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FOOD STANDARDS AGENCY
SCOTLAND
Buidheann Inbhe-Bìdhe an Alba

EXECUTIVE NOTE

THE ADDITION OF VITAMINS, MINERALS AND OTHER SUBSTANCES (SCOTLAND) REGULATIONS 2007 SSI 2007/325

The above instrument is made by the Scottish Ministers in exercise of the powers conferred by sections 16(1)(a), (e) and (f), 17(2), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(a).They have had regard (in accordance with section 48(4A)(b) of that Act) to relevant advice given by the Food Standards Agency. They have carried out consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council. The instrument is subject to negative resolution procedure.

Policy Objectives

1. The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 makes provision for the enforcement in Scotland of EC Regulation 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.

2. The EC Regulation is the first piece of specific legislation to deal with the voluntary addition of vitamins and minerals to food and aims to provide a higher level of consumer protection as well as harmonise legislation across the EU to facilitate intra-Community trade. It also sets provisions to prohibit the addition of other substances to food. A copy of this regulation is attached.

3. The EC Regulation will control the voluntary addition of vitamins and minerals to food by means of positive lists set out in the Annexes, and allows for purity criteria and for minimum and maximum levels of such additions to be set. The Regulation makes provision for the compilation of a list of other substances that may be restricted or prohibited from being added to food. It also sets additional labelling controls.

4. The Scotland Regulations will come into force on 7 August, as will parallel regulations for England, Wales and Northern Ireland, which will ensure even application and enforcement across the UK.

Policy background

5. On 30 December 2006 a Regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods was published as a Regulation (EC) No 1925/2006.

Consultation

6 Interested parties throughout Scotland, including consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other government departments, have been consulted on these draft Regulations.

7. A full list of consultees can be found in Annex B. This meets the consultation requirements of Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

8. The Agency received three responses to the formal consultation, from REHIS (Royal Environmental Health Institute of Scotland), East Ayrshire Council and the Scottish Consumer Council. All of the respondents stated their support for or had no specific comments regarding the implementation of the Regulations. None of the respondents objected to the implementation or offered any drafting comments.

Regulatory Impact

9. Industry have advised that there will be a one off cost associated with re-labelling products that add vitamins and minerals to food products but do not currently give full nutrition information. Enforcement bodies have indicated that there will be a cost associated with having to enforce and monitor these new provisions.

10. A full outline of the costs associated with the EC Regulation can be found in the RIA in appendix A. No RIA has been prepared for the Scottish Regulations as they only designate competent authorities as well as providing for offences and penalties associated with breach of the EC Regulation itself.

Food Standards Agency
June 2007

FINAL REGULATORY IMPACT ASSESSMENT

1. Title of proposal

1.1 The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007

implementing -

Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the Addition of Vitamins and Minerals and of Certain Other Substances to Foods (Formerly – COM(2003) 671 Final]

2. Purpose and intended effects of the measure

Objective

2.1 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.

Devolution

2.2 The Regulation applies in all EU Member States. Provision as to enforcement will need to be made in national regulations for England, Scotland, Wales, and Northern Ireland.

Background

2.3 Currently there are no Community rules on the voluntary addition of nutrients to foods and Member States' national rules vary widely. This impedes the free movement of these products, can create unequal conditions of competition, and thus, have a direct impact on the functioning of the single market.

2.4 Furthermore, some Member States apply national rules on the mandatory addition of nutrients to certain foods (in the UK such rules apply to margarine and flour). In addition, there are Community rules requiring the mandatory addition of nutrients to a number of foods for particular nutritional uses (PARNUTS foods).

2.5 Regulation (EC) No. 1925/2006 is only concerned with the voluntary addition of vitamins and minerals to foods other than food supplements, and it will not affect national rules on mandatory fortification, although it does not exclude the possibility of future harmonisation of mandatory rules.

2.6 In relation to vitamins and minerals added to foods, the Regulation:

- defines the purposes for which additions are allowed;
- lists permitted vitamins and minerals and the substances from which they may be derived (e.g. L-ascorbic acid for vitamin C or ferric ammonium citrate for iron) to be added to foods – the 'positive lists';
- sets criteria for establishing maximum levels of addition (none are set in this proposal) and provides for the setting of minimum levels;
- prohibits the addition of vitamins and minerals to fresh produce and alcoholic drinks;
- lays down specific labelling requirements, including compulsory nutrition labelling; and
- allows for mandatory Community or national provisions.

