# Executive Note

## The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2007 SSI/2007/534

The above instrument was made by the Scottish Ministers in exercise of the powers conferred by sections 16(1)(e), 17(1), 26(1)(a), and 48(1) of the Food Safety Act 1990 and all other powers enabling them to do so. This instrument is subject to negative resolution procedure.

## Policy Objectives

The purpose of the instrument is to implement, in Scotland, Commission Directive 2006/142/EC, amending Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council, listing the ingredients which must under all circumstances appear on the labelling of foodstuffs.

Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, has been implemented into the law of Great Britain by the Food Labelling Regulations 1996 (as amended). The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2007 further amends the Food Labelling Regulations 1996 in Scotland by adding molluscs and products thereof and lupin and products thereof to the list of allergens in Schedule AA1 of these Regulations.

The instrument will ensure that consumers are properly informed about the presence of molluscs and lupin whenever they or their derivatives are used as deliberate ingredients in pre-packed food.

## Policy Background

Food allergy and food intolerance is thought to affect 2 million people in the UK. Symptoms range from relatively mild to life threatening (anaphylactic shock). Although most children who experience allergic reactions from food grow out of it, there is no cure for food allergy or intolerance, and the only way to avoid symptoms is to avoid the food in question.

The Food Labelling Regulations 1996 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.

The Food Labelling (Amendment) (Scotland) (No.2) Regulations 2004 amended these Regulations to include a list of 12 allergens that have to be indicated on the label whenever they or their derivatives are used as deliberate ingredients in pre-packed food, including alcoholic drinks.

The allergenic ingredients listed are: cereals containing gluten (namely wheat, rye, barley, oats, spelt, kamut and their hybridised strains), crustaceans, eggs, fish, peanuts, soybeans, milk, nuts (namely almond, hazelnut, walnut, cashew, pecan nut, brazil nut, pistachio nut, macadamia nut and queensland nut), celery, mustard, sesame

seeds, and sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10mg/litre expressed as $SO_2$

Due to increasing concerns about the allergenicity of lupin and molluscs and following advice from the European Food Safety Authority, the European Commission has extended the list of allergens to include molluscs (gastropods, bivalves or cephalopods) and lupin and products derived from them.

There are no reliable figures on the number of people in the UK affected by lupin or mollusc allergy. Most allergic reactions to lupin have been reported in peanut-allergic individuals, with a cross-reactivity rate to lupin flour in peanut –allergic individuals of around 30%. Allergic cross reactivity (in relation to foods) is when a person who is allergic to one food reacts to a different food that contains either the same allergen or an allergen with a very similar structure. This means they can cause similar allergic reactions. There is no information on the lowest dose of lupin that could cause a clinical allergic reaction.

Research into mollusc allergy suggests that many of the reactions occur in school age children and young adults. There is cross-reactivity between the mollusc species, as well as between molluscs and crustaceans. The lowest dose of mollusc allergen that can cause a clinical allergic reaction is not known.

**Consultation**

Article 9 of EC Regulation 178/2002, laying down the general principles and requirements of food law, requires open and transparent public consultation on the revision of food law, save in respect of measures made in circumstances of urgency. These Regulations were not made in circumstances of urgency and therefore full public consultation was undertaken as follows.

The Food Standards Agency Scotland consulted publicly with a total of 478 stakeholders (industry, consumer groups, and enforcement authorities) on the new instrument. The consultation documents were also made available on the Food Standards Agency website. Within Government, the Food Standards Agency Scotland consulted with the Scottish Government and Scottish Government Health Officials. A total of four responses were received but no substantive comments were received on the draft instrument.

**Financial Implications**

The instrument will impact upon manufacturers and retailers of pre-packed food. These businesses will need to review the origins and composition of ingredients (including compound ingredients), flavourings and finished products to establish whether molluscs or lupin are present. Labels and/or ingredient lists will have to be amended to indicate the allergens, or product formulations changed to remove or replace allergenic ingredients with non-allergenic ingredients. However, molluscs are likely to be a principle ingredient in any pre-packed food and will already be identified on the label.

