

Summary of responses to consultation on:
Draft Guidance on Allergen Control and Consumer Information
England & Wales

Consultation issued: 06 September 2005

Consultation ended: 06 December 2005

Reference No: NAT 146

Questions asked in the Consultation:

1. Should the guidance be voluntary, or should some form of statutory control be introduced, and if so, what form should it take?
2. Should the guidance apply only to the allergens previously associated with this type of advisory labelling (peanuts, tree nuts, and seeds, such as sesame) or should it be more widely applicable? If so, how much more widely should it be applied? Should it apply to all the allergens covered by the statutory labelling requirements for allergenic food ingredients or only part of the list?
3. Are the phrases suggested to convey possible allergen cross-contamination appropriate? Do you have preference for wording that uses the phrases "May contain" or "Not suitable for"? Should the wording indicate that the allergen cross-contamination is likely to be present only on some occasions?
4. What are your views on the suggestion for the development of a single 'allergen symbol' to help consumers locate allergen labelling information?
5. What would be the impact if this guidance remains voluntary, and what would be the impact of any statutory form of control? Does the partial RIA accurately reflect the cost implications for food businesses and are there any other implications for consumers, enforcement officers and businesses which should be taken into account?

Responses are listed alphabetically according to stakeholder group, with groups appearing in the order: members of the public, consumer organisations, SMEs, large retailers and manufacturers, and local authorities.

Please note that specific editing suggestions have not been listed in this summary of responses, but are being considered.

	Name/Organisation	Comments	Agency response
Members of the public			
1.	Toby Anderson, Member of public (and member of Coeliac UK)	<p>Q1. Legal requirements are necessary to ensure labelling guidelines are correctly implemented. Voluntary guidance not strong enough to ensure that consumers are certain that food is safe. Supports option 4, to press EU to implement legislation.</p> <p>Q2. Guidance should cover all the 12 allergens.</p> <p>Q4. A single allergen-alert symbol is not useful. It would be annoying and possibly alarming to see a general allergen alert to a food.</p> <ul style="list-style-type: none"> • Should always include an allergen box on the label even if no allergen ingredients, i.e. box stating none, as quicker and easier to check one box rather than list of ingredients. • Should state 'possible gluten cross-contamination' if some may have occurred. • If quoting "gluten free" the label should include the definition, i.e. no measurable amounts of gluten, less than 200ppm gluten, or less than 20ppm gluten. • Thinks some coeliacs may be reacting to Sweeteners/flavourings derived from gluten-grain, these should have reference to gluten-grain origin on the label. 	<ul style="list-style-type: none"> • The guidance will be introduced on a voluntary basis, but the approach developed will be fed into the impending EU review of food labelling so that it may inform future deliberations. • The idea of a single allergen alert symbol will not be taken forward, as it was generally considered to be confusing and unhelpful. • The FSA advises people to always check the ingredients list, rather than relying on an allergen box which may or may not be present. • Noted. • There is no legal definition of gluten-free at present. Agency-funded research on gluten thresholds is currently underway to address this issue. • Additives derived from allergenic ingredients, including gluten-containing cereals, have to be declared on the label under Directive 2003/89/EC.
2	Danny McKillop, Member of public (Consultant at Unilever)	<p>Q2. Guidance should cover all the 12 allergens.</p> <p>Q3. Standard "may contain" wording would make labels simpler whilst a graduated risk label would give consumers more information. Single "may contain" label is clearest; "ingredient Y may contain X" puts too much responsibility on the consumer.</p> <p>Q4. Supports a single allergen-alert symbol. Would need to be compulsory since absence of symbol might imply the product was allergen-free.</p> <ul style="list-style-type: none"> • Risk assessment and prevention of contamination should be stressed. Cleaning carries risk of failure and testing methods are unreliable, so emphasis should always be on design and layout of equipment. 	<ul style="list-style-type: none"> • Noted. • Comments on phrases noted. Phrases to convey possible contamination will be considered further by the drafting group. • The idea of a single allergen alert symbol will not be taken forward, as it was generally considered to be confusing and unhelpful. • Comments noted – this will be covered in the guidance.
3	Member of public	Q1. Guidance should be statutory. Would raise awareness of the issue.	<ul style="list-style-type: none"> • The guidance will be introduced on a voluntary basis, but the approach developed will be fed into the impending EU review of food

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		<p>Q3. Advisory labels confusing. Use wording 'May contain'.</p> <p>Q4. Doesn't like an allergen symbol, words best.</p> <ul style="list-style-type: none"> • Allergy advice should be on front of pack. • Wants FSA to incorporate statutory guidelines on labelling of products from outside UK, e.g. Holland. • Important for manufacturers, handlers and supermarkets to be aware of accurate labelling and advice in store. • Labels should have allergen box with a set font size, to be easily read. Should be minimum font 12 and on front of pack where possible. 	<p>labelling so that it may inform future deliberations.</p> <ul style="list-style-type: none"> • Comments on phrases noted. Phrases to convey possible contamination will be considered further by the drafting group. • The idea of a single allergen alert symbol will not be taken forward, as it was generally considered to be confusing and unhelpful. • Noted. • Laws on labelling are harmonised throughout the EU. This best practice guidance would be directed at all those selling prepacked foods in the UK – regardless of where the product is actually made. • Noted. • The FSA advises people to always check the ingredients list, rather than relying on an allergen box which may or may not be present.
4.	<p><i>Gill Ward,</i> Member of public (stress counsellor)</p>	<p>Q3. Manufacturers should have flexibility on the wording of allergen labels.</p> <ul style="list-style-type: none"> • Manufacturers should label important information in larger print as often difficult to read and increase the size of relevant nutritional information. 	<ul style="list-style-type: none"> • Consumer research, conducted on behalf of the Agency by the Anaphylaxis Campaign, into advisory labelling suggests that wording should be as simple as possible. Consumers find a variety of phrases confusing. • This is covered in the guidance.
Consumer organisations			
5	<p><i>Michelle Berriedale-Johnson,</i> Allergy Alliance</p>	<p>Q1. Favours the option of voluntary guidance whilst pressing the EU to introduce legislation. Legislation should ensure consistency of message and enforcement although voluntary guidance will improve the current situation.</p> <p>Q2. Apply to all 12 allergens.</p> <p>Q3. Prefer "may contain" as it removes the decision-making responsibility.</p>	<ul style="list-style-type: none"> • The guidance will be introduced on a voluntary basis, but the approach developed will be fed into the impending EU review of food labelling so that it may inform future deliberations. • Comments on phrases noted. Phrases to convey possible contamination will be considered

