Explanatory Memorandum

The Addition of Vitamins and Minerals and Other Substances (Wales) Regulations 2007

This Explanatory Memorandum has been prepared by The Food Standards Agency Wales and is laid before the National Assembly for Wales.

Description

1. These Regulations provide for the execution and enforcement of Commission Regulation (EC)No. 1925/2006 laying down rules to further protect consumers from consuming quantities of any vitamin, mineral or other substance which could be harmful to health and also harmonises legislation across the EU making it easier to trade.

Matters of special interest to the Subordinate Legislation Committee

2. None.

Legislative Background

3. The powers enabling this Instrument to be made are contained in the Food Safety Act 1990. Sections 16(1)(a)(e) and (f), 17(2), 26(a)and (3) and 48(1) of the Food Safety Act 1990 were transferred to the National Assembly and are now exercisable by Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006. This Instrument is subject to the negative resolution procedure.

Purpose and intended effect of the legislation

4. The objective of the Regulation is to harmonise Community rules on the voluntary addition of vitamins and minerals and of certain other substances to food. The aims of the Regulation are two fold: to provide a high level of consumer protection across the Community by ensuring that the products concerned do not present any risk to public health and to facilitate the free circulation of such products within the European Union

5. It also establishes a positive list of vitamins and minerals that can be voluntarily be added to food and the vitamin formulations and mineral substances that can be used. It sets minimum levels of addition for some vitamins and minerals and puts in place provisions to further set minimum and maximum levels.

Implementation

6. These Regulations were made on 10 July 2007 and intended to come in force on 7 August 2007. Similar legislation will simultaneously come into force in England, Scotland and Northern Ireland on 7 August 2007.

7. The implementation of these Regulations would fulfil the UK's obligations under the EC Treaty and will provide Local Authorities with the power to enforce against food business operators who are not in compliance with the new Regulations. Failure to implement them in Wales by the coming into force date of 7 August would lead to inconsistency in UK law.

Consultation

8. The Agency consulted widely throughout the development of 1925/2006, including a full 12 week public consultation. Three responses were received to the consultation in England . **None was received in Wales**. In general, stakeholders have welcomed the proposal as both a means of further protecting consumers and also to aid trade. Where concerns have been raised the Agency has successfully negotiated to protect UK interests. In particular we gained derogation from the provision prohibiting additions to alcohol and thereby removed a threat to the UK tonic wine industry; we also protected the use of trace quantities of vitamins and minerals as authenticity markers against counterfeit alcoholic drinks.

Regulatory Impact Assessment

9. A separate Regulatory Impact Assessment has been carried out which evaluates the risks and benefits associated with the making and coming into

force of EC Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods.

Final Regulatory Impact Assessment

Regulation (EC) No.1925/ of the European Parliament and of the Council on the Addition of Vitamins and Minerals and of certain other substances to food.

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OPTIONS

The following options were available at the proposal stage:

Option 1: Do nothing
Option 2: Oppose adoption of the Regulation
Option 3: Negotiate for adoption of the proposal as drafted
Option 4: Negotiate for adoption of the proposal as drafted (as for Option 3) with changes to the restrictions on the addition of vitamins and minerals.

Each of these options carried a number of risks to consumers, industry and Government; these are discussed below.

Option 1: Do nothing

This was not a credible option. EU Regulations have direct legislative force, and not to participate in the negotiation would have resulted in a less favourable outcome for the UK, for example a ban on tonic wine and authenticity markers in alcoholic drinks.

Option 2: Oppose adoption of the Regulation

This was also an unrealistic option, as was foreseen in the partial RIA. There was general support from most Member States for this proposal and the UK acting alone would not have had the voting capacity to defeat it in Council. In the event one Member State did not vote positively for adoption of the Regulation. The UK also made considerable gains in terms of greater proportionality and securing provision for consumer protection, and a positive vote supported these gains.