The new legislation allows a transition period of 12 months before products have to comply with the new labelling requirements. As such it is anticipated that changes to labelling can be made within food businesses existing product development cycle. Therefore, it is reasonable to assume that overall expenditure will be minimal. Any product reformulation may also be achievable within a businesses commercial formulation cycle.

Local Authorities Coordinators of Regulatory Services (LACORS) have estimated the cost of enforcement of this instrument to be in the region of £20,000 per annum based on a notional figure of 400 samples per year at the cost of £50 per sample.

**Contact**

Christine Green
Food Standards Diet & Nutrition Branch
Food Standards Agency Scotland
01224 285165
Christine.green@foodstandards.gsi.gov.uk

# FINAL REGULATORY IMPACT ASSESSMENT

## 1. TITLE OF THE PROPOSAL

THE FOOD LABELLING (DECLARATION OF ALLERGENS) (SCOTLAND) REGULATIONS 2007

## 2. PURPOSE AND INTENDED EFFECTS OF THE MEASURE

### (i) Objective

The proposed Regulation will implement into Scots law Commission Directive 2006/142/EC which amends Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000, on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

The key objectives of the Food Labelling (Declaration of Allergens) (Scotland) Regulations 2007 are as follows:

- the Regulations will amend the Food Labelling Regulations 1996 by adding two new ingredients, lupin and molluscs, to Schedule AA1.
- the Regulations aim to ensure that consumers are properly informed about the presence of these allergens in the pre-packed foods they buy and are protected from false or misleading descriptions in relation to allergens, while allowing businesses a reasonable time to make the necessary adjustments to labelling.

Separate but parallel legislation will be made in respect of England, Wales and Northern Ireland.

### (ii) Background

Food labelling in Great Britain is governed by the Food Labelling Regulations 1996 (as amended), certain provisions of the Food Safety Act 1990 and the Trade Descriptions Act 1968. 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 and that industry has a clear regulatory framework to work from, which does not restrict product innovation or inhibit the free movement of goods within the EU. Foods sold pre-packed for direct sale and foods sold loose (such as those sold at delicatessen counters or as meals in catering establishments) are exempt from many of the labelling requirements in the Food Labelling Regulations 1996.

The Food Labelling (Amendment) (Scotland) (No.2) Regulations 2004 amended the Food Labelling Regulations 1996 by setting out a list of 12 allergenic ingredients (see appendix 1) that must be declared on the labels of pre-packed foods whenever they or any ingredient originating from the listed allergen are deliberately added to the food.

Due to increasing concerns about the allergenicity of both lupin and molluscs, and following advice from the European Food Safety Authority, the European Commission has extended the list of 12 potential food allergens to include lupin and molluscs (gastropods, bivalves or cephalopods), and products obtained from them.

This new SSI adds a further two ingredients, lupin and molluscs, to the list set out in Schedule AAI of the Food Labelling Regulations 1996.

**Lupin**

Lupin seeds have been eaten by humans since ancient times and are consumed as snacks in several European countries. Lupin flour was introduced into the UK in 1996 and is used, for example, in biscuits, pasta, sauces, as well as a soy substitute. As lupin flour does not contain gluten it is sometimes used in gluten-free foods.

Most allergic reactions to lupin have been reported in peanut-allergic individuals, with a cross-reactivity rate to lupin flour in peanut-allergic individuals of around 30%. Clinical symptoms reported after lupin flour inhalation or ingestion are similar to those reported for other inhalant or food allergens, ranging from mild local reactions to life-threatening systemic anaphylaxis. There is no information on the lowest dose of lupin that could cause a clinical allergic reaction.

**Molluscs**

Some molluscs, like squid, mussels and snails are an important food source, and are used as gourmet products or ingredients. Their use as an added ingredient appears to be limited, but they can be found in some processed foods like soups and sauces and in products like surimi.

There are little data on the age of onset and the lifetime course of mollusc allergy, but research[1] suggests that many of the reactions occur in school-age children and young adults. Mollusc allergenicity is not reliably reduced by food processing and the lowest dose of mollusc allergen that can cause a clinical reaction is not known. There is allergic cross-reactivity between the mollusc species, as well as between molluscs and crustaceans. There is also evidence of allergic cross-reactivity between both molluscs and crustaceans with insects like the house dust mite and cockroach.

