

NHC Consultation Response Analysis Grid

SI

Respondents	Comment	Response
East of England Trading Standards Authority Ltd	The SI appears to restrict enforcement to the Home Authority only, which is out of step with other food legislation, such as the Food Safety Act, which allows another food authority to use its powers and take prosecutions of businesses outside their area. It is important to retain this ability.	We agree that these Regulations need to be consistent with existing legislation, and that any TSO (not just the Home Authority) should be able to take action and the drafting of the SI does not prevent this.
Foodaware	Article 26 of the EU Regulation allows for labels on foodstuffs to be monitored for compliance purposes; we believe that targeted monitoring would be appropriate for this new Regulation. Some market surveillance is needed to ensure that only approved claims are being used. We would also like to know what action FSA plans to take to inform the public of these changes and the impact it may have on the scientific validity of claims made on foods.	The Regulation allows Member States to require Food Business Operators to notify, by way of an example label, when products bearing claims are placed on the market. This provision is to aid monitoring of the market place and would not be used as an enforcement measure. The Agency did not intend to use these powers and when the consultation was issued, at the open meeting, stakeholders were asked for views on whether or not this provision should have an offence attached to it in the SI. As a result of stakeholder comments this was removed from the SI. If in future the Agency feels this provision would be helpful in monitoring the market place an amendment to the SI would be consulted on.
HFMA Holland and Barrett	SI Reg 3(b) - This states that the competent authorities are the port health and local district food authorities, what action will be taken to ensure consistency in interpretation of this complex legislation? SI 7(1)(b) - As a matter of principle and good sense, the reference to Article 26 should be omitted if there is no intention to invoke the notification procedure. If, in future, such a procedure is viewed as desirable, that view should be open to full debate and challenge.	The Agency is developing guidance to compliance with the Regulation and is working with enforcement bodies to provide as much consistency as possible. As a result of stakeholder comments this was removed from the SI. If in future the Agency feels this provision would be helpful in monitoring the market place an amendment to the SI would be consulted on.
LACORS	No guidance is given to possibly extending transitional periods to cope with genuine trade difficulties (e.g. a lack of imprecision in certain definitions – children’s claims being a case in point) in securing compliance. This is an aspect that LACORS and UK trade associations may need to address in separate enforcement guidance. There needs to be a legal time limit for the production of the evidence to substantiate the claim – including the generic and comparative claims since a compound product containing an ingredient may not meet the requirements for the claim which we assume is 3 weeks?	Transitional periods are set by the EC Regulation and there is not scope to extend these in Agency guidance. Although a time limit would be desirable from an enforcement point of view, the EC Regulation does not set one. To impose a national limit would require making legislation that goes beyond the requirements of the Regulation and therefore ultra vires and unenforceable. It will be for enforcement authorities to take a case by case view of what is a reasonable time to produce the evidence, and once that has elapsed to demand that the company

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	<p>There also needs to be the power to issue suspension notices where the dossier is not available or produced in time, as well as a prohibition notice for non-compliant products. This will prevent the establishment and brand recognition of a product whilst legal argument takes place. If a health claim can be established and recognised by the consumer by its brand its impact in the mind of the consumer will continue long after the claim is legally modified or even discontinued. The onus must always be on the producer to substantiate claims rather than on the enforcement authority to disprove them.</p>	<p>withdraw the product or be prosecuted under regulation 7.</p> <p>The Agency will endeavour to monitor the situation, and if the scenario that LACORS fears becomes a reality, then further action could be contemplated, possibly at the Community level.</p>
Stakeholder Meeting 3 rd May	Stakeholders were asked whether they would be happy for the monitoring offence to be removed from the SI – no opposition to this course of action were received.	As a result of stakeholder comments this was removed from the SI. If in future the Agency feels this provision would be helpful in monitoring the market place an amendment to the SI would be consulted on.

RIA

Respondents	Comment	Response
Ayurvedic Trade Association	<p>Section 4.16: It would be instructive to estimate the costs for both ends and the middle of the range of organisations.</p> <p>Section 4.18: Is there a definition of what constitutes a brand name? I have heard that the German authorities have accepted product names in use before a specified date as equivalent to brand name. If this is correct a parallel treatment in UK would seem appropriate.</p> <p>Section 4.24: The estimated cost of £15000 to produce a dossier for the EFSA would make it very difficult for SMEs to put an innovative product on the market.</p> <p>Section 4.25: We will not be able to supply information on the cost of submitting health claims until we find out how much evidence is required.</p> <p>Section 7.9 (Quality): In the context of herbal food supplements, unless the evidence that supports the claim is derived from exactly the same material to which the claim is applied there will unfortunately not necessarily be any close relation between the two. How the customers will be able to make better judgements in these circumstances is not clear.</p>	<p>It is only possible to estimate costs on information submitted; where we have received or found information we have estimated costs.</p> <p>Article 1 does not define brand names, but the scope appears broad enough for most names thought acceptable under general labelling rules (i.e. must not mislead consumers). It will be for the producer to satisfy enforcement officers that the name was in use before 1 January 2005.</p> <p>Product development would include a judgement of the value of a claim on a product and the return on the product against its development cost.</p> <p>Noted.</p> <p>This does not represent a cost or benefit and therefore it is not possible to reflect it in the RIA.</p> <p>This is either a question of substantiation, in which case the</p>