2.7 The Regulation recognises that vitamins and minerals, in a bioavailable form, may be added to foods, whether or not they are usually contained in that food, to take into account:
a deficiency – where clinical or sub-clinical evidence demonstrates one or more vitamins or minerals may be below required recommended levels in the population or in specific population groups;
improved nutrition – of the population or in specific population groups or to take into account potential deficiency from changes in dietary habits; and
evolving science – generally acceptable scientific knowledge on the role of vitamins and minerals in nutrition and consequent effects on health.

2.8 The Regulation also introduces powers to take action at Community level to restrict other substances that may be added to food where there are safety concerns over such additions – see para. 2.19.

2.9 The provisions regarding vitamins and minerals do not apply to food supplements and the Regulation applies without prejudice to existing Community legislation on foods for particular nutritional uses (PARNUTS), novel foods and novel food ingredients, food additives and flavourings and provisions on oenological practices and processes.

2.10 Intra-Community trade difficulties indicate that harmonisation was necessary and justified; in achieving this, the UK recognised that any measures taken in this respect should be proportionate. Current UK controls are generally considered to be sufficient to protect consumers, and have allowed development of a wide range of fortified foods, which, in some cases, make a positive contribution to public health. Many consumers value the variety of choice that has developed in the UK and any restrictions on that choice were only justifiable on public health grounds. The majority of current UK practice appears to comply with the conditions set out in this Regulation (with the exception of alcoholic drinks, in particular the tonic wine sector) and the changes brought by the Regulation should have minimal effect.

Risk assessment

2.11 The Regulation addresses two risks, namely that foods to which vitamins and minerals have been added, for whatever reason, could present a risk to human health; and that different national rules on voluntary addition of vitamins and minerals to foods can result in barriers to intra-Community trade in these products. In addition, the Regulation introduces powers for Community action to be taken where there are safety concerns about the addition to foods of substances other than vitamins and minerals, to address the uncertainties and inconsistencies arising from national actions - see paras. 2.19 and 3.6. Consequential risks from introduction of this Regulation and additional controls introduced into the UK are on burdens to industry and how costs are transferred to consumers. These need to be balanced with trade opportunities leading to savings that could be passed onto consumers and greater consumer protection.

2.12 These risk areas can be further broken down as follows and are discussed below:

i. a risk to consumers from the marketing of food products that are unsafe due to their composition (the quantity or source of vitamin or mineral, or of a substance other than a vitamin or mineral contained) or are inadequately labelled;
ii. a risk of distortion of the single market for food products;
iii. a risk to industry (businesses and their employees) that safe products currently on the market in this country could be removed from sale unnecessarily and costs passed on to consumers; and
iv. a risk that consumer choice could be unnecessarily reduced by removing safe products from the market.

(i) Risk to consumers from marketing of food products that are unsafe due to their composition (the quantity or source of vitamin or mineral, or of a substance other than a vitamin or mineral contained) or are inadequately labelled

2.13 The UK market in fortified foods (sometimes classed with 'functional' foods) is increasing, with consumers taking more of an interest in the importance of diet as it relates to health. Almost a quarter of the adult population claims to eat only foods that they think are good for them and 10% more read food labels than in 2001. Estimates suggest that sales of functional foods and drink in 2003 were over six times the value of those in 1998, and that that market will have doubled in the next few years[1]. An increasing number and range of products with enriched levels of nutrients (or other added substances) is available on the market, with associated claims as to the presence of the nutrient and/or the potential health benefit it provides. When consumed as part of a healthy diet, and sometimes with medium to long-term use, many of these foods are designed to provide an additional benefit beyond their basic nutritional value. On a global scale, value sales in so-called 'functional foods' increased by 60% between 1998 and 2003 and are forecast to rise by a further 40% over the period 2003-2008[2]. Consequently, if current trends continue as predicted, the number of fortified products and product ranges available stands to increase considerably.

2.14 Consumers are becoming more health conscious and, with a trend towards busier lifestyles and a heavier reliance on convenience foods, many have chosen to take

[1] Functional Foods - UK - March 2004. Mintel
[2] Just-food, Research Store 'The World Market for Functional Food and Beverages 2004', Aroq Ltd

more responsibility for their own health and well being to reduce the deleterious affects associated with such lifestyles. While the market in functional foods and drinks increases to keep pace with consumer concerns and health awareness, such an increase in the availability of foods with added vitamins, minerals or other substances may potentially lead to over consumption of particular nutrients - see paras. 2.16-17.