Option 3: Negotiate for adoption of the proposal as drafted

There were some advantages to this option as noted in the partial RIA; but equally, the prohibitions – particularly as affecting tonic wine - were too blunt to have the effect of protecting the consumer while maintaining choice, and would have put unnecessary burdens on industry.

Option 4: Negotiate for adoption of the proposal with changes to the restrictions on the addition of vitamins and minerals

This was the preferred option to deliver the objectives of the Regulation, but also take note of the greatest majority of legitimate stakeholder concerns. Taking this approach in the negotiation, the UK fended off the removal of safe substances from the Annex and the addition of substances untested by EFSA. We gained exemptions and clarifications to protect tonic wine and the use of authenticity markers in alcoholic drinks – a key anti-fraud and consumer safety tool. Adulteration of counterfeit products poses health risks from uncontrolled ingredients, including methanol, which can be lethal. The counterfeit trade can cost consumers and the industry substantial amounts each year.

In order to address concerns about the potential to encourage alcohol consumption, the exemptions here do not allow claims to be made about the addition of vitamins or minerals to alcohol (in effect confirming the ban already in place thanks to the Regulation on nutrition and health claims). Without such claims, there is no question of implied positive health benefits. These conditions, which are encompassed by our proposed amendment, would not affect the tonic wine or spirits industries as the nutrients are added to these products in small amounts and no claims are made.

Deletion of provisions on certain other substances

The Regulation addresses the addition of other substances, as well as vitamins and minerals, and proposals were made to change the way in which the Regulation would control this. Problems acted on in the UK in the past – concerns about Kava-kava – highlighted the need for Community measures to regulate the use of substances across internal borders. Failure to act here (some Member States had suggested looking at these substances elsewhere) would have risked no action on these harmful substances for the foreseeable future. Therefore the UK supported the Commission's view that these provisions would provide an appropriate mechanism by which the Community can further protect consumer safety. Moves to do this via positive listing of authorised products would also have delayed protective measures (assembling exhaustive lists can take years) or would have unnecessarily suspended trade in products that would later have been found to be safe. The UK was successful in retaining the provision of acting on harmful substances on a case by case basis while not disrupting the market in the meantime.

COSTS

Compliance costs

Compliance costs imposed by the Regulation may arise from new mandatory labelling requirements, voluntary dossier preparation, any voluntary reformulation and possible loss of products from the market.

Although Option 1 and 2 above may not have incurred compliance costs for industry they may potentially have led to trade barriers and lost business, and health risks to consumers would have had an uncertain response. Given that the Regulation was accepted by nearly all Member States, and has direct legislative force, failure to implement would lead to the European Court of Justice upholding infraction proceedings against the UK, which would also represent a cost to Government.

Compliance costs – labelling

The pursuit of Options 4 and the subsequent Regulation may require some re-labelling costs to business. These are the additional requirements to provide complete nutritional information on products to which vitamins and minerals have been added. However, many products already carry a nutrition claim relating to the added nutrient and, thus, will carry nutrition information as required by existing labelling legislation. Indeed most pre-packaged food in the UK (estimated at approximately 80%) carries some nutritional information already. Only those products to which vitamins and minerals have been added but that do not carry *full* nutritional information would be required to change their labels. We do not have data on the proportion of the market or the number of products that this might affect, but it is expected to be small.

It is estimated that such re-labelling costs could be up to £1000 per affected product.[1] The transition period until 31 December 2009 allows some time for preparation and adjustment to re-labelling requirements.

Compliance costs – dossier preparation

The list of substances approved for addition to food is quite extensive; nevertheless, some substances previously available are not listed and new substances will be required. Businesses that wish to have vitamin and mineral substances added to the lists of authorised substances would have to bear the costs of preparing dossiers in support of the substance in question, or at least some of the costs if collaboration between companies takes place. This

[1] Information from the British Retail Consortium

would be a new, one-off cost. The cost of safety dossiers can vary considerably, but in previous consultations an average cost of £15,000 has been reported.