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	<p>The efficacy of whole herbal ingredients is sensitive to conditions of growth, harvesting, preparation and storage. It may be too much to consider at this stage but value for money and protection for consumers will be much enhanced by somehow making sure that claims are used only for material that warrants it.</p> <p>Section 7.10 (Conclusions): We would like to make the following points first in summary and in expanded form below:</p> <ul style="list-style-type: none"> - Objective health science is still not fully mature, being rather in a developmental phase; recognition is sought that general acceptance of a health claim by objective science can lag far behind observation by practitioners and scientists. - Health science includes objective knowledge but goes far beyond it and because of this, truths of health science may not be well served by a rigorous objective scientific assessment alone. - Ayurveda, a branch of the complete Vedic science, is a time tested, systematic, mature, health science in the fullest sense of the word that has been officially recognised by WHO - In the assessment of health claims it would be wise and, to be really scientific, necessary to take due account of the precepts and insights on health maintenance and development that the major texts of Ayurveda supply. The wide scope of Ayurveda and the test of time provided by it gives great confidence in their validity and utility. <p>Regulation 1924/2006, Whereas (22) calls for the highest possible standard of scientific assessment. We have considerable concerns that the scientists charged with making the assessment may act in a more conservative manner than the legislators intended, putting large numbers of safe and valuable herbal medicinal products out of reach of the public who want them.</p> <p>It is to be hoped that where evidence for a claim is not fully conclusive that conditional claims will be allowed. Otherwise there seems to be a danger that where the evidence is not cut and dried it will be rejected in total, excluding claims that will be very valuable to the consumers even if not generally accepted by objective science for some time to come.</p>	<p>comment above is relevant, or a commercial decision. This is not something that can be reflected in the RIA.</p> <p>Noted.</p> <p>This is an interesting question, but again not fully relevant to this RIA. It is implicit in industry responses that claims are substantiated by science and have a place in the new Regulatory framework. This RIA is looking at the incremental costs of compliance, although it acknowledges the overall benefits</p> <p>These are issues for the authorisation process and are part of the consideration of the evidence by EFSA. It is not possible to reflect these issues in the RIA.</p> <p>This Regulation only controls the claims that can be made on products and would not prohibit safe products from being sold if no claims are made. EFSA will make a risk assessment, and in translating this into a proportionate response in terms of this Regulation, a judgement by risk managers will be necessary. These comments are noted.</p> <p>The prevailing view between Member States and the Commission is that conditional claims are misleading.</p>
BRC	<p>We believe the estimated cost imposed by this piece of legislation has been exceptionally underestimated.</p>	<p>The Agency has looked in detail at the analysis submitted by the BRC and revised the RIA accordingly. There is some new</p>