2.15 At present there are no specific rules on voluntary fortification of foods at EU or UK level. In addition, there are currently no UK limits on the levels of vitamins or minerals that can be added to foods (or used in the manufacture of food supplements), nor are there rules on the range of vitamins, minerals or other substances[3] that they may contain. Fortification of foods with nutrients is subject to general safety controls provided for in section 7 of the Food Safety Act 1990 which makes it an offence to render a food injurious to health; Articles 14(3)-(4) of European Regulation 178/2002 indicate what factors need to be taken into account when determining whether food is injurious to health. Fortification is permitted providing that the final foodstuff is safe and appropriately labelled, but no specific maximum limits are laid down in the Act or in other UK legislation. It is the responsibility of manufacturers to ensure that products are safe and properly labelled.

2.16 Current intakes of most vitamins and minerals are not thought to be harmful. However, excessive intakes of some vitamins and minerals can have harmful effects, particularly if taken over long periods of time. Thus, foods to which vitamins and minerals are added may present a potential risk to health from the levels present in a single product or, more likely, from a range of products consumed. In such a case, the risk would be the probability of adverse effects occurring and the severity of those effects. In 1997 an Expert Group on Vitamins and Minerals was established to advise on safe levels of intakes of vitamins and minerals from food supplements and, where appropriate, from fortified foods.

2.17 The Expert Group assessed available evidence on safety and its report[4] made recommendations on 31 vitamins and minerals, including advice on additional dietary intake from food supplements and/or fortified foods, where possible. The risk of potential harm differs for each vitamin and mineral and depends on the amount and form of the substance consumed, as well as the period of time over which it is consumed and the susceptibility of the individual/consumer; the amount of one vitamin or mineral that could be considered as excessive (or that could have possible harmful effects) would be different to that for other vitamins and minerals or, in some cases, to different forms of the same vitamin or mineral. Although the Expert Group evaluated the safety of intakes of 34 vitamins and minerals, it was only possible to set an upper level or make recommendations for 31 of them.

2.18 This Regulation contains ‘positive lists’ of vitamins and minerals whose overall safety has already been assessed, but safe intake levels have not. The Regulation provides a framework for the Standing Committee on the Food Chain and Animal Health to set maximum (safe) levels for the addition of vitamins and minerals to foods in future, on advice from the European Food Safety Authority

[3] The exceptions to this are the amino acid tryptophan and the herb Kava-kava, which, under the terms of the Tryptophan in Food Regulations 1990 and Kava-kava in Food (Scotland) Amendment Regulations 2004 respectively may not be added to food.

[4] Safe Upper Levels for Vitamins and Minerals. May 2003. Expert Group on Vitamins and Minerals

(EFSA). The implications of a future proposal will be considered, as necessary, in due course.

2.19 The Commission's explanatory memorandum to the proposal for the Regulation suggested there has been an increasing use in foods of certain other substances or ingredients that are often used in an innovative way or added at levels higher than would normally be consumed and that do not fall under the scope of novel foods legislation. While some national authorities have been taking action to control the use of certain substances based on risk assessments, e.g. Kava-kava in the UK, Community controls would ensure hazardous products are not traded to Member States without such controls and would improve consistency in the single market. The Regulation provides a framework for regulating substances that may be of concern. Examples of such substances that national authorities have controlled include Kava-kava, aristolochic acid, and ingredients of some stimulant drinks.

2.20 As regards the potential risk to consumers of inadequate labelling, the Regulation contains provisions for full nutritional labelling for products to which vitamins and minerals have been added in order that consumers are not misled or deceived. Claims relating to the nutrition and/or health benefits of the product, or of specific ingredients contained in the product, will be covered by the EU Regulation No 1924/2006 on nutrition and health claims made on foods. More information can be found in the Regulatory Impact Assessment (RIA) for that Regulation[5].