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		<p>Q4. Against symbols as can be confusing. List ingredients clearly to allow consumers to make own decision.</p> <p>Q5. Cannot comment on cost implications, although if GMP and HACCP already in place, shouldn't be that many extra costs involved.</p>	<p>further by the drafting group.</p> <ul style="list-style-type: none"> The idea of a single allergen alert symbol will not be taken forward, as it was generally considered to be confusing and unhelpful. The FSA will need to complete a full Regulatory Impact Assessment (RIA) which will identify both costs and benefits.
6	Anaphylaxis Campaign	<p>Q2. Sensible to extend guidance beyond peanut and tree nuts.</p> <p>Q3. Statements should be as simple as possible. "May contain X" is best, do not favour more complicated "ingredient Y may contain traces of X" only need to know there's a risk. Should not use "sometimes" in statements. Statements such as "made in a factory that also handles X" are confusing, should be kept simple.</p> <ul style="list-style-type: none"> Final document should emphasise eliminating or minimising risk of cross-contamination. "May contain" labels should not be regarded as a permanent state of affairs. Discourage use of allergen boxes, should look at ingredients list. Boxes are quick fixes and often incomplete. Use up space that ingredients list could take up in larger font and often complicate labelling. Recipe changes should be indicated clearly, preferably on the front of the pack. Encourage food manufacturers and retailers to provide information to Anaphylaxis Campaign to communicate to members. Should not add possible cross-contaminating allergens to ingredients list. 	<ul style="list-style-type: none"> The guidance will be directed towards those allergens on the statutory EU list (Directive 2003/89/EC) for consistency and because allergens other than tree nuts and peanuts are known to cause severe reactions. Comments on phrases noted. Phrases to convey possible contamination will be considered further by the drafting group. The guidance will stress the importance of only using advisory labelling after a thorough risk assessment has been completed. The FSA advises consumers to always check the ingredients list, rather than relying on an allergen box which may or may not be present. Comments noted – this is covered in the guidance. Agreed. As best practice. possible cross-contaminating allergens should not be added to the ingredients list as this causes confusion about what is an ingredient and what is unintentionally present
7.	Sarah Sleet, Coeliac UK	Q1. Statutory control, otherwise credibility in doubt under voluntary system.	<ul style="list-style-type: none"> The guidance will be introduced on a voluntary basis, but the approach developed will be fed into the

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		<p>Q4. Support single allergen alert box to help customers. However, allergen alert symbol is difficult issue. Already have well-recognised and international “crossed grain” symbol.</p> <ul style="list-style-type: none"> • Appendix III. Include specific mention of Méndez methodology for gluten testing. • Need to invest in education for manufacturers about the issues. 	<p>impending EU review of food labelling so that it may inform future deliberations.</p> <ul style="list-style-type: none"> • The idea of a single allergen alert symbol will not be taken forward, as it was generally considered to be confusing and unhelpful. • Methodology section has been revised. • The Agency is working with the food industry to raise awareness of food allergy/intolerance concerns.
8	Community group	<p>Q1.Guidance should be regulated to be consistent.</p> <p>Q2.Want to extend regulations to include certain pulses, mushrooms and tomatoes.</p> <p>Q3.Prefer the wording “may contain”. Should never use “allergen free”, prefer “free from X”.</p> <p>Q4. Use recognisable typeface for advisory warnings rather than allergen symbol, carried through in ingredients list. Font size 10 or higher, Ariel font recommended by RNIB. Tone and colour contrasts also important.</p> <ul style="list-style-type: none"> • Useful to specify the type of nuts - would stop blanket avoidance. • Should mention staff handling. • Threshold levels of food allergens dangerous because of variation of susceptibility. Mention of 3-4 shrimps is too high. 	<ul style="list-style-type: none"> • The guidance will be introduced on a voluntary basis, but the approach developed will be fed into the impending EU review of food labelling so that it may inform future deliberations. • At present it is intended that the guidance will be directed towards those allergens on the statutory EU list (Directive 2003/89/EC) for consistency. However, if these are amended, the guidance will be amended accordingly. • Comments on phrases noted. Phrases to convey possible contamination will be considered further by the drafting group. • Noted. • Noted. • Staff handling is covered in the guidance. • Mention of 3-4 shrimps removed.
9	Pat Portnoi, Dietician for the Galactosaemia Support Group (GSG)	<p>Q1.Supports use of voluntary guidance followed by statutory control at later date. EU wide.</p>	<ul style="list-style-type: none"> • The guidance will be introduced on a voluntary basis, but the approach developed will be fed into the impending EU review of food labelling so that it may inform future deliberations.