As indicated above we are aware of only one nutrient source (sodium glycerophosphate) that is currently added to tonic wine in the UK but that does not appear on the positive lists. Since this is considered to be of low toxicity and similar to other mineral glycerophosphate salts or those containing sodium, which are already on the approved list and for which safety data would already be available, we would not expect the cost of producing a dossier to support addition of this substance to the lists to exceed £10,000. We would expect this, and indeed the cost of dossiers for any substance, to be able to be spread across several businesses. It should also be noted that new substances may well be novel ingredients, for which existing legislation requires safety dossiers, so this Regulation does not add additional burdens in these cases.

Compliance costs – reformulation

It is possible that some manufacturers may need (or choose) to reformulate their products in cases where they are adding substances that are not already on the positive lists (and have not undertaken to submit a dossier in support of the substance in question), or in sufficient quantities to comply with the Regulation. Such a decision would most likely be based on financial considerations, as it may incur ongoing costs, although practical/technical restraints may also have a bearing on this.

Estimates of the cost of reformulating products are generally in the region £10-25,000 (based on costs of developing a new product). However, and in the case of tonic wine, use of substances not on the list of authorised substances is permissible until 19 January 2014 provided they were in use prior to 19 January 2007. Tonic wine reformulation could cost up to £150,000, which includes the cost of consultation with experts, research on alternative ingredients which are not vitamins or minerals, laboratory testing

and commercial lot testing (with associated losses including excise duty). In addition to this would be the cost of using an alternative mineral source, which is more costly, could be approximately £4 per kilogram, which would amount to an additional annual production cost of up to £450,000. However, this is likely to reduce over time due to the increased demand for this ingredient. An application for authorisation of the substance currently used during the in the seven year transition period will avoid these costs.

Compliance costs – loss of products

The Regulation would not stop products with added vitamins or minerals from being marketed, provided that they comply with its provisions. As outlined above, dossiers may be submitted in support of substances in use (but not on the positive lists) or products may be reformulated to comply with the Regulation. But if neither of these were possible, product withdrawal may be the only alternative. We are not aware of any products that may be affected in this way. However, the threat to tonic wine prior to the agreed derogation was product withdrawal, with the potential loss of sales of more than £30 million[2] per year and subsequent job losses. The derogation has therefore saved this niche sector.

Other costs

As outlined above, there are potential costs to industry (and risks to health) presented by trade in counterfeit branded spirits. While the spirits industry would not have incurred any direct costs if the relevant Recital to the Regulation did not clarify the situation as regards authenticity markers, the potential range of substances for use would have been reduced. This may have had implications for the number of counterfeit products that might have gone undetected while the industry sought alternative sources. However, it is not possible to predict the likely effects or quantify potential costs to industry or consumers that could have arisen as a result. Losses to excise revenue

[2] We only received figures from one manufacturer (admittedly the largest); other manufacturers have tonic wine as a small brand in a larger portfolio and indicated that the loss would be significant, but a small cost to the group.

could also have increased. The Recital on authenticity markers has avoided potential costs here.

Costs for a typical business

An affected business may face the cost of some reformulation of recipes as a result of this proposed Regulation and/or of dossier submission. In addition, re-labelling may be required to provide (additional) nutritional information. No specific figures are available for reformulation costs, the best estimate being between £10-25,000, with the exception of tonic wine for which it could be up to £150,000. We are only aware of one sector (tonic wine) that may need to submit a dossier, with an estimated cost up to £10,000, which could be shared by the businesses concerned. Industry estimates for re-labelling costs are up to £1000 per product.

Administrative Burdens

Businesses wishing to add vitamins and minerals and certain other substances to food under this Regulation will incur some administrative costs and these are highlighted elsewhere in the RIA.

Re-labelling

Re-labelling will be necessary where labelling as currently made does not conform to the requirements of the Regulation, which is estimated to be in the minority of cases. Re-labelling costs are estimated to be at £1,000 per product. The transitional arrangements of up to two years will allow required changes to be made, where necessary, with routine changes made during the normal course of business. We therefore do not consider there will be any additional administrative burden on business from re-labelling.

