EXECUTIVE NOTE

THE FOOD ENZYMES (SCOTLAND) REGULATIONS 2009

SSI/2009/435

Description

The above instrument was made under the powers in sections 16(1)(a), (e) and (f), 17(2), 26(1) and (3), and 48(1) of the Food Safety Act 1990. The instrument is subject to negative resolution procedure and does not amend primary legislation.

Policy Objective

This instrument, which extends to Scotland only, 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. 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.

Legislative Background

This instrument is being made to enforce, within Scotland, 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.

The EC Regulation 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:

- 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.
- 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.
- 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.
- 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 unfair competition and the hindrance of the free movement of goods across the European Community.

- Member States are required to implement by 20 January 2010.

Consultation

In September 2006, FSAS 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 and the summary of this consultation can be found at: http://www.food.gov.uk/multimedia/pdfs/improveagentscotenz.pdf

In July 2009, FSAS issued a 12 week consultation on the new food enzymes SSI. Approximately 235 stakeholders were consulted and FSAS received 2 comments supportive of the Regulation which were from a Local Authority Environmental Health Officer and a medium-large sized company using food enzymes in manufacturing. A summary of these comments are given within the Regulatory Impact Assessment in **Annex 2.**

Other Administrations

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

Impact

The Food Standards Agency Scotland fully consulted all stakeholders on the proposed Regulation. However in the 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. 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.

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Food Standards Agency Scotland
9 December 2009

ANNEX 2

FINAL REGULATORY IMPACT ASSESSMENT

1. TITLE OF PROPOSAL

1.1 Regulation of the European Parliament and of the Council on Enzymes

2. PURPOSE AND INTENDED EFFECT

Objective

2.1 The Regulation is part of a package of European Parliament and Council measures on Food Improvement Agents (the other Regulations cover additives and flavourings).

2.2 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.

2.3 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 Genetically Modified (GM) Food and Feed Regulation (1829/2003) are also authorised under that Regulation prior to authorisation under this Regulation.

3. Background

3.1 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. 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.

3.2 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).

3.3 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.

3.4 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 Scottish Statutory Instrument (S.S.I.) is required to enforce the Regulation and identify penalties for non-conformance.

Rationale for Government Intervention

3.5 Food enzymes (other than those used as food additives) are not currently 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.

3.6 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.

Devolution

3.7 The EC Regulation is directly applicable in the UK however a Scottish Statutory Instrument is required to enforce the Regulation and identify penalties for non-compliance. This Regulation will apply only to Scotland,separate SIs will be established for England, Wales and Northern Ireland.

4. CONSULTATION

With Government

4.1 Government departments including the Scottish Government DG Health were 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

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

Results of Consultation

FSA Scotland

4.3 In September 2006, FSAS 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. This consultation can be found at: http://www.food.gov.uk/multimedia/pdfs/improveagentscotenz.pdf

4.4 In July 2009, FSAS issued a 12 week consultation on the new food enzymes SSI. Approximately 235 stakeholders were consulted and FSAS received 2 comments supportive of the Regulation. One was from a Local Authority Environmental Health Officer in agreement with the Regulations and the other from a medium-large sized company also with manufacturing companies in the USA, Czech Republic and Australia.

4.5 This company produces collagen for food casings and films and uses a specific food enzyme to treat the collagen hide. Their concerns were that their supplier might not add this particular food enzyme to the positive list. This comment has been taken into consideration. The positive list should be established after completion of the risk assessment of all food enzymes for which sufficient information has been submitted during the initial two year period. It is estimated that the Community list for enzymes is likely to come into force in approximately 2016.

FSA England

4.6 In September 2006, FSA England issued a 12 week consultation on the Commission's proposal for a new enzyme Regulation. 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.

4.7 In July 2009, the FSA consulted publically for 12 weeks on the new SI on food additives. Approximately 450 stakeholders were consulted. One response (Local Authority Co-ordinators of Regulatory Services – LACORS) was directly relevant to the food enzymes SI. Comments were provided on the text of the SI and these have been considered when drafting the final SI.