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		<p>Q3.Would be helpful if all companies used the same wording. Phrase of choice “may contain traces of x”. Thinks it’s important to use the word “trace” as otherwise people may think it contains a lot of the allergen and thus restrict their diet. Does not like “not suitable for”.</p> <p>Q4.A single allergen symbol would be useful to highlight where people should look and for those that cannot read or who do not speak English.</p>	<ul style="list-style-type: none"> • Comments on phrases noted. Phrases to convey possible contamination will be considered further by the drafting group. • The idea of a single allergen alert symbol will not be taken forward, as it was generally considered to be confusing and unhelpful.
10.	National Council of Women of GB	<p>Q1.Support statutory regulation - guidance more accepted if statutory requirement and therefore offer more protection. Legal back up essential to substantiate false claims.</p> <p>Q2.12 allergens should be included.</p> <p>Q3.“May contain” now familiar phrase.</p> <p>Q4.Welcome a single allergen symbol if clearly visible and consistent location.</p> <p>Q5.What information is available to assess the cost to Health service and businesses of serious reactions? Time off work, pharmaceuticals etc, from less severe reaction cannot be accurately quantified.</p>	<ul style="list-style-type: none"> • The guidance will be introduced on a voluntary basis, but the approach developed will be fed into the impending EU review of food labelling so that it may inform future deliberations. • The idea of a single allergen alert symbol will not be taken forward, it was generally considered to be confusing and unhelpful. • Benefits, as well as costs, will be identified in the RIA as far as is possible.
SMEs			
11.	<i>Peter Davidson, Dailycer Ltd</i>	<p>Q3.Prefers statements such as “produced in a factory that handles x” and “due to the method of manufacture, this product may contain traces of X”, as provide a graded risk.</p> <ul style="list-style-type: none"> • Consultation does not take into account the different types of food producers. Small businesses have fewer resources for assessments. • Small businesses need flexible process and packaging operations as handling a large number of products and ingredients. Rather than assessing the risk of cross-contamination they would be assessing the degree of the risk; therefore according to the guidance, all products would need “may contain” labelling. 	<ul style="list-style-type: none"> • Comments on phrases noted. Phrases to convey possible contamination will be considered further by the drafting group. • SMEs have been consulted throughout the drafting of this guidance. A simplified version of the guidance will also be produced for small businesses. • The guidance will stress that advisory labelling should only be used after a thorough risk assessment has been completed to avoid blanket labelling.
12.	<i>Nisha Amin, ISP Europe</i>	No specific comments.	
13.	Small business	Improved clarity is good for consumer choice. No other comments.	
14.	<i>Prof. Keith</i>	No specific comments.	

	Name/Organisation	Comments	Agency response
	Anderson, Ventress.		
Large retailers and manufacturers			
15.	Cristina Ramsey, Allied Technical Centre (ATC) on behalf of Associated British Foods plc.	<p>Q1.Favour voluntary guidelines as enable flexibility for allergen management, yet provide good practice guidelines to food businesses.</p> <p>Q2.All 12 allergens should be included, however factors such as allergen severity and prevalence should be considered in order for appropriate actions to be taken.</p> <p>Q3.Both statements serve the intended purpose.</p> <ul style="list-style-type: none"> • To determine Allergen Critical Control points in HACCP is difficult as no thresholds for allergens have been defined, and reliable testing methodology is not yet available. • 1.2 mentions that large companies should refer to sector specific guidance, however no reference is made on where such guidance can be found. • Simplify information on food allergen legislation on pg.8 to help SME. • Suggest minimum of 8-font point as 10 not always possible. • Appendix I table of allergens – should include reference to amount of foodstuff needed to be consumed to trigger reaction. • Appendix III. Dislike use of “non-detectable level in decision tree, as no thresholds identified and methodology under development, so non-detectable is not fixed. • Pg.36 allergen testing methods should give advice on limitations of testing. Not many laboratories have a scope of accreditation that covers allergen analysis. 	<ul style="list-style-type: none"> • Agreed. • Agreed. • Agreed. The guidance will discuss the current lack of thresholds. • Reference to sector-specific guidance has been removed. • Information on legislation has been amended. • Specific reference to minimum font size has been removed. • Thresholds required to provoke allergic reactions in sensitive individuals have yet to be established. However, the Agency will issue a call for research to address this issue in March 2006. The guidance will discuss the current lack of thresholds. • Decision tree re-written. • Methodology section re-written.
16.	Janette Macpherson, Biscuit Cake Chocolate & Confectionery Association (BCCCA)	<p>Q1.Guidance should be voluntary. As such it could be more readily amended. Considers that risk assessment is already covered by existing legislation, therefore additional statutory control unnecessary.</p> <p>Q2.Advisory labelling should apply to all 12 allergens.</p> <p>Q3.Manufacturers should be able to choose their own wording. Agree warnings should be easily visible and legible but don't want size minimum of 10, due to small pack sizes and limited space. Don't like “not suitable” for – consumers should decide for themselves what is suitable. Flexibility needed in wording of labels and font size to minimise costs.</p>	<ul style="list-style-type: none"> • Consumer research, conducted on behalf of the Agency by the Anaphylaxis Campaign, into advisory labelling suggests that wording should be as simple as possible. Consumers find a variety of phrases confusing. Specific reference to minimum font size has been removed, although the