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	<p>On the specific issue of re-labelling, the £1000 cost per label identified in the draft RIA does not take into account:</p> <ul style="list-style-type: none"> - Cost of compliance – understanding the provisions of the legislation, in terms of man hours. We estimate this cost to be in the region of £3 million per year. - The cost of innovation involved. There may be a need to redesign and reformat labels. The estimation of £2 million accounts for the amount of man hours spent redesigning labels. - Due to very short transitional periods which do not allow stock to be used up, there will be an additional cost for having to get rid of existing labels. Estimated cost is £1 million. - Labels will have to be changed several times over the next five years, since different provisions came into force at different times. - The value of 4000 products bearing a claim dates back to 2003. We believe a figure around 6000 is more accurate. Therefore the total cost would be £6 million for changing labels one time, £12 to £18 million if labels have to be changed an average of two to three times. <p>The Regulation not only requires labels to be changed, but also posters, leaflets, recipe cards, TV adverts and magazines any form of commercial communication. Some retailers will have to review about 20.000 recipe cards bearing claims such as healthy and nutritious. We believe that this cost could be in excess of £10 million.</p> <p>The Regulation will have a negative effect on innovation. Any innovative claim will now need to go through a detailed and lengthy approval process which will strongly compromise innovation.</p> <p>Other cost:</p> <ul style="list-style-type: none"> - Consumer confusions – during the first 5 years of the Regulation coming into force the consumer will see the label of the same product changing up to four times. This will certainly reduce consumer confidence in a 	<p>information here over previous consultation responses and this has been taken into consideration. Timing and use of the transition periods would reduce the number of actions and attendant costs a company might need to take to comply with the Regulations and this has mediated some of the estimates provided here. The revisions to the RIA are mainly in Section 4 on costs, and summarised in the Annex summary of costs.</p>
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<p style="text-align: center;">European Advisory Services</p>	<p>brand. This cost cannot be predicted.</p> <ul style="list-style-type: none"> - Losing certain claims that are currently being made and which can be substantiated, due to lack of support by some member states, will result in vast cost. E.g. Glycemic Index claims, not amending Annex I to incorporate low GI claims, will result in an enormous cost. Cost is estimated at 10 million. - Inability to replicate some government messages in any commercial communication will certainly have an implication on the ability of the consumer to understand and familiarise themselves with the campaigns. - This Regulation provides a high advantage to single ingredient companies which will be in a position to invest time and money to develop the science needed for article 14 and article 13 new data claims. The situation created by the novel foods Regulation, where the company gaining approval sells the licence of their product to other companies for their use, will be replicated for these types of claims. Cost is estimated at 3 million. - Strong limitations in the manner in which writers can express messages related to the healthiness and nutrition balance of foodstuffs in commercial communications such as in store magazines. - The cost of having to take products off the market to reintroduce them, several months later. This will be the case for products bearing claims related to the development and health of children and possibly some nutrition claims if annex I is not amended before the three year transitional period. <p>We believe that a figure in the region of 40-45 million is a more accurate estimate of the cost imposed by this Regulation.</p> <p>We feel that some of the statements on the RIA, such as ‘consumers may choose to substitute away from foods which cannot substantiate health claims to those that can’, are not appropriate. Rules prior to the publication of the Regulation stated that any company using claims should be able to substantiate them; therefore the science has had to be available. If the Agency feels that this has not been the case and</p>	<p>Transition periods have now been provided to minimise this.</p> <p>The RIA has incorporated figures provided in this and other responses into the economic modelling, reflected in the annex to the RIA.</p> <p>This comment is based on advice received about consumer confidence rather than an assessment of how far claims are substantiated.</p>
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	companies were making claims they could not substantiate, it may be a failure on enforcement which is unlikely to be rectified by this Regulation.	
Foodaware	Regarding concerns about the effect of the European Food Safety Authority assessment of the authorisation process and the level of scientific proof which will be required to substantiate particular claims. Foodaware considers that the assessments need to be sufficiently rigorous to command consumer confidence and result in health claims on which the public can rely.	Noted
HFMA Holland and Barrett	<p>General Comments</p> <p>The consultation notes refer to four specific cost categories: we have identified a number of other potential impacts though most are not readily quantifiable.</p> <p>Re-Labeling Costs</p> <p>There are several scenarios under which relabelling will be required:</p> <ul style="list-style-type: none"> • Removal of claims for which application will not be made for whatever reason • For existing health claims for which timely applications will be made, compliance with the mandatory labelling information in Art 10.2 (this is not recognised in the draft RIA) • Compliance with the health relationship and conditions of use of approved claims • Removal of claims for which applications are rejected • Changes to take account of other NHCR stipulations (e.g. Art 11 re endorsements) • Relabelling of stock that remains unsold when relevant transition periods end <p>The cost of relabelling has been variously estimated by HFMA members at between £500-£1200 per label/pack and we dispute that all or most of the required relabelling can be accommodated in the normal course of business. Therefore we estimate the likely relabelling cost to HFMA member companies only at very roughly £1.8 million (say, 300 claims x 3 companies each x £1k per product x 2 changes)</p> <p>Reformulation Costs</p> <p>For food supplements, the average cost of reformulation is estimated at up to £3k. However, we think the number of reformulations will be limited</p> <p>Scientific Dossier Costs</p> <p>There are two types of cost:</p>	<p>The Agency has looked in detail at the analysis submitted by the HFMA and revised the RIA accordingly. There is some new information here over previous consultation responses and this has been taken into consideration. Timing and use of the transition periods would reduce the number of actions and attendant costs a company might need to take to comply with the Regulations and this has mediated some of the estimates provided here. The revisions to the RIA are mainly in Section 4 on costs, and summarised in the Annex summary of costs.</p>