(ii) Risk of distortion of the single market for food products

2.21 The UK functional foods and drink market, valued at £835 million in 2003, is forecast to reach £1,720 million by 2007. In 2003, the product sectors with the highest percentage sales in the functional foods market were: breakfast cereals (26%), spreads (20%), stimulation drinks (18%), probiotic yoghurts and drinks (17%) and juice, juice drinks and dilutables (11%). The two main growth sectors are soya dairy-alternative products and probiotic yoghurts and drinks [6].

2.22 National rules on the voluntary addition of vitamins and minerals vary widely. In the UK, addition is generally allowed without any restrictions, provided the food is not posing any risk to health. Other Member States only allow such additions if it can be demonstrated that there is a nutritional need for the addition of the nutrient, or allow the addition of vitamins and minerals specified in a list, but allow different maximum levels to be present in the food; while others prohibit the addition of a few specific vitamins. Thus, within the EU, the size of the market for fortified/functional food products varies widely from one Member State to another; the UK boasts one of the larger and more varied markets. Harmonisation of the single market for these foods has the potential to open up markets for UK products in other Member States.

[5] Partial RIA attached to Supplementary Explanatory Memorandum 11646/03 or see: http://www.food.gov.uk/multimedia/pdfs/healthclaimsria.pdf

[6] Functional Foods - UK - March 2004. Mintel

(iii) Risk to industry that safe products currently on the market in this country could be removed from sale unnecessarily

Positive lists of vitamins and minerals

2.23 During consultation on this Regulation we were not made aware of any substance of importance not in the Annexes of authorised substances, save one (see 2.24 below). However, the Regulation now allows such substances to continue in use until 2014, provided they were in use in foods marketed on 19 January 2007, and that an application for continued use and a dossier of supporting evidence is received no later than 19 January 2010. During this period Member States may continue to apply national rules to these substances. Substances not enjoying this exemption must be removed from foods on the market once they have reached expiry date or 31 December 2009, whichever is the earliest.

Restrictions on addition

2.24 The proposed new conditions for the addition of vitamins and minerals to foods – Article 3 - presented a risk to those sectors of industry that currently add vitamins and minerals to products for purposes other than those permitted by the proposed Regulation. During consultation we discovered that tonic wine producers add certain minerals (one of which is not in the Annex) according to traditional recipes to distinguish their products and to meet consumer expectation and demand. Second, the spirit drinks industry uses vitamins among a pool of substances as chemical markers to verify the authenticity of their products. This is an anti-fraud measure to protect consumers buying branded products. It also has safety implications because of the adulteration of counterfeit products. The UK was successful in the negotiation in getting changes, now reflected in the Regulation, on these two issues. The prohibition on adding vitamins and minerals to alcoholic beverages now has an exemption for tonic wine. Industry claims that the prohibited substance can be replaced but, as noted above there is time to phase this out, or even apply to have it added to the Annex. The use of trace quantities of vitamins and minerals to combat fraud is now not within the scope of the Regulation, as clarified by Recital 13.

Maximum and minimum amounts

2.25 Industry concern about the plans to set minimum and maximum levels for vitamins and minerals continues, particularly as this involves levels to be set for food supplements and intakes from both these and natural sources may for some substances quickly approach maximum levels. This issue will be the subject of a separate negotiation in years to come and will have a separate impact assessment. However, the UK will continue to take a proportionate approach to this and ensure any restriction is based on the grounds of safety based on the best available scientific data.

(iv) Risk that consumer choice could be unnecessarily reduced by removing safe products from the market

2.26 Any reduction in the range of products on the market would reduce consumer choice. Such a reduction would be justified if products were removed on public health grounds, but would otherwise be unnecessary. We were only made aware of a problem with tonic wine and authenticity markers (paras. 2.23-24), for which we obtained a successful outcome. Other than this any effect should be minimal. However, we should note here that the setting of maximum levels and better intake data may redefine safety considerations and could lead to a restriction on new fortification for some substances.

Business sectors affected

2.27 In addition to the effects discussed above on tonic wines and authenticity markers, all food businesses fortifying products that do not carry full nutrition labelling would be affected by the requirements for labelling and the attendant costs.

3. Options

The following options are available at this 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

3.1 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

3.2 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

3.3 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

3.4 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.

3.5 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 reinforcing the ban contained in 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 tabled 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

3.6 The Regulation addresses the addition of other substances, as well as vitamins and minerals, and proposals were made to change how the Regulation would control this. Problems highlighted in the UK in the past – including concerns about Kava-kava, aristolochic acid and some ingredients of stimulant drinks –highlighted the need for Community measures to regulate the use of substances that may be of concern. 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.