	Name/Organisation	Comments	Agency response
		<p>Q4.Concerned about allergen symbol, would be one on almost all the BCCCA's products so of no real benefit to consumer.</p>	<p>reference to Clear Labelling Guidance remains.</p> <ul style="list-style-type: none"> The idea of a single allergen alert symbol will not be taken forward, it was generally considered to be confusing and unhelpful.
17.	<p><i>Andrea Martinez-Inchausti,</i> BRC</p>	<p>Q3.Would like explanation as to why wording reverted back to “may contain”. Is this based on consumer research? Think that “Ingredient Y contains traces of X” complicates. Suggested statements in section 5.3 may preclude a number of valid alternative options for indicating cross-contamination risk. Each business should be able to use the phrase they believe appropriate provided it is clear, otherwise too restrictive. Suggest replacing two suggested phrases (paragraphs 3 and 4) with sentence specifying that a clear and comprehensive phrase should be used to inform the consumer of the possible presence of an allergen due to cross-contamination. Specific phrases may be suggested as examples. Phrases such as “not suitable for” should not be ruled out, as some retailers have identified that consumers like to see this on labels.</p> <ul style="list-style-type: none"> Feels current wording of guidance would lead to blanket use of “may contain” warnings, since ingredient suppliers would not guarantee absence of allergens. Generally difficult to carry out a risk assessment of possible cross contamination of the growing, harvesting and transport of raw products. How might this be practically achieved? Need to separate legislation from guidance. Reference to the General Food Law article 19 suggests that trace presence of allergens could trigger a recall, this is straying from guidance into interpretation. Particularly unhappy with ‘Unintentional presence’ section of Appendix II (p.31/top p.32) regarding a product being “defective” and the manufacturer being “negligent” if a product has allergen cross contamination. This advice will lead to defensive labelling. Material on allergen risk assessment or allergen ranking has been omitted or diluted. Including a common risk management approach in the guidance, and a common decision on whether to use ‘may contain’ labelling based on allergen ranking, would help retailers and achieve consistency for consumers. Strongly support allergen ranking into high, medium and low risk, with peanuts, nuts, sesame, fish and shellfish (and lupin) in high-risk group, milk and egg in medium risk group and sulphites, gluten, wheat, soya, celery and mustard in low risk group. Ranking based on the likely form of the allergen, severity of the reaction to the allergen, incidence in the UK population, possible source of cross-contamination, action taken to prevent it and estimation of possible quantity in final product. If there is the possibility of a high-risk allergen being present in foods, at levels likely to be clinically significant, a ‘may contain’ label should be added to the product. Labelling would not be required for the allergens in the low risk group provided GMP and HACCP are employed. Egg and milk have been used extensively in the industry, mainly in liquid and powder form, and advisory labelling 	<ul style="list-style-type: none"> Consumer research, conducted on behalf of the Agency by the Anaphylaxis Campaign, into advisory labelling suggests that wording should be as simple as possible. Consumers find a variety of phrases confusing. The meaning of “May contain X” was understood by the majority of consumers. More practical advice regarding the sourcing of raw materials will be added to this section. Comments noted. Information on legislation has been amended. Risk management section re-written. More examples included to help retailers decide whether advisory labelling is necessary. This will be considered further, although it is questionable whether the 12 allergens can be ranked since the least common allergen can still provoke severe symptoms in sensitive individuals. However, the guidance will highlight the need for a risk-based judgement and list the factors (including how common adverse reactions are to that particular food) to be considered

	Name/Organisation	Comments	Agency response
		<p>has not been applied in the past. Evidence suggests that this has not resulted in unacceptable risk to consumers. Labelling would only be required in exceptional circumstances with clinically significant levels of cross contamination.</p> <ul style="list-style-type: none"> • A consistent and effective risk management process can only be achieved with allergen threshold data. • Inconsistency between guidance and previous labelling guidance, regarding pine nuts and chestnuts. • Indication of recipe changes may not always be practical and highlighting a new ingredient may make the product unattractive to consumers. Consumers have the responsibility to always check the ingredients list and, where present, the allergy box. • Should not specify font size. Font 10 is preferable but not always possible. Don't want packaging to be regarded as non-compliance if not of font 10, although is clearly legible. 	<p>for each allergen.</p> <ul style="list-style-type: none"> • Thresholds required to provoke allergic reactions in sensitive individuals have yet to be established. However, the Agency will issue a call for research to address this issue in March 2006. The guidance will discuss the current lack of thresholds. • Wording amended, now consistent with the labelling guidance. • Agree that allergic consumers do owe themselves a particular duty of care to scrutinise food labels more closely than an average consumer does. • Specific reference to minimum font size has been removed, although the reference to Clear Labelling Guidance remains.
18.	<i>Julian Cooper, British Sugar</i>	<p>Q1.Favour voluntary guidance as it enables flexibility whilst providing best practice guidelines. Q2.Advisory labelling should extend to all twelve allergens. Q3.Both statements serve the intended purpose of informing the allergic consumer.</p> <ul style="list-style-type: none"> ▪ Difficult to determine allergen critical control points in a HACCP system, as thresholds for allergens have not yet been defined and reliable allergen testing methodology is not yet available. Appendix III use of term "non-detectable level" unrealistic because of this. Table in Annex I should also include reference to amount of foodstuff that needs to be consumed to trigger reactions. • P.36 allergen testing methods should give advice on limitations of testing. • 2.1 includes a list of common food allergens in the UK, but should include all 12 listed in the EU legislation also, otherwise others may not be considered. • Simplify information on food allergen legislation on pg.8 to help SME. • Font 10 would be the ideal font size, however suggest minimum of 8-font point as 10 not always possible. 	<ul style="list-style-type: none"> • Thresholds required to provoke allergic reactions in sensitive individuals have yet to be established. However, the Agency will issue a call for research to address this issue in March 2006. The guidance will discuss the current lack of thresholds. • Methodology section re-written. • List amended to include all 12. • Information on legislation has been amended. • Specific reference to minimum font size has been removed.
19.	<i>Ruma Tamuli, CMi</i>	<p>Q1.Guidance should be voluntary. Voluntary guidance would set best practice. Statutory control could lead to confusion and red tape, and could cause blanket "may contain"</p>	<ul style="list-style-type: none"> • Noted.