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	<p>Substantiations for Article 13 Claims HFMA and member experience of the preparation of substantiations for Article 13 claims is that each substantiation takes 2-5 person-days depending on the nature of the claim and the experience of the individual involved, and the assistance provided by HFMA experts. The HFMA and its members are themselves likely to justify 40-50 claims which suggests a total cost of up to £100k</p> <p>Cost of preparation will typically range between £10k-£25k with a mean cost of c.£20k per product. The costs of relatively straightforward submissions are estimated as c. £15k. Such costs will further force suppliers to lose sales by discontinuing products for which there is a real, but modest, consumer demand.</p> <p>Submission of Art 13 Claims to the FSA We estimate that submission of claims in the requisite template format may take up to an estimated c.100 person-days (30 mins per application @ 8-hour day) which might cost c. £2k-£3k</p> <p>Cost of Amending Marketing Materials There will be an unknown incremental cost in making ad hoc changes to ads, brochures, websites etc.</p> <p>Cost of Staff/Customer Training This further unknown incremental cost is particularly applicable to marketing, sales & customer service functions</p> <p>Cost of Loss/Dilution of Claims In certain instances, companies will consider the cost of claim substantiation commercially unfeasible and will lose sales or suffer margin erosion as a result of discontinuing claims</p> <p>Cost of Loss of Differentiation The Art 13 List will encourage companies to use claims that they wouldn't otherwise have been in a position to substantiate; this may result in switching of market shares between companies and the erosion of margin resulting from loss of differentiation. This effect would be exacerbated by the deceleration of product innovation that will result from EFSA's proposed delay in receiving Art 13.5. applications (see below)</p> <p>Opportunity Costs Very major potential costs are the opportunity costs caused by:</p>	
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	<ul style="list-style-type: none"> • The stated EFSA approach to 13.5 ('emerging science') claims and their insistence that these will not be reviewed until after January 2010 • Possible EFSA intransigence in reviewing the merits of claims based on 'emerging science' • The increased timelines for product development and getting new products onto the market <p>The UK natural health products industry owes much of its growth to early adoption of products based on 'emerging science' that eventually becomes well-accepted science e.g. wholefoods, probiotics</p> <p>Other Economic Impacts: Positive These include:</p> <p>Elimination of 'rogue competitors' Rigorous enforcement of the NHCR may reduce the number of unsubstantiated claims on the UK market but this is highly sensitive to the success of current efforts to eliminate the use of 'unfair & illegal' claims used by offshore operators, particularly those based in the Channel Islands</p> <p>Enhanced consumer credibility for claims This is a possible benefit but probably far more than offset by the opportunity costs identified above</p> <p>Ability to make claims in other Member States This would seem more credible if the UK already benefited from a notably more liberal regime than in other Member States. But the situation in other countries varies a great deal; for instance, the Benelux countries take a rather more liberal approach to claims for herbal supplements ('botanicals')</p> <p>Ability to make substantiated & approved Disease Risk Reduction Claims Food supplement suppliers might benefit from the use of substantiated claims of this sort if the MHRA accept the validity of such claims!</p> <p>'Ability to charge price premium for products with claims' This is probably easier to conjecture than realise particularly given an overall increase in the prevalence of health claims in the market</p>	
LACORS	<p>With regard to Appendix 1 the range of additional costs is listed as £20-50 000. LACORS considers that the costs will be at the top end of this range. For example £50 000 would equate to 200</p>	<p>These costs have been taken into consideration in Section 8 and the appendices.</p>

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	<p>enforcement authorities taking 10 samples per year with an analytical cost of £25/sample. This may prove to be an underestimate of the true costs and does not take into account the need to access expert sources of advice to clarify the borderlines between permitted and prohibited health claims and between health and medicinal claims.</p>	
<p>Lochaber Beekeepers (Scotland)</p>	<p>The cost burden of analysis of honey is beyond the reasonable level to be expected of a small scale amateur beekeeper. The estimation of sugar content with a refractometer is possible, just, but other contents are so expensive to estimate that only large scale commercial producers could sustain the costs.</p> <p>The complexity of the labelling increases the expense of the label and, with minimum orders of 500 labels, frequent changes to the labels will probably lead to large wastage costs and the need to repeat order.</p> <p>The value of detailed nutritional information to the knowing consumer was doubted, and the value to the “unknowing” consumer of a detailed technical analysis was regarded – given the example of the troubles experienced even with giving useful data with regard to food salt content – with considerable scepticism.</p> <p>The general view seemed to be that the intentions were good but that the ultimate practical value would be small, with a lot of time and money dedicated to a small outcome.</p>	<p>The information here does not contradict that already taken into account for UK industry and has been taken into account in the revised RIA.</p>
<p>Maximuscle</p>	<p>Section 5.4: Complying with the regulation is very costly for SMEs, especially when it comes to putting together dossiers. Maximuscle is concerned about proposals to allow EFSA to charge for authorisation process as this would be a serious disadvantage for the SMEs, especially when the claims that the company submits, can be used by everyone in Europe. We are calling for the UK Government to protect the interests of the SMEs by voting against such measures at the EU level.</p>	<p>The consultation on EFSA charging was conducted by the Commission between November last year and February 2007. Responses are available on the Commission’s website. The UK commented that charges for authorisations should only be made where the company gets a specific individual commercial benefit as a result, and that SMEs should have special consideration (sliding or no fees).</p>

