

PARTIAL REGULATORY IMPACT ASSESSMENT

(Please note this document will be revised according to comments received)

1. Title of Proposal

- 1.1 **Guidance on Allergen Control and Consumer Information** - Best Practice Guidance on Controlling Food Allergens with Particular Reference to Avoiding Cross-Contamination and Using Appropriate Advisory Labelling (e.g. covering 'may contain' labelling).
- 1.2 The colloquial title of the guidance is "'May contain' Guidance' however it will be referred to throughout this RIA as 'this Guidance'.

2. Purpose and Intended Effect

(i) Objective

- 2.1 The objective of this Guidance is both to provide best practice guidance on handling allergens and to recommend appropriate labelling for cross-contamination with allergens. It should be noted that this guidance has no statutory force.
- 2.2 Industry representatives, in collaboration with consumer support organisations, approached the Food Standards Agency to ask the Agency to produce a comprehensive document on allergen advisory labelling. Various sectors of the industry had issued their own advice on handling either nuts or allergens more generally but it was thought that a comprehensive, overarching document with government backing would provide guidance for industry on the approach to take to the control of allergens in food production.
- 2.3 It was decided that this Guidance should also provide best practice advice on ways of reducing/eliminating allergen cross-contamination and providing appropriate labelling information (for example, "may contain" labelling). The information will also be useful for enforcement bodies that inspect and advise food producers and retailers; the Local Authorities Co-ordinators of Regulatory Services (LACORS) were part of the stakeholder group that helped produce the draft guidance.
- 2.4 The intended effect of this Guidance will be to reduce the unnecessary use of such warning labels giving allergic consumers greater choice when selecting pre-packed foods whilst also ensuring that where such warnings are used, consumers understand the risk involved.

- 2.5 The Board of the Food Standards Agency is committed to protecting consumers by improving food safety and by giving honest, clear information. A key aim set out in the Agency's Strategic Plan for 2005-10 is to enable consumers to make informed choices. For those consumers with food allergies and food intolerances, it is vital that they are fully informed about the nature and content of the foods they are buying.
- 2.6 The European Union has competence in the area of food labelling and has indicated that allergen advisory labelling could be considered within its proposed review of food labelling laws announced in 2004. Therefore, the UK would not want to legislate in this area at this time. However, by developing voluntary guidance now, the UK will be in a position to influence EU discussions in the future.
- 2.7 This Guidance will apply across the UK, but a separate RIA will be produced in Scotland.

(ii) Background

- 2.8 Food allergy and food intolerance are both types of food sensitivity. When someone has a food allergy, his or her immune system reacts to a particular food as if it were a threat and if someone has a severe food allergy, this can cause a life-threatening reaction. Food intolerance does not involve the immune system and is generally not life-threatening. However, if someone eats a food they are intolerant to, this could make them feel ill or affect their long-term health.
- 2.9 Approximately 1-2% of the adult population in the UK and about 5-8% of children have a true food allergy, which equates to about 1.5 million people. The symptoms of an allergic reaction can vary and the reactions can be more or less severe on different occasions. Most allergic reactions to food are relatively mild; however, sometimes they can be very serious, even life threatening, and this is known as anaphylaxis or anaphylactic shock. When someone has an anaphylactic reaction they can have symptoms in different parts of the body at the same time, including rashes, swelling of the lips and throat, difficulty breathing and a rapid fall in blood pressure and loss of consciousness.
- 2.10 As some individuals can react to just a few milligrams of the food they are sensitive to, cross-contamination needs to be reduced/eliminated where possible or, if this cannot be achieved, the individual needs to be informed of the risk. The avoidance of low-level presence of allergens due to cross-contamination is particularly relevant for those allergenic foods which are more likely to have life-threatening consequences when present at very low levels in foods and those which affect a higher proportion of those with allergies.
- 2.11 Coeliac disease (also known as gluten intolerance) is an auto-immune disease, which means the body's immune system attacks itself. In this

condition, gluten (a protein found in cereals such as wheat, rye and barley) triggers a process resulting in destruction of the lining of part of the intestine. This can lead to malabsorption and other health consequences. The type of reaction it causes is different to a food allergy and it does not cause anaphylaxis. Many people with coeliac disease are undiagnosed. Until recently, coeliac disease was thought to affect about one in 1,500 people in the UK. However, evidence published in February 2004 suggests that about 1 in 100 have the condition.