Scientific dossiers

Scientific dossiers need to be submitted to add substances to the lists of authorised substances. Evidence from other consultations was that an average risk assessment dossier would cost £15,000 to prepare. This may include the cost of work business would do themselves during the normal course of business, and

include non-administrative costs, such as substantiating the safety of the substances to the companies' own satisfaction before adding it to food. Where new ingredients are introduced, these would be normal costs in the novel foods procedures. Evidence from the Administrative Burdens Measurement Exercise carried out in 2005 suggests a much lower figure for preparing dossiers (that is assembling the evidence in the form required by the Commission).

BENEFITS

Option 1: Do nothing

This option would have afforded no benefit, with additional dis-benefits as for Option 2.

Option 2: **Oppose adoption of the Regulation**

This would not have been possible, and would have afforded no benefits. We would have been forced to accept a situation less advantageous to the UK consumer and more onerous on UK industry. Continuation of current national provisions would not have been an option since the Regulation would have direct legislative force and it presents a potential disadvantage in terms of trade for UK industry in the single market since other Member States would implement the Regulation. Furthermore, non-implementation would constitute a breach of the UK's obligations under the EC treaty and lead to action in the European Court of Justice. In addition, this option would have failed to deliver improved consumer protection and thus the risk to consumers from the marketing of food products that are unsafe due to their composition or are inadequately labelled would remain.

Option 3: Negotiate for adoption of the proposal as drafted

The main benefit of this option would have been to public health and consumer safety through the control of the addition of vitamins and minerals to food in the national diet. However, there is no appreciable benefit from the ban of the addition of small amounts of a mineral to tonic wine in terms of public health.

An additional benefit of the harmonisation of legislation in this area is the elimination of trade problems such as obstruction of the free movement of products, unequal conditions of competition, and the opening of new markets for fortified products in the rest of the Community. This is also true under Option 4. It is not possible to put a figure on the financial benefit of this, but industry welcomes the measure on these grounds.

Option 4: Negotiate for adoption of the proposal with changes to the restrictions on the addition of vitamins and minerals

As above, the main benefit will be to public health and consumer safety through the control of the addition of vitamins and minerals to food in the national diet. This is not thought to be a major public health risk at current levels of fortification, but the cost of regulation in this area is not likely to be great and this is considered to be a proportionate measure, particularly as the trend for fortification is to increase, which may give rise to more defined risks. Furthermore, the derogation from the ban on the addition of vitamins and minerals to alcohol is a benefit to consumer choice, by continuing to allow access to tonic wine, a traditional product peculiar to the UK. It will also offer protection to consumers (and industry) from the health risks (and costs) of trade in counterfeit products, such as spirits, which caused at least two deaths in 2004[3].

The harmonisation of legislation in this area will bring the additional benefit of eliminating trade problems such as obstruction of the free movement of products, unequal conditions of competition, and a restrictive impact on the functioning of the single market. It is not possible to put a figure on the financial benefit of this, but industry welcomes the measure on these grounds.

Deletion of provisions on certain other substances

As discussed above this would have gone further than our Option 4 and offered no benefit. If the provisions of Chapter III and Annex III to deal with substances other than vitamins and minerals were not included in this proposal, substances of potential health concern would be unlikely to be dealt

[3] Communication from the Gin and Vodka Association, February 2005

with in the foreseeable future, if at all. Therefore, retention of these provisions secured further consumer protection by reducing the potential risk to health presented by the use of some other substances where there are safety concerns. There will also be greater consistency in the Single Market as national restrictions are replaced by EU arrangements, linked to risk assessment.

Please see Appendix 2 for a summary of benefits.