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GUIDANCE FORMAT & FOREWORD

Respondents	Comment	Response
<p>ASDA, Co-operative Group Ayurvedic Trade Association BRC, CRN East of England Trading Standards Association Ltd, LACORS FDF, Federation of Bakers HFMA, Holland and Barrett Lochaber Beekeepers' Association PAGB SWERCOTS Yorkshire and Humberside Trading Standards</p>	<ul style="list-style-type: none"> • General agreement that format is good, particularly Q&A section; better indexing would help. • A web-based, interactive version would be convenient, with facility to ask additional questions. • More flow diagrams would help. • Less jargon and repetition, with links to text of Regulation would clarify the text. • The FSA should look to review the document after a period of time, say 18 months to 2 years. 	<ul style="list-style-type: none"> • The Agency hopes to develop a web-based version – the format was chosen with this in mind. • We have used more flow diagrams and tables where appropriate and reduced repetition. • We cannot provide links to corresponding parts of the Regulation, as we do not control amendment of this and the guidance may become out of date. • We have tried to avoid jargon, but when referring to EU legislation this is not always possible. • We have updated the guidance as necessary, e.g. when the list of health claims is complete, transition periods expire and as case law develops.

GUIDANCE SECTION 1 QUICK BUSINESS GUIDE

Respondents	Comment	Response
<p>ASDA ATC Limited Federation of Bakers BDA, BRC, CRN Co-operative Group FDF HFMA, Holland and Barrett IDFA LACORS, SWERCOTS</p>	<ul style="list-style-type: none"> • The Small business quick guide is not that helpful and would be better converted to an executive summary. • Needs further clarification and interpretation of scope; in particular commercial communication and the prohibitions and exemptions, especially labelling of non pre-packaged foods. • There should be better cohesion between sections and Q&A sections, e.g. on food supplements being out of scope. • This overview refers to parts of the Regulation not yet enacted, e.g. nutrient profiles and health claims; and the references to the Community Register could confuse. • There should be an explanation of the Article 13 process and reference to the template and screening criteria. • Drafting improvements required. 	<ul style="list-style-type: none"> • Agency agrees the need to convert the small business quick guide into an overview and summary. • We have clarified certain key issues, such as commercial communication and prohibitions in Article 12, and exemptions. • In an overview it is not possible to include everything, and the other Sections and the Q&A are there to give more detail. • The Guidance needs to look ahead, but we have tried to clarify where things have yet to come into force (including improving tables on transition periods). • The Agency does not feel this guidance is the place to go into detail on the Article 13 process; details of this are outlined on the web-site in papers relevant to that process. • Have noted the need and acted upon suggestions to improve the drafting of the guidance.

GUIDANCE SECTION 2 SCOPE

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Respondents	Comment	Response
<p>ASA, ASDA, BRC, Brakes Group Co-operative Group, Nutritional Therapy Council UK, CRN East of England Trading Standards Association Ltd, FDF, GSK, IDFA Holland and Barrett, LACORS Maximuscle, Provision Trade Federation VLCD Group, Vitabiotics</p>	<ul style="list-style-type: none"> • Commercial communications needs to be better explained with examples and how labelling, advertising and presentation fits into it, and where nutrition labelling or Article 10 is relevant to control advertising. • Guidance needs to better focus on the target audience, the final consumer, as a limitation to the scope. • Clarification is needed that wholesalers to retailers and producers to health professionals (needs defining) are out of scope. • More clarification needed on the position of PARNUTS – including especially sports foods. • Position of “free from” and common names needs clarifying. • Interaction with other food law (and definitions) should be covered, including diagrams to illustrate. • Examples of what is in and what is out of scope should be given. • The effect of the Regulation on the internet could be more fully explained. 	<ul style="list-style-type: none"> • The Agency has worked up a fully revised section on commercial communications, with examples in the Q&A section. • A new section on the final consumer has been included. • Where possible and within the constraints of the guidance we have sought to clarify who and what type of claims are in and out of scope and given as many examples as possible in the Q&A section. • We have now given a full list of relevant legislation in the text and in a table in the annexes with links to where to access them, plus appropriate Q&As. • We accept the need to illustrate the text with examples and flow diagrams and we have made full use of these. • We have clarified that commercial communications on the internet come into scope. However, control of the internet is a difficult issue and we cannot hope to solve it here. • We have tried to clarify use of ‘free from’, statements about ingredients and common names as far as we can. • We cannot hope to cover all examples or give more refined advice pertinent to specific products; food business operators must open and continue a dialogue with their Home Authority to ensure they comply with the Regulation and satisfy enforcement officials.

GUIDANCE SECTION 3 HOW TO MAKE A CLAIM

Respondents	Comment	Response
<p>ASDA, ASA, ATC Limited, BRC, Co-operative Group, CRN, EAS East of England Trading Standards Association Ltd, FDF GSK, HFMA IDFA, LACORS, PAGB Provision Trade Federation, SWERCOTS</p>	<ul style="list-style-type: none"> • The guidance does not give clear advice on how to make claims during and after the transitional periods. • Clarification is sought on how the claims regulation, in particular nutrient profiles, will work together with new labelling initiatives. • Clarify what is covered in Article 11 on national associations and charity endorsements and if international associations are covered. 	<ul style="list-style-type: none"> • Noted. We have clarified when to comply with this Regulation and pre-existing legislation and the effect of the transition periods. • We have addressed this in the Q&A, and suggest that we continue a dialogue here to encourage those making use of labelling initiatives and ensure compliance with this Regulation. • This guidance does not go into detail for compliance with Article 11 and we will address this with additional guidance in consultation where necessary in 2008.