- 2.12 The Food and Drink Federation have already produced their own guidance in this area and both the British Retail Consortium and the Institute of Grocery Distribution have produced voluntary guidance on handling nuts. However, industry considered it would be preferable if there was a single document to ensure a consistent approach to handling allergens.
- 2.13 People shopping for those with food allergies and intolerances need clear specific labelling of both deliberate allergenic ingredients and possible cross-contamination in order to be able to make informed food choices. The presence of an undeclared, unintended allergen in food destined for consumption is potentially life threatening. However modern processing methods mean that foods not intended to contain a particular allergenic ingredient may be produced in the same factory or even on the same production line, as one containing that ingredient.
- 2.14 At the end of 1997, the Ministry of Agriculture, Fisheries and Food wrote to food manufacturers and retailers, asking them to improve their quality control measures and manufacturing processes so as to avoid the use of 'defensive' or 'may contain' labelling'. Some companies already had measures in place to minimise nut trace contamination and had introduced food labels such as 'May Contain Nuts' to warn consumers of the possible presence of nuts in the product. However, since that time, the use of these warning labels on food products has increased. This may have been a consequence of foods becoming more complex, or in response to the increasing incidence of food allergy in the UK population and therefore to increasing consumer demand for allergen information.
- 2.15 The Food Labelling (Amendment) (England) (No. 2) Regulations 2004 are now in place. Equivalent Regulations apply in Scotland, Wales and Northern Ireland¹. These Regulations implement Directive 2003/89/EC of the European Parliament and the Council, dated 10 November 2003, amending Directive 2000/13/EC. The rules aim to ensure that consumers are properly informed about the nature and substance of the foods they buy and are protected from false or misleading descriptions. They also aim to ensure that industry has a clear regulatory framework, which does not restrict product innovation, or inhibit the free movement of goods within the EU.

¹ The Food Labelling (Amendment) (England) (No.2) Regulations 2004 - SI2004/2824; The Food Labelling (Amendment) (No.2) (Scotland) Regulations 2004 - SI2004/472; The Food Labelling (Amendment) (No.2) (Wales) Regulations 2004- SI2004/3022 (W.261) and The Food Labelling (Amendment No.2) Regulations (Northern Ireland) - SR 2004 No.469.

- 2.16 This legislation does not cover allergenic foods that may be present unintentionally as a result of cross-contamination at some point during the manufacture or transportation of the food. Therefore, there is a need for suitable guidance on when it is appropriate to use advisory labelling and what it actually means.
- 2.17 In 2002 the Food Standards Agency published the results of two separate pieces of consumer facing research^{2,3}. Both reports highlighted consumer concern about the overuse of “may contain’ labels and the lack of clarity of those labels then in use. It was apparent from the reports that some consumers preferred to be presented with the facts about manufacturing conditions in order to make their own judgements. The reports were also critical of the amount of time it takes to find such labels, their legibility and on the variety of warnings in use. Consumers found the various phrases confusing as they assumed they indicated a hierarchy of risk.
- 2.18 Whilst it is helpful for those with severe food allergies to be alerted to such possible allergen cross-contamination, there is general agreement between the food industry, consumers and enforcement bodies that excessive use of these food allergen warning labels not only restricts consumer choice but also devalues the impact of warnings. These stakeholders are also concerned that the variability between different food manufacturers and retailers in relation to the way in which they convey information about possible allergen cross contamination leads to consumer confusion.
- 2.19 At the end of 2003 the Agency consulted stakeholders on two forms of warning label which would alert consumers to the possible presence of three allergens. The results of this consultation were inconclusive. However, many of the respondents felt that any officially sanctioned guidance on the use of warning labelling should include, as a pre-requisite, guidance on how to handle allergens and how to make judgements on the need to give warning information. Such guidance would lead to better management of allergen cross-contamination, and could lead to a reduced need for such labels.
- 2.20 In June 2004 the Food Standards Agency issued consultations on the Food Labelling (Amendment) (England) (No. 2) Regulations 2004 and equivalent Scotland, Wales and Northern Ireland Regulations. As part of this consultation respondents were asked for their comments on ‘may contain’ labelling and a number of respondents commented on the need for better control of this form of labelling.