Anaphylactic reactions and death have been reported in mollusc-allergic patients. Molluscs, specifically cuttlefish, squid, abalone, oyster and snail have been implicated in food-dependent, exercise-induced anaphylaxis.

**Timetable for Directive**

- 22 December 2006 - EC Directive 2006/142/EC was published in the Official Journal and entered into force on 12 January 2007.
- Member States must transpose the Directive into national legislation by 23 December 2007.

[1] http://www.efsa.europa.eu/etc/medialib/efsa/science/nda/nda_opinions/1396.Par.0001.File.dat/nda_op_ej327_molluscs_en1.pdf

- 23 December 2008 – After this date all label changes should be in place.

**(iii) Rationale for Government Intervention**

Directive 2006/142/EC will ensure that those consumers with lupin or mollusc allergies are properly informed about the allergens in the foods they buy and are protected from false or misleading descriptions. This is in line with the Agency's commitment to ensure that consumers are properly informed and can make informed choices through accurate labelling. Consumers who are allergic or intolerant to lupin or molluscs will be able to benefit from the declaration of this additional information of these specified allergens in food products.

**(iv) Risk Assessment**

There are three options for the implementation of the provisions of Commission Directive 2006/142/EC. These are:

**Option 1**: Do nothing
**Option 2**: Implement EC requirements
**Option 3**: Implement EC requirements and extend labelling to cover non-prepacked foods (loose and pre-packed for direct sale)

**The preferred option of the Agency is Option 2**.

**Option 1: Do nothing**
This would not fulfil the Agency's commitment to provide the consumer with comprehensive labelling information in order to allow them to make fully informed choices and would not provide adequate protection to the health of consumers who are allergic or intolerant to lupin or molluscs. This option would also risk infraction proceedings from the Commission against the UK under Article 226 of the EC Treaty. Other Member States could also initiate proceedings under Article 227. Option 1 is therefore not a practical or desirable option.

**Option 2: Implement EC requirements**
Implementing the Commission Directive would fulfil the UK's obligation under the EC Treaty, ensure consistency of labelling rules across the EU, facilitate informed consumer choice, improve health protection for certain consumers and allow UK manufacturers to operate freely and competitively within the single market. Allergen information is not required in the case of food which is sold loose, food which is pre-packed for direct sale and fancy confectionery products, therefore, it would not be required for lupin or molluscs either.

**Option 3: Implement EC requirements and extend labelling to cover foods sold non-prepacked (prepacked for direct sale and sold loose)**
Under Directive 2000/13/EC Member States have the option to use national provisions to extend the labelling requirements for pre-packed foods to food sold non-prepacked. Option 3 would extend the labelling requirements to cover foods which are sold non-prepacked, for example, in delicatessens, bakeries, some health food shops, restaurants, take-aways and sandwich bars. This proposal goes beyond the

scope of Directive 2006/142/EC. In addition, the 2004 amendment to the Food Labelling Regulations 1996 placing 12 allergenic foods on the Schedule AAI list was not extended to cover allergen declarations for non-pre-packed foods. Implementing option 3 would result in different requirements for lupin and molluscs, which would be confusing for consumers, industry, and enforcers.

## 3. Consultation

### (i) Within Government

The new measure does not impact directly on the work of other government departments but the Scottish Government, Scottish Government Health Officials and the Department for Business, Enterprise and Regulatory Reform (BERR) were consulted since this Directive will impact on their responsibilities.

The Local Authorities Coordinators of Regulatory Services (LACORS) were consulted and they have estimated the cost of enforcement to be in the region of £20,000 per annum based on a notional figure sample of 400 samples at £50 per sample.

The costs of reading the legislation and guidance, estimated to take approximately 1 hour, will be incurred by both businesses and local enforcement authorities

### (ii) Public Consultation

The Agency in Scotland consulted with a total of 478 stakeholders from industry, consumer groups and enforcement. A meeting with representatives of small food businesses was proposed as part of this consultation and businesses in Scotland were invited to take part. However, this offer was not taken up.