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<ul style="list-style-type: none"> • Is there a definition of health professionals? • Examples of non-beneficial claims - and therefore out of scope – would be useful. • Would like clarification of condoning excess consumption, and how to decide what of a substance is available to the body. • More is needed on rate and amount of weight loss, covering testimonials and diet programmes. • The link with 90/496, what is a significant amount and the lack of RDAs for a number of substances requires more clarification, to cover portion size and patterns of consumption. • The requirement that claims be in the context of food ready for consumption in line with manufacturers’ instructions requires some clarification given the different instructions manufacturers give. • The interpretation that proof of scientific substantiation is required goes beyond the Regulation; that a claim is on the list in the Community register should be enough. • More guidance is needed on differentiating between nutrition and health claims. 	<ul style="list-style-type: none"> • There is no definition of health professionals in the Regulation and it is not therefore possible to make one in this guidance. • The guidance cannot give exhaustive examples, but attempts to illustrate where possible. We have noted several comments about inappropriate examples and amended as necessary. • Labelling or advertising that condones excess consumption must be dealt with on a case by case basis. Some additional guidance may come out of the Article 13 process. Bioavailability will be linked to the scientific evidence and those making claims should have a good idea of this; we will encourage the Commission to give advice via conditions of use for claims. • In light of comments, we have redrafted the section and Q&A covering rate and amount of weight loss to try to set some limits, but this is an area where enforcement action and case law will be needed for an authoritative interpretation. • The default position for “significant amount” is taken from the nutrition labelling directive and is 15% of the RDA. However, some flexibility is indicated here, as it is in Regulation (EC) 1925/2006 on the addition of vitamins and minerals and certain other substances to foods, where alternative minimum amounts can be set. What is a “significant amount” is likely to be determined by the scientific evidence. As this will have to be judged on a case-by-case basis the Agency is not in a position to offer further clarification in this guidance. This is not a new requirement: under previous legislation foods business operators have had to ensure they do not mislead consumers, which would include there being an adequate amount present in the product to warrant the claim. • We have tried to give some further advice in regard to portion size and pattern of consumption. • Discussion at Commission working group, in relation to dehydrated foods, has suggested that this is interpreted as being about products that could or should not be consumed in any way other than that instructed by the manufacturer. This is reflected in the guidance. • Article 6 requires that food business operators justify the use of the claim. This infers having access to the scientific basis of the claims and being able to show this. We have recast the guidance to reflect this. • The Commission guidance that helps differentiate between these claims is now referenced.
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	<ul style="list-style-type: none"> A number of drafting improvements suggested, including moving text to more appropriate sections and correcting small errors, such as reference to customary names in the Food Labelling regulations. 	<ul style="list-style-type: none"> We have taken on board the many useful comments to improve drafting and recast this and other sections accordingly.
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GUIDANCE SECTION 4 HOW TO MAKE A NUTRITION CLAIM

Respondents	Comment	Response
<p style="text-align: center;">Arla Foods ATC Limited ASDA BRC BSDA East of England Trading Standards Association Ltd FDF GSK HFMA IDFA LACORS, LACORS Provision Trade Federation Seafish</p>	<ul style="list-style-type: none"> Adult reference values for nutritional labelling should not apply when making a claim on children’s produce. Clarification is needed about what is “the same meaning to the consumer” e.g. a list of examples. It is not clear which nutrition labelling format to use; the reference to 90/496 is inadequate here. The conditions in the Annex apply per 100g or 100ml; 90/496 allows labelling per portion – is the same flexibility available for claims? Clarity needed on sugar claims (sugar / sugars). Further clarity needed on application of transition periods, e.g. date when goods with claims are put on the market, application throughout the EU (not just UK), and examples of proofs of this. More is required on how to apply to update the list of nutrition claims. Comparative claims: there were a number of comments about the criteria in the Annex at odds with Article 9; and out of line with criteria in Codex; clarification needed on how to indicate differences when such a declaration would not comply with the conditions in Article 9 or the Annex. One respondent recommended a ‘tick list for compliance’ would be useful. (This comment was also made in relation to Section 5 health claims). 	<ul style="list-style-type: none"> The Regulation references 90/496 which requires adult RDAs. We can not take a contrary interpretation here, but if this creates difficulties can take the problem to the Commission. It would not be appropriate to try to create an exhaustive list of synonyms and could restrict flexibility – this is best left to enforcement. We cannot stipulate which format to use, as the Regulation references 90/496; this is being amended. The Conditions in the Annex must be respected. Where the condition references the ‘significant amount’, some flexibility may be possible and the guidance now explains this. We have tried to make more explicit when to use ‘naturally occurring sugars’ by reference to the ‘sugar free’ condition. We have revised and updated the section and tables explaining transition periods. The guidance makes clear that this is possible and invites food business operators to contact the Agency. Clarification of comparative claims has been considered at length by the Commission and Member States. This culminated in Commission guidance, referenced in this guidance, and we have redrafted key sections in light of this. There is an intention to align conditions with those of Codex. We have included this. (For both nutrition and health claims)