² Nut Allergy Labelling – Report of Research into the Consumer Response published by the Food Standards Agency in December 2002 FSA/0726/1202

³ May Contain’ Labelling – The Consumer’s Perspective published by the Food Standards Agency in May 2002 FSA/0582/0502

(iii) Rationale for Government Intervention

- 2.21 The main drivers for developing this guidance have been:
- The pressure from consumers to have a consistent approach to the allergen information on the labels of pre-packed foods, to enable them make informed choices about the foods they buy;
 - The range of phrases/wording currently being used has led to consumer confusion and mistrust of such labelling;
 - The lack of authoritative advice and consistent practice has also meant that industry has been confused, leading to inconsistent decisions being taken on when to label; and
 - The industry desire to produce allergen information, which is helpful to consumers.
- 2.22 The effects of doing nothing in this instance would be that the food industry would not receive the help they had asked for to develop a logical, uniform approach to allergen labelling and the current unsatisfactory situation would continue. In addition, in response to the increasing consumer demand for allergen information, large companies would be likely to impose their own allergen control systems on their suppliers further back along the food chain. This would lead to an increase in the variability of the systems in use across the food industry, which would further increase consumer confusion.
- 2.23 In addition, consumers would continue to be increasingly confused about the meaning of some allergen labelling and through their ignorance, take a chance with the result that their next meal might, at best make them ill, or at worst, kill them. Also, some consumers would continue to assume that the predominance of allergen labelling is simply a case of the manufacturers 'covering themselves' against being sued and ignore them.
- 2.24 This situation has evolved over the last decade and the number of allergen warning labels continues to increase. The number of consumers affected by food allergy and food intolerance also continues to grow and therefore the number of consumers requiring help in understanding the meaning of allergen warning labels continues to grow.
- 2.25 Doing nothing at this point would not be a responsible position to take.

(iv) Risks to industry of increased burden in terms of more hazard control measures and costs of labelling

- 2.26 The Food Labelling (Amendment) (England) (No. 2) Regulations 2004 and the equivalent Regulations that apply in Scotland, Wales and Northern Ireland, require manufacturers to provide information on deliberate ingredients. These Regulations do not cover the unintentional presence of those allergens in pre-packed foods that can result from cross-contamination with the allergen during the manufacture or transport of the food. However, many of the larger food manufacturers, retailers and food service companies already have established traceability arrangements, primarily in order to reduce business

risk. In addition, the EU General Food Law Regulation which came into force on 1 January 2005, introduced a broad non-prescriptive traceability requirement. Furthermore, many manufacturers already operate both Hazard Analysis and Critical Control Point (HACCP) and Good Manufacturing Practice (GMP) systems. It would not be difficult for many manufacturers to build on these three systems to control relevant food allergens and therefore there would be little, or no, increase in the burden to much of the food industry in terms of the implementation of allergen control procedures.

- 2.27 As it is proposed that this Guidance should be voluntary, any label changes can be worked into existing label change cycles, thereby further reducing any costs to manufacturers. In addition, by having the procedures from the guidelines in place to routinely check on manufacturing operations, such an overall “health check” would find any weaknesses in the system, enabling corrective actions to be taken. A key benefit of auditing the system in this way would be to provide evidence of due diligence in managing allergens and also reduce the likelihood of having to execute a product recall due to inaccurate allergen labelling. These potential savings would help offset any slight increase in control and labelling burden.