The draft implementing Scottish Statutory Instrument was subject to a full 12 week consultation period. A total of four responses were received including one no comment. Of the three respondents who provided comment all were in agreement that Commission Directive 2006/142/EC should be implemented into UK law. One of these respondents also noted that the accompanying guidance notes could be made clearer for businesses. The Agency has since redrafted the Guidance Notes.

## 4. OPTIONS

There are three options for transposing the provisions of Directive 2006/142/EC. These are:

### Option 1 – Do nothing

Do not implement Directive 2006/142/EC into UK law. However, this option could put consumers at risk from incomplete labelling. It would also create differences between Member States and lead to barriers to trade within the single European market. As mentioned previously, this option would also risk infraction proceedings from the Commission against the UK under Article 226 of the EC Treaty.

### Option 2: Implement EC requirements

Implementing fully the provisions of Directive 2006/142/EC into UK law would fulfil the Agency's commitment to ensure that consumers are properly informed through accurate labelling, which would enable food allergic consumers to make informed choices. The Agency believes that there may also be some associated benefits for businesses as a result of increased consumer confidence in products carrying more informative labels.

This option would fulfil the UK's obligation under the EC Treaty, ensure consistent labelling rules across the EU, facilitate informed consumer choice and allow UK manufacturers to operate freely and competitively within the single European market.

**Option 3 – Extend implementation to cover foods sold non-prepacked (prepacked for direct sale and loose foods)**

This option would go beyond the provisions of Directive 2006/142/EC by extending consumer protection into an area previously not covered by legislation. In addition, any legislation to extend these provisions for lupin and molluscs to cover foods sold other than pre-packed would not be consistent with the provisions for the other allergenic ingredients on Schedule AA1 of the Food Labelling Regulations 1996.

Food labelling legislation is harmonised at an EU level and currently does not address the issue of allergen advisory labelling for foods sold either pre-packed for direct sale or foods sold loose. However, the European Commission is currently reviewing all food labelling legislation and could include this area, but this will take at least 4 years. It is difficult for the UK to introduce national measures in an area of EU competence. If the UK were to implement national legislation now, there could potentially be two changes for businesses – i.e. one now and another following the review by the European Commission.

## 5. COSTS AND BENEFITS

### (i) Sectors and Groups affected

It is estimated that 1 in every 55 children have a peanut allergy[2] and it is thought that approximately a third of these children will react to lupin. In 1999 a French research team investigated the risk of cross-allergy to lupin in 24 people who were allergic to peanuts[3]. They found that 44 per cent reacted positively to a skin prick test with lupin flour and seven out of eight who took challenge tests reacted positively. The principal allergen in lupin flour was also found in peanuts.

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[2] Tariq, SM et al. Cohort study of peanut and tree nut sensitisation by age 4 years. (1996) *British Medical Journal* **313** 514-517 and Hourihane JO, Aiken R, Briggs R, Gudgeon LA, Grimshaw KE, Dunngalvin A, Roberts SR. The impact of government advice to pregnant mothers regarding peanut avoidance on the prevalence of peanut allergy in United Kingdom children at school entry. J Allergy Clin Immunol. 2007 May;119(5):1197-202

[3] Moneret-Vautrin DA, Guérin L, Kanny G, Flabbee J, Frémont S, Morisset M (1999). Cross-allergenicity of peanut and lupine: The risk of lupine allergy in patients allergic to peanuts *J Allergy Clin Immunol 104:883-8*

The proposed legislation will help those with food allergies to lupin and molluscs to avoid foods which contain these ingredients. However, the new legislation will potentially affect manufacturers and retailers of pre-packed foods as these businesses will need to review the origins and composition of all ingredients, flavourings and finished products to establish whether any of these newly-specified allergens are present. Labels and/or ingredient lists will also have to be amended to indicate the specified allergens, or product formulations changed to remove or replace them with non-allergenic materials.