4. Costs

Compliance costs

4.1 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.

4.2 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

4.3 The pursuit of Options 4 and the resultant Regulation in its adopted form 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.

4.4 It is estimated that such re-labelling costs could be up to £1000 per affected product[7] but, the transition periods available – expiry date or 31 December 2009, whichever is the sooner – should allow such costs to be absorbed in routine label changes.

Compliance costs – dossier preparation

4.5 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 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.

4.6 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

4.7 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

[7] Information from the British Retail Consortium

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.

4.8 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. However, a cheaper option would be to apply for authorisation of the substance currently used in the seven year transition period.

Compliance costs – loss of products

4.9 The Regulation would not stop products with added vitamins or minerals from being marketed, provided that they comply with the provisions of the proposal. 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 proposal. 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[8] per year and subsequent job losses. The derogation has therefore saved this niche sector.

Other costs

4.10 As outlined in para. 3.4 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 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 could also have increased. The Recital on authenticity markers has avoided potential costs here.

Costs for a typical business

4.11 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-

[8] 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.

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

4.12 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 in the RIA.

Re-labelling

4.13 Re-labelling will be necessary where it currently does not conform to the requirements of the Regulation - 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

4.14 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).

Please see Appendix 2 for a summary of costs.

5. Benefits

Option 1: Do nothing

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

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

5.2 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

5.3 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.

5.4 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

5.5 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[9].

5.6 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

5.7 As discussed above (para. 3.6) 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 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

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

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.

6. Small firms impact test

6.1 The Small Business Service (SBS) was contacted during the early stages of negotiation on this Regulation for information and advice on assessing its potential impact on small business. Together with a contact at the Forum of Small Businesses, they were also consulted formally on the proposal in January and November 2003. We also contacted several trade associations to assist in reaching relevant businesses that may be affected by the proposal. One such association – the Wine and Spirits Association – commented that the proposal could cause difficulties for the alcoholic drinks industry. We received a response to the second consultation from a tonic wine producer expressing concern that the restriction regarding alcoholic drinks would have a major impact on that industry, but assessment of costs was not included at this stage. This respondent went on to become the representative for the Association on this issue – see below. During the consultation process in Scotland the Forum of Private Business (Scotland) Ltd and the Federation of Small Businesses (Scottish branch) were also contacted. No responses were received from either.

6.2 Other industry responses highlighted current uses for vitamins and minerals that would not be permitted by the Regulation, which may affect certain industry practices but no specific businesses (small or otherwise) or costs were identified. Our research indicated that “smoothie” manufacturers were a sector that could be affected by the positive lists in the proposal but contact with one such small business confirmed that their current practice would conform to the proposal. We were aware that a parallel Regulation concerning nutrition and health claims might have significant implications for a range of small businesses, including those producing food supplements, but the bulk of this Regulation does not apply to food supplements; any potential impacts on such businesses would need to be assessed on a case-by-case basis when proposals are made within the Community to restrict or prohibit specific substances, other than vitamins and minerals – see para. 2.19.

6.3 As indicated above, in the UK, tonic wine producers were the businesses likely to be affected most by this proposal. We were aware of one such producer that qualifies as a small business, employing some 35 staff, with a turnover of approximately £30m. In view of the potential effect on tonic wine, and in addition to the formal consultation procedures and stakeholder meetings that have involved these producers, we held a meeting with representatives of the relevant companies in April 2004 in order to agree possible options for amending the proposal to reduce (or remove) the possible impact on tonic wine. We maintained regular contact as negotiations progressed and obtained more detailed information on possible costs and other implications (reflected elsewhere in this RIA) for the sector and, particularly, the small business concerned.

6.4 The tonic wine producers were made aware that, since the UK secured agreement to amend the proposal to allow the continued addition of small amounts of mineral sources to tonic wine, they would either need to submit a dossier for sodium glycerophosphate (production of which would not be expected to exceed £10,000) or reformulate the product to use one of the mineral substances permitted by the

Regulation. Their estimates indicate that such a reformulation, which would involve a more expensive ingredient (potassium glycerophosphate), would be possible but could cost them up to an additional £450,000 in production costs per year. However, they have also indicated that this cost could reduce over time due to an increase in demand for this ingredient. It would be for the producers to consider their options accordingly, but they have a choice of a less expensive option in applying for listing of the substance used. Our success in getting the derogation ensures that for this company there is no immediate threat to the business, avoiding job losses and loss of sales, approximately £30 million per year.