3. Consultation

(i) Working Group/Stakeholders

- 3.1 In 2001/2002 the Food Standards Agency carried out two separate pieces of consumer facing research projects. Both projects highlighted consumer concern about the overuse of allergen warning labels (‘may contain’ labels) and the lack of clarity of those labels then in use. The reports claimed that when such labelling was first introduced it was considered responsible and helpful to allergic consumers, but as the range and number of products labelled in this way increased, consumers questioned whether the food suppliers were using them defensively to protect themselves.
- 3.2 The research has shown that many allergic consumers openly declare that they disregard ‘may contain’ labelling as they do not believe that such a huge proportion of food products on sale may put their lives at risk, and many are cynical about the reasons behind their use.

(ii) Consultation on Wording

- 3.3 During 2004 the Agency consulted consumers about their preferences for the phrases ‘Not suitable for peanut/nut/sesame allergic consumers’ and ‘Not suitable for people with peanut/nut/sesame allergy’. 33% (England) and 14% (Scotland) of the respondents were consumers. 63% (England) and 75% (Scotland) of the responses from consumers preferred the second statement and one respondent was happy with either phrase (2% for England and 3% for Scotland).
- 3.4 The major points made by respondents were:
- generally in favour,

- the longer phrases should not be used as an excuse to decrease print size (plus other comments on the need to maintain overall labelling clarity),
- phrases should be allergen-specific,
- did not like the phrases using 'not suitable for...',
- there is need for risk assessment and guidance,
- one respondent suggested the hospitality industry could adapt the second phrase for use on menus,
- a few suggestions were made on the use of symbols to help children in particular, and also including a braille version,
- supplementary advice on 'free-from' was needed,
- advice on labelling of vegetable oil would be helpful.

(iii) Consultation on of the Food Labelling (Amendment) (No.2) Regulations 2004

- 3.5 Between June and September 2004 over 1000 interested parties UK-wide were consulted during the implementation of The Food Labelling (Amendment) (England) (No.2) Regulations 2004 and the equivalent Regulations for Scotland, Wales and Northern Ireland. A number of respondents commented on the need for better control of the use of 'may contain' labelling. For example, one respondent said "If a product genuinely 'may contain' an allergen then this should be stated together with the reason and expected levels of the allergen." A summary of responses to the England consultation is available at:
<http://www.food.gov.uk/multimedia/pdfs/allergenresponsesengland.pdf>.
 A summary of responses to the Wales consultation is available at:
<http://www.food.gov.uk/multimedia/pdfs/allergens.pdf>

(iv) Stakeholder Drafting Group

- 3.6 The Food Standards Agency convened a working group of stakeholders to draft voluntary guidance on the use of allergen labelling. Organisations involved in the drafting of this document included:

Anaphylaxis Campaign
 British Retail Consortium
 Cullinane Associates Ltd
 Food and Drink Federation
 Hallmark Analytical Ventures Ltd
 H J Heinz Co Ltd
 Institute of Grocery Distribution,
 LACORS
 Marks & Spencer plc
 Somerfield Stores Ltd
 Unilever UK.

4. Options

4.1 There are four options to be considered, these are:

1. Do nothing
2. Produce new national legislation covering allergen advisory information.
3. Produce voluntary best practice guidance.
4. Produce voluntary best practice guidance and press for EU legislation.

Option 1 – Do nothing

4.2 If the Government decided not to act, consumers with food allergies and food intolerances would continue to be confused and ill informed about the risks posed by the food they buy. In addition, a significant number of costly product recalls due to mislabelling and accidental cross-contamination would continue to happen each year, and also, further proliferation of the use of such labels would mean that consumer choice would become even more restricted. Those allergic consumers who choose to disregard allergen advisory information labelling, or simply do not understand its meaning, risk their lives by consuming these foods.

Option 2 - Produce new national legislation covering allergen advisory information labelling

4.3 Food labelling legislation is harmonised at an EU level and currently does not address the issue of allergen advisory labelling. However, the European Commission is currently reviewing all food labelling legislation and could include this area, but this will take at least 5 years. It is difficult for the UK to introduce national measures in an area of EU competence. Any statutory provisions at this time could impose extra burdens on UK businesses compared with the rest of the EU and also create barriers to trade. It would be difficult to go straight to national legislation at this time because, if UK were to take unilateral action now, this may mean two changes for businesses.