	Name/Organisation	Comments	Agency response
		<p>labelling.</p> <p>Q2.Guidance should apply to 12 allergens. Could also include kiwi and lupin if they become declarable.</p> <p>Q3.Suggested phrases: “may contain (traces of) X” and “ingredient Y may contain (traces of) X” are suitable. “May contain” more practicable than “not suitable for” phrase. Not advisable to indicate that cross-contamination is likely only on some occasions as impracticable to manufacturers and confusing to consumers.</p> <p>Q4.Allergen symbol is better than text as simpler to use by the consumer and takes up less space for the manufacturer.</p>	<ul style="list-style-type: none"> • At present it is intended that the guidance will be directed towards those allergens on the statutory EU list (Directive 2003/89/EC) for consistency. However, if these are amended, the guidance will be amended accordingly. • Comments on phrases noted. Phrases to convey possible contamination will be considered further by the drafting group. • The idea of a single allergen alert symbol will not be taken forward, it was generally considered to be confusing and unhelpful.
20.	Co-operative Group	<p>Q.3. Co-op uses warning such as “made in a factory handling X”. Concerns about the use of “may contain” statements, why does the FSA suggest changing back to use of “may contain”? If advice is to use “may contain” then “ingredient Y may contain traces of X” complicates the message.</p> <ul style="list-style-type: none"> • Inconsistency advice for tree nuts in the Appendix I table with that in the labelling guidance (Section 12.9), which mentions chestnuts and pine nuts for allergen labelling, whereas this document suggests these should not be considered for cross-contamination labelling. 	<ul style="list-style-type: none"> • Consumer research, conducted on behalf of the Agency by the Anaphylaxis Campaign, into advisory labelling suggests that wording should be as simple as possible. Consumers find a variety of phrases confusing. The meaning of “May contain X” was understood by the majority of consumers. • Reference to pine nuts and chestnuts changed so as to be consistent with allergen labelling guidance (Section 12.9).
21.	<i>Michael Hunt, FDF</i>	<p>Q1.Voluntary, as needs to be flexible, proportionate and risk-based. Legal text would be inflexible and over-burden SMEs.</p> <p>Q2.Applicable to all 12 allergens but should embody a risk-based approach to take account of factors such as allergen severity and prevalence.</p> <p>Q3.Does not support use of “not suitable for”. Simpler and briefer expressions better as consistent wording.</p> <p>Q4.Does not support development of symbol unless at EU level and symbol use should remain voluntary, in addition to ingredients list.</p> <p>Q5.Not envisaged to have a substantial cost impact.</p>	<ul style="list-style-type: none"> • Noted. • Agreed. • Comments on phrases noted. Phrases to convey possible contamination will be considered further by the drafting group. • The idea of a single allergen alert symbol will not be taken forward, it was generally considered to be confusing and unhelpful.

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		<ul style="list-style-type: none"> • Guidance must be subject to regular review due to rapid development in this area. • 2.3 Remove soya from list of foods that can trigger anaphylactic reactions as not so potent as the other allergens in this list, and table states “anaphylactic reactions occur rarely”. • 3.5 Make clear the legal requirement of labelling 12 allergens in ingredients list, as distinction from voluntary use of allergen box. • 5.2 FDF questions the value of positive claims, and does not wish guidance to create enforcement expectations for the use of such expressions as “now contains”. • Does not wish to promote use of allergy panels because of consequences if absence of panel is taken to imply absence of allergens. Also, a consumer allergic to a food not in EU 12 list might assume that all allergens have been considered, such that any others not included in the box are absent. • Use of advisory labelling where justified on the basis of a risk assessment should be stressed throughout the document. Suggested inclusion in first paragraph of section 1.1 and in section 3.5. • Does not believe that it was the consensus view of stakeholders that certain phrases should be used, but that simple wording should be used. • 5.3 If considering the species of nut, account must be taken of the potential of cross-contamination with other nut species. • Free from. Should re-word to reflect that current Codex Standard for gluten-free foods does not include reference to levels of gluten in foods but is based on nitrogen content of the cereal grains, and that Codex levels are still only proposals. • Appendix 1. Need to ensure that wording does not suggest to SMEs to discount completely all but the most severe allergens, for example “3 or 4 medium sized shrimps” what about 1 or 2, or smaller fragments? Clarify high, mid and low mg ranges. • Appendix II. Should be a clear distinction between legal requirements and guidance. Reference to General Food Law regulation (178/2002) article 14 suggests that trace 	<ul style="list-style-type: none"> • If the allergens on the statutory EU list (Directive 2003/89/EC) are amended, the guidance will be amended accordingly. • Soya removed from list. • Noted and amended. • Comments noted. • Noted. The FSA advises people to always check the ingredients list, rather than relying on an allergen box which may or may not be present. • Agreed. The guidance will stress the importance of only using advisory labelling after a thorough risk assessment has been completed, throughout the document. • Consumer research, conducted on behalf of the Agency by the Anaphylaxis Campaign, into advisory labelling suggests that wording should be as simple as possible. Consumers find a variety of phrases confusing. The meaning of “May contain X” was understood by the majority of consumers. • Noted. • Text on Codex standard amended. • Reaction levels and reference to 3-4 shrimps removed from table. • Comments noted. Information on legislation has been amended.