Impact on the regions

6.5 Any regional differences in benefit due to the new legislation would depend upon the location of the relevant business. We are not aware of any differential impact.

Test run of business forms

6.6 There are no new forms associated with this piece of legislation.

7. Competition assessment

7.1 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 who 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.

7.2 The outcome of the negotiation to allow a 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.

8. Sustainable development

8.1 The Food Standards Agency does not consider that implementing this Regulation will have any impact on sustainability issues.

9. Racial equality

9.1 The Food Standards Agency does not consider that implementing this Regulation will have any impact on racial equality issues.

10 Public services threshold test

10.1 We have considered the requirement to undertake completion of the cost calculation table for this test. Local Authorities Coordinators of Regulatory Services (LACORS) have indicated that a small additional cost for submitting samples for analysis would be incurred (approximately £50 per sample) but that this would not represent a significant cost and, accounting for additional staff time, the total additional cost would not exceed £60,000 per year. Based on these estimates, a public services threshold test has been carried out - see table attached at Appendix 1. As there are no costs to consumers, charities or the voluntary sector and the total additional costs to enforcement authorities falls well below the threshold figure of £5 million, the Regulatory Impact Assessment is not required to address impacts on public services or staff.

11. Enforcement and sanctions

11.1 Provision will be made in domestic legislation for execution and enforcement of the Regulation's requirements 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 Coordinators of Regulatory Services (LACORS) 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. [10]

12 Implementation and delivery plan

12.1 The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 will implement EU Regulation 1925/2006 on the addition of vitamins and minerals and certain other substances to foods. Separate but parallel legislation will be made for Wales, England, and Northern Ireland.

12.1 12.2 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 in a proportionate fashion. 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.

13. Monitoring and review

13.1 Articles 15 and 16 of the Regulation provides for future evaluation of the impact of the Regulation, including its effects on the evolution and consumption of fortified foods and changes in nutrient intakes or dietary habits for the population. The

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

provisions require the Commission to present a report to the European Parliament and the Council before 1 July 2013, on the basis of information provided by Member States.

Post-implementation review

13.2 In line with Scottish Executive guidance, we will review the continued effectiveness of this Regulation through the use of a Review Regulatory Impact Assessment that will be completed within 10 years.

14. Consultation

14.1 The Food Standards Agency held formal consultations on the proposal in January and November 2003. Detailed responses were received from at least 14 organisations in each case. A Stakeholder meeting was held on 9 February 2004 and a further meeting with key interested parties was held in September 2004 to address particular issues of concern and discuss possible solutions. These included the conditions for, and restrictions on, the addition of nutrients which affect alcoholic drinks. Also discussed were the concept of nutrient profiling, and maximum and minimum amounts. All stakeholders welcomed the proposal, and broadly supported the UK negotiating lines, although concerns were expressed about some of the detail - mainly tonic wines and authenticity markers but also the procedure proposed for 'other substances', the 'positive list' of vitamins and minerals, and transition periods - as reflected elsewhere in this RIA (paras. 2.23-4, 2.26-7). Some stakeholders provided specific data to support particular UK issues and consultation continued with key stakeholders on such issues, where necessary.

14.2 After adoption and publication of the Regulation, implementing Regulations and Guidance to compliance, together with a Partial RIA were prepared, and these were subject to Public Consultation from 1 March to 24 May 2007. A final stakeholder meeting was also held 3 May. This consultation focused on the implementation, and responses largely agreed with the approach taken by the Agency. A final revised estimate of costs to enforcement is reflected in this Final RIA.

15. Summary and recommendation

15.1 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 EC 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.

15.2 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 be 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.

15.3 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.

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed: …… Minister of State for Public Health

Date:.....……

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Appendix 1

PUBLIC SERVICES THRESHOLD TEST: REGULATION (EC) No. 1925/2006 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 Coordinators 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[11]
1. 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 £20-50,000, 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.

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

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

Appendix 2

SUMMARY OF COSTS (SECTION 4) AND BENEFITS (SECTION 5)

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.