Option 3 - Produce voluntary best practice guidance

4.4 The production of a single document would be helpful to consumers and would provide much needed guidance for industry on when to label and what form of words to use. It would encourage a consistent approach by industry and provide a standard to be referred to by local authorities taking enforcement action. Consumers would receive superior information on which to base an informed decision about the foods they purchase.

Option 4 - Produce voluntary best practice guidance and press the EU to take action to implement legislation

4.5 Producing voluntary guidance for the UK industry to work towards now, whilst pressing the EU to introduce action as part of the EU review of food labelling in this area, will encompass all the benefits in option 3 and ensure a level

European playing field. It would also allow the UK to influence any future negotiations on EU scheme based on experience gained here.

4.6 Option 4 is our preferred option.

5. Costs and Benefits

(i) Sectors and Groups Affected

5.1 The business sectors affected will be food manufacturers and retailers where businesses sell prepacked foods and those manufacturers supplying prepacked foods for catering establishments.

5.2 The guidance should also help enforcement authorities to identify and address misleading labelling.

5.3 Allergic consumers should find more consistent and transparent labelling practices, providing them with a greater choice.

(ii) Racial Equality

5.4 The Food Standards Agency does not consider that adoption of this voluntary guidance will have any impact on racial equality issues.

(iii) Summary costs and benefits table

| Option | Total benefit per annum: economic, social, administrative and enforcement | Total cost per annum: economic, social, administrative and enforcement |
|--------|---|--|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |

This table will be completed after the consultation when information on potential impacts has been obtained.

(iv) Equity and Fairness

5.5 It is proposed that this should be a voluntary measure and therefore should not disadvantage UK industry and should not act as a barrier to trade. However, multinational companies may decide to follow the UK lead and change the labels on products sold in other EU countries.

(v) Costs

Option 1 – Do nothing

5.6 This option would not involve any costs to industry. However, there is a continuing risk of costly product recalls due to accidental cross-contamination.

- 5.7 The costs in terms of the health effects for a consumer with food allergies or food intolerances are in terms of ill health and, in extreme cases, death. Consumer choice would continue to be limited and the financial costs for allergic consumers are higher than those who are not on a special diet. An FSA study on “May Contain Labelling – The Consumer Perspective”⁴ found that nut allergic consumers took an average of 39% longer to shop and paid 11% more for food. The average weekly household food expenditure is £43.50 (Source: ONS – Expenditure and Food Survey 2003-2004), so that nut allergic customers (and their whole families) spend £4.79 extra per week and £249 extra per year on food (and non-alcoholic drinks). If 1% of the 25 million households in Great Britain (Source: ONS) are affected, the total annual cost would be £62.25m. It is not known by how much clearer labelling would reduce this amount. However, more informative labels that are based on a sound risk assessment may give consumers greater choice and may therefore reduce this cost.
- 5.8 There is a cost to the National Health Service for every anaphylactic shock reaction, which results in a 24-hour stay in hospital. The reference cost for an average 24-hour emergency admission in an inpatient ward is £429.00.

Option 2 - Produce new national legislation covering allergen advisory labelling

- 5.9 The effect of complying with any statutory allergen advisory labelling will vary according to present practices of individual businesses, the number and types of products they produce and the commercial decisions they have taken. The relative cost burden may be higher for businesses responsible for substantial numbers of product labels and producing at low volumes or for smaller businesses. Initial discussions with trade/retail organisations indicate that these proposals would have little or no cost for the largest businesses that have already implemented allergen control management practices.
- 5.10 Many food manufacturers and retailers already follow HACCP, GMP and traceability for microbiological purposes and so including the risk management of allergens should not add significantly to these procedures.
- 5.11 Many retailers, brand owners and manufacturers already use their own allergen definitions. However, it would be necessary for some manufacturers to re-print labels by certain dates to comply any new legislation. The cost of changing a food product label is estimated to be in the region of £1,000 per product.
- 5.12 Manufacturers would be required to build on existing systems of hazard control used to inform labelling of deliberate allergenic ingredients and extend this to cross-contamination (however, the costs could be offset against cost savings arising from the likely reduction in product recalls due to the improved control procedures in place).