	Name/Organisation	Comments	Agency response
		<p>presence of allergens could be dangerous such as to trigger a recall, and as such is straying from guidance into interpretation.</p> <ul style="list-style-type: none"> • Consider a Trade Descriptions Act offence in respect of untrue “allergen free” claims. • Use of “may contain” labels in UK may create barriers to trade with countries that do not accept its use. • Appendix III. Recommends development of an agreed approach to quantifying risk to be used in conjunction with decision tree. As such, need action level data for allergenic foods, as otherwise difficult to determine when to use advisory labelling and difficult for enforcement. Also difficult to say “non-detectable” without such levels. • Allergen testing methods section should be set in the context of cleaning assessment. Does not give advice on limitations of testing and considerations regarding its use. SMEs are unlikely to have laboratories or contract out expensive work and might tend to rely on swabbing and use of test kits. Should make clear that testing is a selective monitoring operation and does not give yes/no answer on allergen presence. Tests should not be thought of as simple mechanisms to decide whether or not to use precautionary labelling. Concerned by positive commendation of ATPase test, shouldn’t recommend particular tests but give advice on principles and limitations of each. • Use of “cross-contamination”, some prefer “cross contact” because of impression of undesirable “contaminants”, suggested definition of term mentions the contaminant is not unwholesome but may be problematic for those with particular allergies. 	<ul style="list-style-type: none"> • Legislation already exists covering misleading labelling (Food Safety Act 1990). • Noted. • Thresholds required to provoke allergic reactions in sensitive individuals have yet to be established. However, the Agency will issue a call for research to address this issue in March 2006. The guidance will discuss the current lack of thresholds. Appendix III re-written. • Methodology section has been revised. • Noted. The term “cross-contamination” will be defined in the glossary and mentions that the contaminant itself is not unwholesome.
22	Foodaware: the Consumers’ Food Group	<p>Q1.Encourage voluntary labelling in interim, but seek statutory requirements that can be enforced EU wide.</p> <p>Q2.All 12. Not necessary for fruit and veg. to be included. Producers should be advised where they can get up to date information on new and emerging allergens.</p>	<ul style="list-style-type: none"> • The guidance will be introduced on a voluntary basis, but the approach developed will be fed into the impending EU review of food labelling so that it may inform future deliberations. • The guidance will be directed towards those allergens on the statutory EU list (Directive 2003/89/EC) for consistency. However, if these are amended on the basis of new scientific information, then the guidance will

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		<p>Q3.“May contain” considered confusing by consumers. Prefer statements such as “does not contain X” or “contains Y”.</p> <p>Q4.Members support the use of a single allergen alert symbol, like the crossed grain for gluten-free.</p> <p>Q5.Want more emphasis on the application of guidance within catering sector, especially school meals, and therefore encourage public sector bodies to support the guidance. FSA need to report whether manufacturers take guidance into account.</p> <ul style="list-style-type: none"> Want the FSA to improve understanding of the causes, the foods affected and actions that might prevent further increases in food allergies. 	<p>be amended accordingly. Information of food allergens can be found on our website: www.food.gov.uk, and on the EFSA website: http://www.efsa.eu.int/</p> <ul style="list-style-type: none"> Comments on phrases noted. Phrases to convey possible contamination will be considered further by the drafting group. The idea of a single allergen alert symbol will not be taken forward, it was generally considered to be confusing and unhelpful. The FSA is currently working on separate guidance on the provision of allergen information for loose foods, including food in cafes/restaurants, and school meals. The Agency’s food allergy and intolerance research programme investigates the causes and mechanisms underlying food allergy.
23	Food supplier	<p>Q2.Not all allergens present the same risk. Have cross-contamination incidents involved allergens other than peanuts, tree nuts and sesame? Guidelines should be restricted to these 3 well-documented cases, until greater clarity on the number of cases for other 9. If decide to include all 12 allergens, then firmer and clearer guidance on the level of control appropriate to each is needed. Want 12 allergens ranked based on relative risks of each allergen and the level of control appropriate for each, to provide practical advice to industry.</p> <p>Q3.Do not like either phrase. Need concise and easily understood wording. Suggest both, so</p>	<ul style="list-style-type: none"> The guidance will be directed towards those allergens on the statutory EU list (Directive 2003/89/EC) because allergens other than tree nuts and peanuts are known to cause severe reactions. It is questionable whether the 12 allergens can be ranked since the least common allergen can still provoke severe symptoms in sensitive individuals. However, the guidance will highlight the need for a risk-based judgement and list the factors (including how common adverse reactions are to that particular food) to be considered for each allergen.