GUIDANCE SECTION 5 HOW TO MAKE A HEALTH CLAIM

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Respondents	Comment	Response
<p>ATC Limited ASDA BNF BRC BSDA CRN East of England Trading Standards Association Ltd, FDF Food Additives and Ingredients Association HFMA Holland and Barrett GSK IDFA International Council on Amino Acid Science LACORS Maximuscle PAGB Provision Trade Federation Vitabiotics VLCD Industry Group</p>	<ul style="list-style-type: none"> • Several respondents commented that the guidance does not do enough to explain the difference between types of health claim. • The need for a definition of generally accepted scientific evidence and what levels of science required was a recurrent comment. • Advice of wording of health claims was sought (a list of acceptable words). • Further guidance was sought on required labelling when making a health claim, particularly in relation to Articles 5 and 10. One comment was that this should be explicit in the Community Register, as part of the conditions of use, together with warning statements. It should also be made clear that this is not always relevant for all products, e.g. PARNUTS. • Comments noted that the guidance does not give any advice on the question of tolerances. • Several comments noted that there was lack of advice about disease risk claims, particularly type of risk factor. • There were numerous comments about claims referring to children's health and development, including about a transition period, distinction with Article 13 (growth and development) claims, and products aimed at children. • More guidance was required on products vs. diets and medication and diets. • The provisions about proprietary claims were thought not to be presented as well as they could. How these claims would be kept exclusive and transition periods were unclear. • Some respondents thought it unclear how the Article 13 list would be updated and how (and when) the Article 13.5 process would work. • There was concern expressed about the EFSA guidelines and requests for examples of how to submit A13.5 and 14 claims. 	<ul style="list-style-type: none"> • We have tried to explain the types of claim and the routes for authorisation, as these distinctions are relevant for the transition periods. But otherwise, for compliance with the Regulation, a detailed explanation is not required. • The Regulation does not define generally accepted scientific evidence, so it is not possible to provide a definition – this would go beyond guidance on compliance. EFSA will assess the claims and has now published guidance on the Article 14 process. This indicates levels of acceptable science. • There is nothing in the Regulation and no advice from the Commission on this, so it is not possible to devise something for the guidance. • The guidance will be amended to try to clarify these requirements. The guidance cannot determine how the Community Register will be formatted, but these comments may be useful in discussions with the Commission. Particular products cannot be excluded from labelling requirements, although in some cases they only apply “where appropriate”. • The question of tolerances is to be considered in the revision of food labelling and the amendment of 90/496 and this is the place to pursue this. • The guidance is more about compliance with authorised claims, whereas this addresses the route for authorisation. The guidance now gives more on this, not least through cross-reference to the Commission guidance where this is discussed fully. • The guidance now echoes – and cross references – the Commission guidance where this is dealt with. Claims and product ranges are separate, the latter can feature Article 13 claims except when exclusive to children. • Statements about diets may be health claims and the guidance tries to point to where borderlines might be. On interaction with medication, warning statements are required (Article 10); but if the claims infer replacing medicines, this could be seen as a medicinal claim and the guidance cannot provide for case by case assessment. • The guidance now has a revised part on transition periods. How these claims will be kept separate from more generic claims is not clear; we can bring this up with the Commission at the appropriate time. • This has now been clarified in the guidance (EFSA has conceded the need to consider A13.5 claims). • This is not the purpose of the Agency guidance. EFSA guidelines are now available. • This has been clarified in the guidance.

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	<ul style="list-style-type: none"> • Clarification was requested about the status of Article 13 claims excluded from the list – what transition is available. • There were a number of comments and requests about the UK process for the Article 13 list. 	<ul style="list-style-type: none"> • These have been noted, but this guidance is not the place to deal with these concerns.