⁴ ‘May Contain’ Labelling – The Consumer’s Perspective published by the Food Standards Agency in May 2002 FSA/0582/0502

- 5.13 There may be some additional cost associated with ensuring that existing products, and the development of new products, comply and some reformulation may be necessary.
- 5.14 There may also be an associated cost for additional cleaning regimes between production runs or separation of production and storage areas, as well as monitoring any new procedures.
- 5.15 It is possible that there will be public sector costs for enforcement of this guidance and this figure will be included at a later date.

Option 3 - Produce voluntary best practice guidance

- 5.16 As above, however, as implementation is voluntary, companies will be able to absorb additional cost like label changes into normal business cycles. This will be a particular advantage for smaller companies.

Option 4 - Produce voluntary best practice guidance and press the EU to take action to implement legislation

- 5.17 This option would be similar option 3 but further changes might be required if any subsequent EU legislation was not comparable with the voluntary guidance provided nationally. However, the development of voluntary guidance in the UK at this time could help inform the development of any subsequent EU system.

(vi) Benefits

Option 1 – Do nothing

- 5.18 No change for the industry and none for the consumers either.

Option 2 - Produce new national legislation covering allergen advisory labelling

- 5.19 By producing legislation in this area, consumers would be given choice and have more confidence in the food industry.
- 5.20 Manufacturers would not have the option of introducing changes at a time suitable to them to spread the financial impact of changes. However, this would be offset by a reduction of product recalls due to mislabelling and accidental cross-contamination and could be used to provide evidence of due diligence in managing allergens.

Option 3 - Produce voluntary best practice guidance

- 5.21 The benefits for consumers would be in terms of better choice and more reliable information. The benefits for manufacturers would be to have guidance on how to handle allergens and a reduction in the number of product recalls.

Option 4 - Produce voluntary best practice guidance and press the EU to take action to implement legislation

5.22 The benefits of voluntary guidance are discussed in 5.20 and 5.21 above. In addition, this option puts the UK in a position of influence within the EU should the EU decide that it wants to introduce EU guidance or legislation in this area.

(vii) Environmental

5.23 There are no foreseeable environmental effects.

6. Small Firms Impact Test

6.1 Our exploration of the draft proposals with the Small Business Service and the Forum of Private Business did not identify any significant impact. However, should any be identified during the public consultation, we will investigate further. We have worked closely with SBS in preparing for this consultation and they are happy with our approach.

7. Competition Assessment

7.1 The results from the competition filter indicate that the proposed guidance will have no significant impact on the competitive structure within the food industry. Under the voluntary option, firms are able to choose whether to follow the best practice advice on handling allergens and appropriate labelling for cross-contamination of allergens. Should firms choose to follow the guidance and to change their labelling, then these changes may be absorbed into the normal business cycle of changing labels.

7.2 Whilst under the legislative option the ability to absorb any labelling costs into the regular cycle will be reduced, these costs are expected to be limited. It is estimated that it costs around £1000 to amend each label. However, these costs will be borne equally by all manufacturers, and, as such, it is not expected that the structure and dynamics of the industry will be affected. Similarly, it is not expected that this guidance will have any effect on barriers to entry.

8. Enforcement, Sanctions and Monitoring

8.1 Legislation, including sanctions, is already in place to protect consumers against misleading labelling. The proposed Guidance provides a common interpretation of what should be considered when labelling food when there is a risk of allergen contamination. This Guidance has no statutory force it will not be enforced and we will not check compliance with it. Therefore it is anticipated that there will be little or no increased costs for enforcement, sanctions or monitoring.

8.2 The Guidance is anticipated to help enforcers improve labelling in this area without resorting to legal action and may eventually reduce enforcement costs.

[Sections 9-12 will be completed after the consultation, as per Cabinet Office guidelines]

9. Implementation and Delivery Plan

10. Post-Implementation Review

11. Summary and recommendations

12. Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed

Date

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