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		<p>that “Ingredient Y may contain X” explains why a product “may contain X”. Need agreed definition as to the precise meaning of each statement.</p> <p>Q5. Industry already put cost and effort into complying with new legislation. Burdensome if “may contain” labelling was also a legislative requirement for all 12 allergens.</p> <ul style="list-style-type: none"> • Guidance in this area desperately needed by industry for consistent approach and understanding. • Examples refer mainly to nuts. If guidance is to address all 12 allergens then need wider range of examples. • Terminology of threshold doses in mg not helpful. Useful if document explained how test results, often given in ppm, could be converted to mg in final portion size. • Threshold data for fish and shellfish seem high – several prawns or a gram of fish. 	<ul style="list-style-type: none"> • Comments on phrases noted. Phrases to convey possible contamination will be considered further by the drafting group. • Noted. Wider range of examples will be included. • Noted. Table of allergens has been amended. • Noted – mention of 3-4 shrimps and grams of fish removed.
24.	Infant and Dietetic Foods Association (IDFA)	<ul style="list-style-type: none"> • Suggest new wording regarding gluten-free foods, emphasising that the Codex standard of 200ppm is based on the nitrogen content of the cereal grains and is only a draft proposal. Should clarify that proposed levels are 20ppm for foods made of cereals which are naturally free from gluten, 200ppm for foods rendered gluten-free, and 200ppm for products made of a combination of both. • The wording on pg.20 “in the absence of formally validated methods of analysis” is misleading, since the R5 ELISA antibody method of gluten detection has been temporarily endorsed (type 1). The level of 20ppm is the lowest level in which there is confidence in measurements using R5 ELISA. 	<ul style="list-style-type: none"> • Noted. Wording has been amended • Noted. Sentence included on this method.
25.	<i>Peter Berry Ottaway, IFST</i>	<p>Q1. Not appropriate to introduce specific legal sanctions for non-compliance of guidelines as risk-assessment and food safety in general already enforced. Unfeasible to introduce statutory controls on the use of “may contain” labelling since unable to quantify what is “safe” in respect of the trace presence of allergens. However local authority could take action if no HACCP-based allergen management scheme is in place. Products falsely labelled “free from” should be liable for enforcement.</p> <p>Q2. Apply to all 12 allergens and to any other allergens, which may potentially be present, as chosen by the business.</p> <p>Q3. Phrase should be prominent and in consistent location. Phrase should be concise and precise. Wording should be flexible.</p> <p>Q4. Considers it unnecessary to develop a symbol, lack of understanding of meaning.</p>	<ul style="list-style-type: none"> • Noted. Legislation already exists covering misleading labelling (Food Safety Act 1990). • Agreed. • Consumer research, conducted on behalf of the Agency by the Anaphylaxis Campaign, into advisory labelling suggests that wording should be as simple as possible. Consumers find a variety of phrases confusing. The meaning of “May contain X” was understood by the majority of consumers. • The idea of a single allergen alert

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		<p>Ingredients list most important, all allergen information should appear adjacent to ingredients list. Encourages use of box with “contains” and “may contain” allergens next to ingredients list.</p> <p>Q5.No comments on financial implications.</p> <ul style="list-style-type: none"> The new EU labelling legislation should extend to labelling of cross-contamination. Businesses need to be made aware of the potential seriousness of the presence of allergens, with authorities giving guidance to businesses on “may contain” labelling use. 	<p>symbol will not be taken forward, it was generally considered to be confusing and unhelpful. The FSA advises people to always check the ingredients list, rather than relying on an allergen box which may or may not be present.</p> <ul style="list-style-type: none"> The approach developed from this document will be fed into the impending EU review of food labelling so that it may inform future deliberations. The Agency is working with the food industry to raise awareness of food allergy/intolerance concerns.
26.	Chris Dabner, National Association of Master Bakers	<p>Q1.Voluntary best practice. Recommend readers to read and apply the guidance, but no legal requirement and not enforceable. Appendix II unhelpful in this regard as implies legal responsibility, which could cause businesses to adopt precautionary approach.</p> <p>Q2.To deal with all 12 allergens risks diluting the message. Emphasis should be on the allergens that cause the most problems in terms of instances and severity of reactions, i.e. peanuts, tree nuts, seeds such as sesame. Suggest allergen ranking.</p> <p>Q3.Phrases less important than there being a clear and understanding rationale behind their use. What is considered the “best phrase” keeps changing!</p> <p>Q4.Allergen symbol totally impractical. Will override the concept of trying to apply a risk-based approach and to rank the allergens. Consumers will just shop on the basis of the symbol, and not buy the product irrespective of whether the symbol indicates the presence of celery or peanut. Needs to be agreed by the EU, otherwise food from the EU without the symbol may be assumed to be safe.</p> <p>Q5.The RIA does not reflect the cost, as it contains no costings. If a business wishes to carry out a risk assessment this will take: the number of lines they produce, the number of ingredients they use, the number of suppliers they use, etc. and a considerable amount of time. Then if decide to alter production process: involves product reformulation, source</p>	<ul style="list-style-type: none"> Information on legislation has been amended. The guidance will be directed towards those allergens on the statutory EU list (Directive 2003/89/EC). It is questionable whether the 12 allergens can be ranked since the least common allergen can still provoke severe symptoms in sensitive individuals. However, the guidance will highlight the need for a risk-based judgement and list the factors (including how common adverse reactions are to that particular food) to be considered for each allergen. The idea of a single allergen alert symbol will not be taken forward, it was generally considered to be confusing and unhelpful. Comments noted. The FSA will need to complete a full Regulatory Impact Assessment (RIA) which will give further details of

