

Explanatory Memorandum to The Food Enzymes (Wales) Regulations 2009.

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

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Food Enzymes (Wales) Regulations 2009. I am satisfied that the benefits outweigh any costs.

GWENDA THOMAS A.M
Deputy Minister for Health and Social Services

21 December 2009

1. Description

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.

2. Matters of special interest to the Subordinate Legislation Committee

None.

3. Legislative background

Welsh Ministers have the powers to make these Regulations under sections 16(1)(a), (e) and (f), 17(1) and (2), 26(1)(a) and (b), 2(e) and (3), and 48(1) of the Food Safety Act 1990 enable these Regulations to be made. Functions transferred to the National Assembly for Wales are now exercisable by Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006.

These Regulations are being made to enforce, within Wales, 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. Purpose & intended effect of the legislation

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 unequal and unfair

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

Regulation (EC) No. 1332/2008 on food enzymes is part of a package of European Parliament and Council measures on Food Improvement Agents (the other Regulations cover food additives and flavourings). This 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.

The aim of the EC Regulation 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 Regulation (EC) No. 1829/2003 on genetically modified food and feed are also authorised under that Regulation prior to authorisation under this Regulation.

Regulation (EC) No. 1332/2008 is directly applicable in the UK; however a Welsh Statutory Instrument (SI) is required to enforce the Regulation and identify penalties for non-compliance in Wales. The Food Enzymes (Wales) Regulations 2009 make it an offence to place on the market, use or fail to label a food enzyme or food enzyme preparation that is not on the approved EC list (once established) as mentioned in Article 17 of the Regulation (EC) No. 1332/2008. Separate but parallel legislation will be made for England, Scotland and Northern Ireland.

5. 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). Across the UK, approximately 450

stakeholders were consulted. In total, 22 responses were received; only a small number related to the Enzymes proposal, however consumers welcomed enhanced controls on Food Enzymes and Industry welcomed the benefits from a harmonised EC market. There were no responses to the consultation from stakeholders in Wales.

In July 2009, the FSA consulted publically for 12 weeks, on the new SI on food enzymes. Across the UK, approximately 450 stakeholders were consulted and three responses were received relating to food enzymes. Of these, one (Association of Bakery Ingredient Manufacturers (ABIM)) 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. There were no responses to the consultation from stakeholders in Wales.

REGULATORY IMPACT ASSESSMENT

6. Options

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.

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.

7. Costs & benefits

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

Summary of costs and benefits – Option 2

Change	Benefit	Cost
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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.

8. Competition Assessment

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.

9. Post implementation 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.