EXPLANATORY MEMORANDUM TO

THE FOOD ENZYMES REGULATIONS 2009

2009 No. 3235

1. This explanatory memorandum has been prepared by The Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 Food enzymes (other than those used as food additives) are not subject to specific harmonised controls across the EC, but are regulated as processing aids under the national legislation of some of the different Member States. This instrument enforces EC measures which introduce harmonised controls for enzymes, whether used as food additives or processing aids, in the production of food stuffs and provides a high level of consumer protection.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 This instrument is being made to enforce, within England, Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97.

4.2 The EC Regulation is directly applicable in the UK, however a Statutory Instrument (S.I.) is required to enforce the Regulation and identify penalties for non-compliance.

5. Territorial Extent and Application

5.1 This instrument applies to England. Separate S.I.s will be made for Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- ***What is being done and why***

7.1 Enzymes are substances (usually proteins) that catalyse (i.e. increase the rate of) chemical reactions. As such, they can be useful in the production of food, achieving results which might be too time consuming or expensive by other methods.

7.2 As indicated above, food enzymes (other than those used as food additives) are not subject to specific harmonised controls across the EC, but are regulated as processing aids under the national legislation of some Member States. There are different levels of regulation of enzymes used as processing aids in different Member States. France and Denmark already have national

controls and other Member States would be likely to introduce them if there were no EC harmonising measures.

7.3 Whilst the current non-harmonised controls do not necessarily prevent a high level of consumer protection, there is scope for "weak links" in the chain and consumers are not currently benefiting from the assurance given by a single Community-wide authorisation procedure. The new EC Regulation introduces a positive approval system for all food enzymes whether used as food additives or as processing aids in the production of foodstuffs, whereby all will be assessed for safety.

7.4 Without harmonised controls, manufacturers need to be aware of (and comply with) all of the different controls in the Member States with which they wish to trade. The new EC Regulation prevents the creation of conditions of unequal and unfair competition and the hindrance of the free movement of goods across the European Community.

- ***Consolidation***

7.5 Regulation (EC)1332/2008 introduces, for the first time, specific harmonised controls for the use of enzymes in food and as such does not consolidate previous legislation.

8. Consultation outcome

8.1 Within government

We have consulted with Defra, the Better Regulation Executive and Small Business Service. Local Authorities will be responsible for enforcement of these measures and their coordinating body was consulted as part of the full public consultation on the Commission proposal and on the enforcement SI.

8.2 Public consultation

In September 2006 the FSA launched a 12 week public consultation on the Commission's proposal for a new Enzyme Regulation (as well as Commission proposals on Additives and Flavourings). Approximately 450 stakeholders were consulted and a summary of the 22 responses can be found at **http://wwwfood.go.uk/consultations/consulteng/2006/?completed=Yes**

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

In July 2009, the FSA consulted publically, for 12 weeks, on the new SI on food enzymes. Approximately 450 stakeholders were consulted and three responses were received relating to food enzymes. Of these, one (Association of Bakery Ingredient Manufacturers) was of direct relevance to the enforcement SI. The ABIM were generally in support of harmonised controls on food enzymes. They also responded to the request in the consultation document for more detailed economic data on implementation and this has helped inform the impact assessment.

9. Guidance

9.1 Government will contribute towards the establishment of an implementing Commission Regulation which will set provisions for the content and presentation of an application, criteria for the validity of applications, and transitional measures. Once this is finalised, cross-EC guidance will be developed.

10. Impact

10.1 An Impact Assessment is attached to this memorandum.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 UK companies are not producers of enzymes but prepare formulations of them. FSA discussions with small firms in this sector suggest that, with long implementation periods, reformulation and re-labelling will not have an immediate significant cost impact, as changes can be gradually introduced when product packaging becomes due to be reprinted and formulations reviewed.

12. Monitoring & review

12.1 The new Regulation will be reviewed, in the UK, within 2 years after the Community list for enzymes coming into force. It is estimated to come into force in approximately 2016.

13. Contact

James Ridsdale at the Food Standards Agency Tel: 020 7276 8559 or email: james.ridsdale@foodstandards.gsi.gov.uk can answer any queries regarding the instrument.

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	**Impact Assessment of a Regulation of the European Parliament and of the Council on Enzymes**	
Stage: Final	**Version:** 8	**Date: 24 November** 2009

Related Publications: Enzymes Regulation: http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2008:354:SOM:EN:HTML
European Commission Impact Assessment: http://ec.europa.eu/food/food/chemicalsafety/additives/ia425.pdf

Available to view or download at:

http://www.food.gov.uk/consultations/

Contact for enquiries: Dr James Ridsdale **Telephone:** 020 7276 8559

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

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

What are the policy objectives and the intended effects?

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

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

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

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

2) Accept the EC Regulation as drafted and provide for its enforcement in the UK

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

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

In the UK, within 2 years after the Community List of Approved Enzymes coming into force. It is estimated to come into force in approximately 2016.

Ministerial Sign off For Final stage Impact Assessments:

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) the benefits justify the costs.

Signed by the responsible Minister:

Gillian Merron.....Date: ***7th December 2009***

Summary: Analysis & Evidence

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

COSTS

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

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

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

Total Cost (PV) **£ 10,000**

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

BENEFITS

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

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

Total Benefit (PV) **£ 0**

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

Harmonised controls across EC will make trade simpler.