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		<p>different ingredients, find new suppliers, which in turn require writing new recipes, documents and procedures, and carrying out training etc. this will take more time and considerable costs. To validate allergen control plans involves expensive test kits.</p> <ul style="list-style-type: none"> • Clarify that applies only to pre-packed foods. Misleading as document gives impression that the new allergen labelling legislation applies to all foods, rather than only pre-packed foods, should be clearly stated. • States that guidance is intended for SMEs but no SMEs in acknowledgements. Lack of involvement? SMEs do not have the technical resources, ability to generate documents and procedures, management and training that large companies have. • Majority of members would not carry out factory trials or consumer testing of new products. Several recommendations in Manufacturing section (section 4) are impractical or impossible for small bakeries. • The craft baking industry has a unique problem with respect to allergenic ingredients, due to use of many of 12 allergens (gluten, milk, egg, soya, sesame, tree nuts, and possibly peanuts, mustard and celery). If not deliberate ingredients real risk of contamination. Craft bakeries produce a wide range of different products everyday with short production runs, with products made and sold that day. Common to have several different products prepared at same time and in close proximity, not possible to have physical segregation. • Argue that rather than reformulation, i.e. to remove soya flour, it is safer to have soya clearly declared as an ingredient due to risk of cross-contamination. • Mention that pine nuts, chestnut and coconut are not covered by the legislation, by mentioning them suggest that they can cause an allergic reaction and need to be considered. 	<p>anticipated costs.</p> <ul style="list-style-type: none"> • Noted. Text will be added stating that this guidance (and the legislation) only applies to pre-packed foods. • SMEs have been consulted throughout the drafting of this guidance. A simplified version of the guidance will also be produced for small businesses. • Comments noted. • Comments noted. The guidance recognises it may not be possible to have physical segregation in these circumstances. But it may be possible to segregate by time and guidance will cover this. • As best practice, should avoid adding possible cross-contaminating allergens to ingredients list as this causes confusion about what is an ingredient and what is unintentionally present. • These foods have been reported to cause allergic reactions in certain sensitive individuals. However wording has been changed so as to be consistent with allergen labelling guidance (section 12.9).
27.	Nestle UK Ltd.	<ul style="list-style-type: none"> • Appendix 1 –the inclusion of severity of reaction information and frequency may be misleading to SMEs and lead to inappropriate risk management decisions. For example, saying 3-4 medium shrimps is sufficient to trigger a severe reaction may lead to the idea that one shrimp in a finished product by cross contact is not a problem. • Would like FSA to investigate if the Merchant Shipping Act would apply to products supplied at sea, since food supplied to airlines is covered by the Warsaw Convention. 	<ul style="list-style-type: none"> • Reaction levels and reference to 3-4 shrimps removed from table. • Prepacked food sold by airlines or at sea is subject to usual labelling requirements in so far as within the

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		<ul style="list-style-type: none"> P.36 testing methods, ATPase test non-specific, tap water has background ATP contamination, could show presence of microorganisms, residual food or potential allergens. Allergens are not homogeneously distributed along the production line so negative swab in one place may not be reflection of entire area. 	<p>jurisdiction. Meals (catering) sold on airlines or at sea are classified as loose foods. There are currently no allergen labelling rules that apply to foods sold loose, such as in catering establishments.</p> <ul style="list-style-type: none"> Comments noted. Methodology section has been re-written.
28.	Diana Axby, Provision Trade Federation (PTF)	<ul style="list-style-type: none"> Many retailers have already adopted allergen policies; FSA guidance will only be of value if all parties agree to adopt the approach contained in the guidance. Does not take into account risk status of the allergens, so some recommendations such as reformulation are unreasonable for less hazardous foodstuffs. Welcomes the risk-based approach to warning statements as experienced overuse of “may contain” labels when risk is actually very small. Wants revision of the wording “sample products containing the major food allergens should not be distributed indiscriminately or offered where unsupervised children can take them”. This could have severe implications for shops offering tasting trays and samples. Appreciates the need to control sampling of products containing nuts, but not for dairy products, as milk allergics would be aware of milk content. More clarity on risk assessment of raw materials, especially if supplier in third country. 	<ul style="list-style-type: none"> Comments noted. The guidance will highlight the need for a risk-based judgement and list the factors (including how common adverse reactions are to that particular food) to be considered for each allergen. Wording amended. Comments noted.
29.	John Mayes, Waitrose	<p>Q5.Keep advisory labelling as simple as possible, like “may contain traces of x”. Unnecessary to state possible contamination of individual ingredients or other ingredients used on site.</p> <ul style="list-style-type: none"> It would be useful to provide guidance on the levels of allergens in finished products that require advisory labelling. Where advisory labelling is used, the manufacturer should hold evidence of the possible source of cross contamination (which allergen), action taken to prevent the cross contamination, and the risk assessment of the product. The mention of manufacturer negligence in Annex II will encourage defensive labelling. Interested to know how to practically achieve risk assessment of cross contamination of growing, harvesting and transport of products. 	<ul style="list-style-type: none"> Comments on phrases noted. Phrases to convey possible contamination will be considered further by the drafting group. Thresholds required to provoke allergic reactions in sensitive individuals have yet to be established. However, the Agency will issue a call for research to address this issue in March 2006. The guidance will discuss the current lack of thresholds. Information on legislation has been amended. More practical advice regarding the sourcing of raw materials will be

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		<ul style="list-style-type: none"> Doesn't think it possible to enforce minimum font size, but allergen labelling should be of same font size as ingredients list and easily visible. 	<p>added.</p> <ul style="list-style-type: none"> Specific reference to minimum font size has been removed, although the reference to Clear Labelling Guidance remains.
Local Authorities			
30.	<i>Les Bailey,</i> LACORS	<p>Q1.Guidance should be voluntary, as legal sanctions already exist under 178/2002/EC and Food Safety Act 1990.</p> <p>Q2.Guidance should apply to full list of 12 allergens.</p> <p>Q3.Prefer "may contain" to "not suitable for".</p> <p>Q4.Allergen symbol not needed as majority of manufacturers use allergen box, which is clearly understandable.</p> <p>Q5.Guidance will be of value to industry and enforcers. Enforcement costs are unlikely to increase significantly.</p> <ul style="list-style-type: none"> Unsure that EHOs and TSOs would be able to offer advice on appropriate testing methods. Would like clarification on use of ATPase as an indicator. 	<ul style="list-style-type: none"> The FSA advises people to always check the ingredients list, rather than relying on an allergen box which may or may not be present. Comments noted. Methodology section re-written.