Competition Assessment

Initial results from the competition filter indicate that there is unlikely to be any significant negative impact on competition. The Regulation applies to a wide range of food manufacturers and in the main, might impose one-off costs in terms of labelling or reformulation. In many cases it is likely that these changes will be absorbed into the regular cycle of changing labels (since the UK was successful in securing a full 2 year transition period before enforcement). In this case, many firms will face no additional costs as a result of the regulation. For those firms who are required to change their labels outside of the normal cycle, they will face one-off costs estimated in the region of £1000 per product. These costs are unlikely to increase concentration of the market. Neither will they significantly increase barriers to entry as there will be no higher set-up, or ongoing, costs for new entrants whom must develop new labels anyway. Furthermore, by harmonising legislation across the EU and eliminating some of the current barriers to trade, competition will be further encouraged as firms compete in a larger market.

The outcome of the negotiation to allow derogation for tonic wine means companies in the UK tonic wine sector may continue to operate in a niche sector, with no effect on competition. However, as noted in para 4.8, reformulation or application for authorising the unlisted substance will impose additional costs which in this small sector could lead to market exit and thus increased concentration. Alternatively, co-operation between producers would maintain the current situation at a reduced unit cost.

Consultation

The Agency consulted widely throughout the development of 1925/2006, including a full 12 week public consultation which ended on 24 May 2007. Three responses were received to the consultation in England. None **was received in Wales**. In general stakeholders have welcomed the proposal as both a means of further protecting consumers and also to aid trade. Where concerns have been raised the Agency has successfully negotiated to protect UK interests. In particular we gained derogation from the provision prohibiting additions to alcohol and thereby removed a threat to the UK tonic wine industry; we also protected the use of trace quantities of vitamins and minerals as authenticity markers against counterfeit alcoholic drinks.

Enforcement and sanctions

Following the adoption of this Regulation, it is proposed that provision will be made in domestic legislation as to enforcement by food authorities, with offences and penalties applied in line with the Food Safety Act 1990. Given that there are currently no EU or UK rules on the voluntary addition of nutrients to foods, the Regulation is likely to present a minimal additional burden on the enforcement operations of local food authorities. As indicated above, Local Authorities Co-ordinators of Regulatory Standards (LACoRS UK) have indicated that a small additional cost for analysis of samples to check the vitamin or mineral source would be incurred. Based on an estimate that approximately 200 samples per year may be taken at a cost of £50 per sample, even accounting for additional staff time and costs, the total additional cost would not be expected to exceed £60,000 per year[4].

Post Implementation review

The Addition of Vitamins, Minerals and Other Substances (Wales) Regulations 2007 will provide for the execution and enforcement of Regulation (EC) No.1925/2006 of the European Parliament and of the Council

[4] This figure was revised upwards from £50,000 after comments from LACoRS during the consultation on implementation of the Regulation.

on the addition of vitamins and minerals and of certain other substances to foods. Separate but parallel legislation will be made for England, Scotland, and Northern Ireland.

Guidance to the food industry and enforcement stakeholders on compliance with this Regulation has been drawn up by the Food Standards Agency which will help businesses to comply with the legislation. This guidance has been subject to public consultation and was generally welcomed by all stakeholders. It is currently being revised in the light of comments received and will be published on the Agency's website in due course.

Summary and recommendation

At present there are no specific rules on voluntary fortification of foods at EU or UK level, nor are there laid down limits on the levels or range of vitamins and minerals that can be added to foods. The Government accepts that there is a case for EU legislation covering voluntary fortification of foods to overcome barriers to trade, but conditions set should be only those necessary to protect public health. This Regulation sets conditions for the addition of vitamins and minerals to foods, contains positive lists of substances whose safety has already been assessed and provides a framework for maximum (and minimum) levels of addition to be set in future. Together with additional labelling requirements, these provisions will provide a basis for increased consumer protection. Given the nature of the measure, the cost implications mostly affect the food industry but some of these costs have been substantially reduced by securing the amendments to the proposal during negotiations, as outlined above.

