

Explanatory Memorandum to the Flavourings in Food (Wales) Regulations 2010

This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 24.1.

Member's Declaration

In my view this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Flavourings in Food (Wales) Regulations 2010. I am satisfied that the benefits outweigh any costs.

Gwenda Thomas AM

Deputy Minister for Social Services

7 December 2010

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1. Description

This Statutory Instrument will provide for the execution and enforcement of Regulation (EC) No 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods ('the EU Regulation').

2. Matters of Special Interest to the Constitutional Affairs Committee

None

3. Legislative Background

Welsh Ministers have the required powers to make these amending Regulations under 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.

This Instrument is subject to the negative resolution procedure.

4 Purpose and Intended Effect of the Legislation

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 principles¹ (BAPs) which may be present in flavourings and food ingredients with flavouring properties. This instrument enforces the EU Regulation which introduces harmonised controls for the assessment and authorisation of flavourings and their source materials used in food. This provides a high level of consumer protection.

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 provides 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 In the interest of clarity and efficiency, this legislation has been replaced by the EU Regulation - EU Regulation 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with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 completion of the evaluation programme these substances will be transferred into a

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

new European Union List of flavouring substances and their source materials provided under Regulation 1334/2008.

The EU Regulation is directly applicable in the UK, for the most part, from 20th January 2011; however a Statutory Instrument (SI) is required to enforce the Regulation and identify penalties for non-compliance. As such, this instrument is being made to enforce, within Wales, the provisions of the EU Regulation.

The objectives of the EU Regulation are:

- To create a single instrument for the evaluation and authorisation of certain flavourings, food ingredients with flavouring properties, their source materials and their conditions of use in or on foods;
- To provide for the creation of an EU list of flavourings and their source materials;
- To confer on the Commission powers to update the list of flavourings;
- To formalise the role of the European Food Safety Authority (EFSA) for the risk assessment of flavourings;
- To move from BAP controls in food and drink to risk-based controls. The maximum levels established for these substances will be based on EFSA opinions and will focus on the food or the food categories that contribute most to dietary intake;
- To introduce provisions for the labelling of flavourings sold as such to food manufacturers or to the final consumer, and for the responsibilities of food business operators in respect of these products; and
- 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.

5 Consultation

In September 2006 and July 2010, the FSA carried out 12 week public consultations a number of responses were received - none were received from Welsh stakeholders. Further details of the consultation undertaken are included in the RIA below.

6 Regulatory Impact Assessment

6.1 Options

Doing nothing would mean that food flavourings and food ingredients with flavouring properties would continue to be regulated subject to the current provisions. Doing nothing would mean a breach of the UK's obligations as an EU Member State, and could give rise to infraction proceedings against the UK by the Commission in the European Court of Justice under Article 258 of the Treaty of Functioning of the EU.

Making the Regulations will ensure that Wales is in line with the EU and would ensure a high level of protection for consumers. Industry will also benefit from uniform safety measures and free trade across the EU.

6.2 Costs and Benefits

It is anticipated that 345 food manufacturing businesses in Wales will be directly affected by the proposed Regulations². Table 1 breaks down these businesses by region and size, 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.

The businesses that are likely to be affected are:

- 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.

Making the Regulations will benefit the food manufacturing industry because of the consolidation and simplification of this legislation. It is estimated that the proposed changes are likely to save an organisation the time equivalent of one person-day per year. To quantify the savings an hourly rate of £25.19³ has been applied to a production manager which is multiplied by the time equivalent of one person-day per year per organisation, 7.5 hours. This equates to an annual cost saving per food manufacturing business of £189⁴. When applied to 345 businesses, it equates to a total annual cost saving of £65,189 in Wales⁵.

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

⁵ £188.955 * 345 = £65,189

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

The herb and spice industry will incur a minimal new cost associated with scientific and technical updating of the list of substances to be monitored for levels of BAPs. Assuming industry adopted an approach of widely testing batches, the total cost to the herb and spice industry in Wales is estimated to be £128,101. However, if industry works to typical values the total cost could be significantly less.

Table 3 – Cost of BAP limits by region and firm size⁶

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

New provisions for labelling of natural flavourings will require prescribed terms to be used when referring to flavouring as 'natural' in the ingredient list. Information on the frequency at which businesses re-label products is limited, however discussions between the Agency and stakeholders have indicated that a re-labelling cycle of three years would be a reasonable assumption, and re-labelling costs tend to fall in the range of £1,500 - £3,000 per product.

Assuming a three-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 would come into force. It is therefore assumed that 33% of applicable products will be re-labelled when the legislation comes into force, and 67% will require re-labelling. It is estimated that this will amount to a one-off cost to industry in Wales of £1.05 million.

Table 4 – 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

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).

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.

It will be necessary for all businesses and local authorities to spend some time becoming familiar with these Regulations. There may be a small one-off cost associated with this.

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

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

The second IO requires a producer or user of food flavourings to inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the flavouring. It is considered that any additional cost of these new requirements would be minimal.

Local authorities are responsible for enforcement of current legislation on flavourings, and in consultation with Local Authority Coordinators of Regulatory Services (now known as Local Government Regulation), it was established that any additional costs of enforcement of these provisions would be minimal.

7. Consultation

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 450 stakeholders were consulted across the UK and 22 responses were received - none were received from Welsh stakeholders. 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 Annex A

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, FSA felt that the agreed on-going evaluation would provide a more focused risk-based solution which is proportionate and allows action to be taken sooner, if concerns arise.

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

The enforcement authorities welcomed the proposed simplification of the legislation.

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

In July 2010, the FSA further consulted publicly on a draft enforcement Statutory Instrument ('SI') for 12 weeks. Approximately 340 stakeholders were consulted across the UK. No responses were received from Welsh stakeholders and none of the ten UK responses received warranted changes to the SI as drafted.

8. 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 or modify the structure of the market.

9. Small Firms Impact Test

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

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

10. Implementation and Review

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