5. OPTIONS

5.1 **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.

5.2 **Option 2 - Make appropriate domestic Regulations**
Accept the EC Regulation as drafted and provide for its enforcement in Scotland

5.3 **Costs and Benefits of options**

Benefits

5.4 **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.

5.5 **Option 2** – Make appropriate domestic Regulations for the enforcement of the Enzyme Regulations

5.6 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.

5.7 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.

5.8 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. This would ensure that Scotland is not left out of step with the EC and so is not open to infraction proceedings.

Costs

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

5.10 **Option 2**

Across the rest of the UK, this industry is small (fewer than 10 companies) and focused on producing food enzymes preparations. As far as the FSA is aware there are no producers of food enzyme preparations in Scotland. 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).

5.11 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 has 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.

5.12 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.

Cost to Industry

5.13 Summary of costs and benefits – Option 2

Businesses and local authorities will be required to familiarise themselves with the legislation which incurs an estimated one-off time cost of approximately £10,000.

Change	**Benefit**	**Cost**
Evaluation of enzymes	Ensures consumer protection.	£10K – one-off familiarisation costs to businesses and local 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

6. Administrative Burden Costs

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

6.2 The first IO is a requirement for producers or users of a food enzyme, when requested, to inform the European Commission of the actual use of the 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 businesses as being negligible.

6.3 The second IO is a requirement for producers or users of food enzymes, to inform the European Commission of the actual use of a 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. The FSA consider these new IOs are justifiable for the benefit of consumer protection which they bring.

6.4 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.

7. **Impact on other Government Departments**

We have consulted with the Scottish Government DG Health who were kept informed of progress in negotiations relating to the European Directive through regular progress reports. No adverse comments were received from any departments.

8. **Small Firms Impact Test**

8.1 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.

8.2 Our discussion with a small firms representative in this sector suggests 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).

9. **Legal Aid**

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

10. **'Test Run' of Business Forms**

There are no forms associated with this piece of legislation.

11. **Competition Assessment**

11.1 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 the companies Novozymes and Danisco based in Denmark, 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.

11.2 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.

11.3 After consultation with the 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.

11.4 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.

12. Enforcement, Sanctions and Monitoring

Enforcement

12.1 Local Authorities will be responsible for enforcement of these measures and have been consulted as part of the public consultation on early proposed Regulations. The impact on the public sector is believed to be minimal. There will also be ongoing and unchanged administration costs to food authorities for monitoring and enforcing the new Regulations.

Sanctions

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

Simplification

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

Monitoring

12.4 The new Regulation will be reviewed, in the UK, within 1 year of the Community List for Enzymes coming into force. It is not possible to put a date to this at this time as EFSA have an undetermined time period to evaluate food enzymes, but it is estimated to be approximately 2014.

Implementation and Delivery Plan

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

14. Post Implementation Review

The Agency will continue to consult with Local Authorities, industry and other stakeholders to evaluate the effectiveness of and experience with the legislation. In accordance with the Scottish Government's, Business Competitiveness Division**,** guidelines, this RIA will be reviewed, as appropriate, in order to establish that it is "fit for purpose" therefore not adding any additional burdens to businesses. In line with Scottish Government's guidance, FSA Scotland will review the continued effectiveness of this

Regulation through the use of a Review Regulatory Impact Assessment that will be completed within 10 years.

15. Summary and Recommendation

15.1 Two options have been identified either 1) the legislation remains the same or 2) the Regulation is implemented into Scots law which will ensure that the UK is in line with the rest of the EC.

15.2 **Option 2 is the preferred option** which would ensure a high level of protection for consumers. Currently, food enzymes (other than those used as food additives) are not 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. Industry would therefore also benefit from the uniform safety measures and free trade.

16. Declaration and Publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed ……..

Date ……..

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