GUIDANCE SECTION 6 TRANSITION PERIODS

Respondents	Comment	Response
Angel Technology Ltd, ASDA, BRC British Meat Processors Association BNF, Co-operative Group, CRN, EAS, FDF, GSK, HFMA, Holland and Barrett Maximuscle, Seafish VLCD Industry Group Vitabiotics	<ul style="list-style-type: none"> • Some respondents thought that the references to transition periods throughout the guidance were not efficiently collected all in one place here. Specific Q&As would be useful, as would <u>one</u> summary table. • Respondents felt that references to application of rules were unclear as to whether it was the claim or the product that was at stake. • Some commented that there was lack of clarity about the status of claims during the EFSA validation. • There were comments about the lack of clarity around the need to meet a qualifying date to trigger some transition periods. • Comments about the status of claims referring to children's development and health were repeated here. 	<ul style="list-style-type: none"> • It is necessary to refer to transition periods in context, but the guidance does now summarise them all in one place and in one table. Suitable Q&As are provided. • The Regulation uses language more appropriate to products and the claim must be on a product, but we have now clarified that the Regulation controls the claim rather than the product. • This is now clarified in the guidance. In addition, the UK list of candidate health claims is published on the Agency web-site to aid transparency. • This has now been redrafted to be clearer. • This is covered above. In addition a transition period now exists and is explained in the guidance.

GUIDANCE SECTION 7 ENFORCEMENT

Respondents	Comment	Response
ASDA, ASA, BRC, East of England Trading Standards Association Ltd, FDF LACORS	<ul style="list-style-type: none"> • One comment indicated that enforcement bodies and their codes of practice were not properly represented. • Detail about Home Authority principle not needed here. • Additional points were raised about time limits for production of evidence, lack of technical expertise among enforcement officers and powers to issue suspension notices whilst collecting evidence. 	<ul style="list-style-type: none"> • The text has been redrafted for accuracy. • The term is used several times, so an explanation is given. • These issues go beyond the competence of this guidance.

GUIDANCE SECTION 8 QUESTIONS AND ANSWERS

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Respondents	Comment	Response
Angel Technology Ltd, ASDA, ATC Limited, Brakes Group BRC, British Meat Processors Association, BNF, Co-operative Group CRN, EAS, FDF, Federation of Bakers GSK, HFMA, HJ Heinz Group, Holland and Barrett, International Council on Amino Acid Science, LACORS Margaret Anderson Assocs, Maximuscle, PAGB, Seafish, SWERCOTS, Tesco Stores Ltd VLCD Industry Group, Vitabiotics	<p><i>Respondents had detailed comments on all questions in this section. We have highlighted and summarised those points not otherwise covered in the above summary comments.</i></p> <ul style="list-style-type: none"> • Some respondents disagreed with interpretations here (e.g. status of ‘antioxidants’). • Some additional questions were suggested following earlier comments about the need for greater clarification or a corresponding Q&A. • Q&A about allergenic claims needed to clarify these. • Q&A about scope of nutrition claims and highlighting of ingredients. • Q&A about commercial communication. • Q&A about claims referring to recommendations of health professionals. • Q&A about weight loss. • Q&A about significant amount • Q&A about “diet”. • Q&A about comparative claims. • Clarification around ‘without prejudice to PARNUTS’ • Advice on the method of analysis for fibre. 	<p><i>Where we could add examples or otherwise illustrate points, as requested by many respondents, we have done so in the Q&A section, in many cases using questions posed by respondents.</i></p> <ul style="list-style-type: none"> • Where possible we have revised interpretations, giving as much detail as we can without going beyond the Regulation. In some cases this means we must await case law. On antioxidants, we are guided by the Commission. • The Agency has included as many additional questions as possible. • Noted, and the guidance now includes such a reference. • The corresponding requests have been met in the Q&A section and where possible the views of respondents have informed the text. • This is covered in the section on scope and references the Commission guidance that explains this. • This is still under consideration by the European Commission and it is not possible to give further advice in this guidance at this time.

GUIDANCE SECTION APPENDICES

Respondents	Comment	Response
ASA, BRC, BNF, BSDA, CRN, East of England Trading Standards Association Ltd, HFMA, Holland and Barrett, LACORS, PAGB Seafish, SWERCOTS,	<ul style="list-style-type: none"> • Some did not find the summary guide to regulation useful, but on balance most did, but with improvements. • Most thought the reference to JHCI could now be deleted. 	<ul style="list-style-type: none"> • Summary has been revised and references to JHCI deleted.

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GUIDANCE STAKEHOLDER MEETING / OTHER COMMENTS

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Respondents	Comment	Response
<p>NHC consultation meeting attendees, ASDA, BNF, BSDA, ATC Limited, Co-operative Group, CRN, East Ayrshire Council (SCOTLAND), FDF, Federation of Bakers, GSK, HFMA, Holland and Barrett, PAGB, Seafish, Yorkshire and Humberside Trading Standards</p>	<ul style="list-style-type: none"> • There were some additional comments about the detail of certain nutrition claims, such as “no added sugars”, “energy reduced”, and which of the liquid/solid conditions should apply to certain foods. • More detailed definitions were requested for a number of points. 	<ul style="list-style-type: none"> • The revised guidance tries to deal with these points. • It is not possible to add definitions where none exist in the Regulation. Where possible interpretations have been made, but the foreword warns that the guidance cannot be authoritative here.