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

Key Assumptions/Sensitivities/Risks We estimate that a one-off familiarisation time of 1 hour per organisation will be required with a total cost to the whole industry of £10,000.

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

What is the geographic coverage of the policy/option?				UK
On what date will the policy be implemented?				January 2010
Which organisation(s) will enforce the policy?				Local Authorities/PHAs
What is the total annual cost of enforcement for these organisations?				£ Negligible
Does enforcement comply with Hampton principles?				Yes
Will implementation go beyond minimum EU requirements?				No
What is the value of the proposed offsetting measure per year?				£ N/A
What is the value of changes in greenhouse gas emissions?				£ N/A
Will the proposal have a significant impact on competition?				No
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** £ N/A

Evidence Base (for summary sheets)

Reason for Intervention

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

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

Intended effect

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

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

The key objectives of the measure are as follows:

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

Background

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

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

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

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

Options

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

Option 2 – Accept the proposed new Enzymes Regulation and provide for its enforcement in the UK.

Costs and benefits of options

Benefits

Option 1 – Under this option, the current legislation would remain in place, with which industry and enforcement authorities are familiar. There are therefore no incremental benefits to this option.

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

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

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

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

Costs

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

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

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

There are also new requirements for the labelling of enzymes not sold to the final consumer (business-to-business sales). This may impose a small cost on businesses from relabeling products provided to other businesses. However, these costs are expected to be mitigated in two ways. Firstly, Article 11(4) allows, by derogation, for some of the prescribed information to be put solely on the sales dockets accompanying a consignment, which means that the labelling changes specifically required by the Regulation will be reduced (though businesses could choose to make other changes). Secondly, the Regulation gave a transition period of one year to help take

account of label change cycles. This should enable businesses to incorporate any changes into normal relabeling cycles and therefore the additional costs from the relabeling requirements is expected to be small.

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

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

Summary of costs and benefits – Option 2

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

Administrative Burden Costs

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

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

The IO second requires a producer or user of a food enzyme to inform the European Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the food enzyme. Information obtained from business on similar information obligations during the Administrative Burdens Measurement Exercise carried out in 2005 suggests that the administrative cost, over and above what a business would do commercially, of providing a dossier to the Commission would be £9 each time. The requirement is likely to be a contingent and rare requirement which will not be a regular burden on industry.

We consider these new IOs are justifiable for the benefit of consumer protection which they bring.

Summary of Administrative Burden Costs

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

[1] Median hourly wage rates excluding overtime (2008) for Science and Technology professionals of £17.83 (£23.18 including overheads at 30% in line with standard cost model), Environmental Health Officers £14.94 (£19.42 including overheads) (source: Annual Survey of Household Earnings (2008)); time required 1 hour per organisation; 10 affected businesses, 469 local authorities and approximately 40 Port Health Authorities requiring separate familiarisation time.

Consultation

i) Within government

We have consulted Defra, the Better Regulation Executive and Small Business Service. Local Authorities will be responsible for enforcement of these measures and their coordinating body was consulted as part of the full public consultation on early proposals.

ii) Public consultation

In September 2006 the FSA launched a 12 week public consultation on the Commission's proposal for a new Enzyme Regulation (as well as the rest of the Food Improvement Agents Package). Approximately 450 stakeholders were consulted and a summary of the 22 responses can be found at **http://wwwfood.go.uk/consultations/consulteng/2006/?completed=Yes**

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

In July 2009, the FSA consulted publically for 12 weeks, on the new SI on food enzymes. Approximately 450 stakeholders were consulted and three responses were received relating to food enzymes. Of these, one (Association of Bakery Ingredient Manufacturers) was of direct relevance to the SI. The ABIM raised concerns and provided information on costs with respect to business-to-business labelling changes within this sector. However, as explained above, the Agency believes that such costs will be small because of the derogation allowing information to be included on the sales dockets accompanying a consignment, rather than requiring relabeling of the product itself.

Enforcement

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

Simplification

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

Implementation and Review

The new Regulation came into force on 20 January 2009; however some provisions will apply after this date. It will be implemented in the UK by secondary legislation which will include enforcement provisions. Separate but parallel legislation will be required for England, Scotland, Wales and Northern Ireland.

The new Regulation will be reviewed, in the UK, within 2 years after the Community List for Enzymes coming into force. It is estimated to come into force in approximately 2016.

Specific Impact Tests: Checklist

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	Yes
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Annexes

Competition Assessment

Food Enzymes Market

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

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

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

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

Small Firms Impact Test

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

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

European Commission has confirmed that authorisation will generally be for food enzymes themselves (and not for formulated products).

Sustainable development

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

Race equality issues

The proposed Regulation does not have an impact on race equality.

Gender equality issues

The proposed Regulation does not have an impact on gender equality.

Disability equality issues

The proposed Regulation does not have an impact on disability equality.

Appendix

Options

Options considered during discussion of the proposal:

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

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

- Oppose broadening the proposal to include all processing aids.

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

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

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

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

The Commission's proposal did not call for complete removal of all enzyme residues, however some of the groups we consulted and some Member States

were in favour of this. We considered this carefully and came to the conclusion that removal of all enzyme residues, when used as processing aids, would in many cases be technically un-achievable. At the very least, it would be a significant change for the food industry and its impact would need to be considered carefully.

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

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

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