The most widespread cost, which will affect businesses that add vitamins and minerals to food products but do not currently give full nutrition information, is a one-off cost for label changes. These costs will have been mitigated by the transitional period that has been secured. Tonic wine businesses (three have been identified) may incur a cost for dossier preparation, or reformulation. Through consultation we have only been notified of one mineral source that is

'missing' from the positive list and, given the similarity of this substance to other mineral salts on the positive list, the cost of producing a dossier to support addition of this substance to the list is not likely to exceed £10,000. Estimates of the potential cost of reformulation, where this may be necessary, are generally in the region £10-25,000. For one tonic wine manufacturer specifically, it is envisaged that such costs could be up to £150,000 if it were necessary to use non-mineral ingredients, although an alternative ingredient is listed and reformulation costs could be reduced if this is found suitable. Another alternative would be to apply for authorised use of the current substance, at a cost in the region of £15,000 for risk assessment studies. Similarly, the potential for loss of sales of up to £30m in the tonic wine sector will not now be a concern.

The Government's view is that, in the interests of consumer choice, fortified foods that are safe and properly labelled should be allowed on the market. Option 4 delivered the most proportionate measure in the circumstances, minimising costs to industry, maximising benefits to consumers and public health and finding favour with other Member States as best meeting the objectives of the measure for harmonising the rules on the addition of vitamins and minerals (and other substances) to foods.

Appendix 1

PUBLIC SERVICES THRESHOLD TEST: PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE ADDITION OF VITAMINS AND MINERALS AND OF CERTAIN OTHER SUBSTANCES TO FOODS

In line with Cabinet Office guidance, a Public Services Threshold Test must be carried out for any proposal impacting on the public sector. For proposals impacting on the public sector only, the Test determines whether a regulatory impact assessment (RIA) should be completed.

Local Authorities Co-ordinators of Regulatory Services (LACoRS) have indicated that an additional cost to enforcement authorities and to public analysts to analyse foods to check compliance with these new Regulations would be incurred. The following Public Services Threshold Test was completed in accordance with Cabinet Office guidance and in consultation with LACoRS.

1. Cost calculation table

Number of public service staff Affected	Time impact per person	Time impact per group	Total monetary costs per annum
28 public analysts (plus enforcement officers)	Not available	Not available	£20-60,000[5]
Totals			**£20-60,000**

2. Threshold criteria for undertaking an RIA

The total additional monetary costs to all UK enforcement authorities and public analysts is anticipated to be up to £20-60,000, which is well below the threshold criteria of £5 million. As such, an RIA to address impacts on public services or staff is not required.

[5] Figure based on LACORS' estimate of these costs

The new Regulations may attract political or media interest and a partial RIA has been produced which addresses the potential costs and benefits involved.

Appendix 2

SUMMARY OF COSTS (SECTION x) AND BENEFITS (SECTION x)

Option	Costs	Benefits
1. Do nothing	Infraction proceedings	0
2. Oppose adoption of the Regulation	Infraction proceedings	0
3. Negotiate for adoption of the proposal as drafted	Costs to business: Increased safety concern from spirit fraud. Reformulation (£10,000-25,000 per affected product) and re-labelling (up-to £1000 per product). Tonic wine SME may be forced to contract/ close (turnover £30m). Public Sector cost: LACORS enforcement (£20,000-60,000).	Reduced safety risk from excess consumption of vitamins and minerals. Opportunities for UK trade.
4. Negotiate for adoption of the proposal as drafted (as for Option 4) with changes to the restrictions on the addition of vitamins and minerals.	Costs to business: Reformulation (£10,000-25,000 per affected product) and re-labelling (up-to £1000 per product). Tonic wine producers need to produce a dossier (£10,000). Public Sector cost: LACORS enforcement (£20,000-60,000).	Reduced safety risk from excess consumption of vitamins and minerals. Consumer safety and business protection from counterfeit trade in branded spirits. Reduces risk to consumers and industry of losing existing products from the market. Opportunities for UK trade.