Member States have implemented the Flavourings Framework Directive and have applied the maximum levels established for BAPs differently.

6.4 Consumers benefit from harmonised EU controls for flavourings which ensures a high level of consumer protection, enable the free movement of safe and wholesome food and takes into account the new scientific and technological developments.

7. Food manufacturers

It is anticipated that 645 food manufacturing businesses in Scotland will be directly affected by the new Regulation[2] and a total of 5,925 food manufacturing businesses across the UK. 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 and is 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.

7.1 This option will benefit the food manufacturing industry because it consolidates and simplifies legislation. The FSA estimates 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 £25.19[3] 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[4]. When the saving per business is applied to 645 food manufacturing businesses, it equates to a total annual cost saving to food manufacturers of £121,876 in Scotland. Table 2 displays the annual benefits broken down by firm location and size.

[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.

[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

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**

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

8. Costs

8.1 Cost to the Food Manufacturing Industry

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

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

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

8.4 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.

8.5 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 have told the FSA that they are 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.

8.6 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[5] 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[6]

Location/firm size	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

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

8.8 Information on the frequency at which businesses re-label products in this category is limited, however discussions between the FSA 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[7].

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	£12,000,000	£18,000,000	£24,000,000

[5] Based on calculations provided by the Seasoning and Spice Association (SSA)
[6] £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).
[7] 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

re-labelled			

8.9 Estimates of the total cost of re-labelling are detailed in the table above. Discussions between the FSA 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 (£1500 and £3000).

8.10 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.

8.11 FSA assumes 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 £1.959 million in Scotland. The Food and Drink Federation agreed with these labelling cost estimates. Table 5 displays the labelling costs to industry broken down by region and firm size.

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

Location/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.

Equivalent Annual Costs (EAC) for Industry per location

8.12 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[8]. Under Standard HMT Green book guidance a discount rate of 3.5% is used.

8.13 A total one-off cost to industry in Scotland is an estimated £1,959,494. This yields an EAC of approximately £367,735 in Scotland over 6 years. Table 6 displays the labelling EAC for industry by location.

Table 6 – Labelling - Equivalent Annual Cost (EAC) for Industry per Location

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

8.14 Further information on BAPS, targeted risk based monitoring and labelling of natural flavourings is provided on page 19 on the **UK Government's negotiating position on Flavourings - UK Options/ Achievements.**

9. Familiarisation costs

9.1 Industry

There will be a small 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[9].

9.2 There are 645 food manufacturers in Scotland which could be directly affected by the Regulation. A wage rate of £25.19[10] 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 two and a half hours, to give a one off familiarisation cost to industry in Scotland of £40,625. Table 7 displays the one off familiarisation cost to industry broken down by location and firm size.

[8] 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.

[9] 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.

[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 a 'Production manager' is used £19.38 plus 30% overheads).

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**

Familiarisation - Equivalent Annual Costs (EAC) for Industry

9.3 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 Scotland is £40,625. This yields an EAC of approximately £7,624 in Scotland over 6 years. Table 8 displays the familiarisation EAC for industry by location.

Table 8 – Familiarisation - Equivalent Annual Cost (EAC) for Industry per Location

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

Reformulation costs

9.4 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

9.5 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[11]. To quantify the overall familiarisation cost to enforcement authorities, we multiply the familiarisation cost per LA by the number of LAs in Scotland 32, which gives a one-off total familiarisation cost to LAs in Scotland of £1.300. Table 9 displays the familiarisation cost and the number of LAs per location.

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

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)

9.6 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 Scotland is £1,325.** This yields an EAC of approximately £249 in Scotland over 6 years. Table 10 displays the EAC for Enforcement Authorities by location.

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

10. Administrative Burden Costs

10.1 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.

[11] 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).

10.2 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. The FSA also notes 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.

10.3 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. The FSA considers that any additional costs of these new requirements will be minimal.

11. Scottish Firms Impact Test

11.1 Earlier drafts of the EU Regulation have received comments from industry on a UK basis, including small businesses and many of their views and suggestions have been incorporated into the final Regulation. In order to determine the impact on small flavouring businesses the FSA has 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.

11.2 The UK considered that the setting of BAPS 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 as these are present in food due to the use of herbs and spices (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.

11.3 The EU Regulation came into force on the 20 January 2009 and has already been the subject of a full consultation during 2006-2007, including a Regulatory Impact Assessment. The enforcement provisions contained within the Scottish Statutory Instrument will not introduce any new criminal sanctions or civil penalties, nor are there any new or additional forms associated with them. Therefore the FSA in Scotland did not hold face to face discussions with business during the consultation on this instrument.

12. 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.

13. Test run of business forms

There are no new or additional forms associated with this piece of legislation other than the information obligations described under the Administrative Burdens section on page 13.

14. Legal Aid Impact Test

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

15. Sustainable Development

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

15.2 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.

15.3 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.

15.4 Some negative environmental and social impacts have been identified due to the re-labelling of products using natural or smoke flavourings with 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.

16. Statutory Equality Duties

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

17. Enforcement, sanctions and monitoring

17.1 Enforcement

Enforcement of the Regulations in Scotland will be the responsibility of the Local Authority Environmental Health Departments and they have been consulted as part of the public consultation.

17.2 FSA in England were advised by their Local Authorities 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.

18. Sanctions

The criminal sanctions within the food flavourings Regulations would apply in the case of prosecution against those in breach of the new Regulations.

19 Monitoring

The effectiveness and impact of the 2010 enforcing Regulations will be monitored via feedback from stakeholders as part of the ongoing policy process. Agency mechanisms for monitoring and review include: open forum stakeholder meetings, surveys and general enquiries from the public.

20. Implementation and Delivery Plan

EC Regulation 1334/2008 came into force on 20 January 2009, and will apply from 20 January 2011. The publication of the enforcing regulations will be communicated to stakeholders by email, letter and to Local Authorities by the monthly Enforcement Report. This will be done shortly after the S.S.I. has been published on the Office of Public Sector Information's website

21. Post-implementation review

The new Regulation came into force on 20 January 2009, and will apply from 20 January 2011. It will be enforced in Scotland by secondary legislation and will be enforced in England, 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.

22. Summary and recommendation

Overall the UK supports 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.

22.1 Summary cost and benefits table

Annual Costs and Benefits		
	Benefits Simplification	**Costs** BAPS
Option 1	----------	----------
Option 2	£121,876	£239,494

Total One Off Costs	
Familiarisation costs to food manufacturers	£40,625
Familiarisation costs to LA	£1,325
Labelling costs to industry	£1,959,494

Equivalent Annual Costs	
Industry Familiarisation	£7,624
Labelling	£367,735
Local Authority/Enforcement	£249

23. Declaration and publication

Final Stage –

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

the benefits justify the costs I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Minister signature …….

Ministers title …….

Date …….

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.