**(ii) Benefits**

**Option 1 – Do nothing**
Under this option, the current rules would remain unchanged. Food manufacturers would continue to indicate the presence of the specified allergens as stipulated in Annex IIIa of Directive 2000/13/EC before it was amended by Directive 2006/142/EC.

**Option 2: Implement EC requirements**
Implementing the Directive would fulfil the UK's obligation under the EC Treaty ensuring consistent labelling of pre-packed foods across the EU.
Consumers will benefit from the new rules, as more comprehensive labelling will increase information and choice. In particular, those with food allergies and food intolerance to lupin and molluscs will find it easier to select products that do not contain the ingredients that they are trying to avoid.

There is evidence that those with food allergy spend a longer time doing their shopping[4]. The new rules may therefore reduce associated search costs for consumers as the labelling of products containing lupin and molluscs and their derivatives should be clearer and more consistent. However, the amount and value of time saved is difficult to quantify. In addition, potential reductions in fatalities or near fatal reactions requiring hospitalisation as a consequence of this legislation are likely to further increase the benefits.

Industry may also gain benefits from the proposed Regulations through increased consumer confidence as a result of products carrying more informative labels and the facilitation of trade as UK manufacturers can operate freely and competitively within the single European market. However, there will be a cost to industry from reading the new legislation and changing the labels on a small number of pre-packed foods; this is set out in more detail in the cost section below.

**Option 3: Extend implementation to cover foods sold non-prepacked**
Under this option consumers may benefit, as more comprehensive information on all of the ingredients in Schedule AA1 of the Food Labelling Regulations 1996 would be available to them from all outlets where foods are sold other than pre-packed, for example bakeries and restaurants.

[4] Gowland 2002, 'May Contain' Labelling – The Consumer's Perspective.

There is evidence which suggests that foods purchased from catering and fast food outlets present a greater risk to food allergic consumers than pre-packed foods, in terms of the number of fatal and near-fatal allergic reactions occurring. Although not broken down between pre-packed and non-pre-packed foods, current estimates indicate that around 10 people die each year in the UK alone as a result of allergic reactions to food[5]. In 2004 there were 355 hospital admissions in Scotland caused by anaphylactic reactions to food[6]. There is a cost to the person concerned and to the National Health Service for every anaphylactic shock reaction, which can result in a stay in hospital. Detailed costs are not available for Scotland. However, it is thought that costing set out for England would not be dissimilar in Scotland. In 2005 the average cost for (non-elective) treatments of shock and anaphylaxis in England was £471 per treatment[7]. Without intervention, allergic reactions as a consequence of allergic consumers not realising that a food contains an ingredient to which they are allergic, will continue to occur.

**(iii) Costs**

**Option 1 – Do nothing**

Doing nothing has implications for both the direct costs to the NHS and indirect costs to the wider economy from allergy related illnesses. The direct cost to the NHS of managing allergic diseases has recently been estimated at over £1 billion per annum in the UK[8] and primary care prescribing costs are around £0.9 billion per annum, or 11% of the total drugs budget. However, the proportion of this relating to lupin and mollusc allergy is likely to be low when compared to hay fever and asthma due to environmental factors. The recent Department of Health review on allergy services [8] highlighted, that the indirect costs of allergic diseases, such as school or workdays lost, lower productivity or diminished quality of life, are potentially huge. However, these were not quantified.

This option would also risk infraction proceedings from the Commission against the UK under Article 226 of the EC Treaty; other member states could also initiate proceedings under Article 227. Option 1 is therefore not a practical option.

**Option 2 - implement fully the provisions of Directive 2006/142/EC**

Under this option, the new rules will affect producers of pre-packed foods that contain the specified allergens (molluscs and lupin) which are not currently identified on the label. We would expect some of the food industry to undertake a re-design of labels, with the effect varying according to the number and types of products they produce. The British Retail Consortium has estimated the costs of re-labelling a product line at approximately £1000 each. It is anticipated that changes can be made within manufacturers' existing commercial labelling cycles. Any costs arising should therefore be minimal. The one year transitional period will also cushion the effect of any costs that may be incurred as a result of having to remove products from sale.

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[5] Pumphrey and Gowland "The Journal of Allergy and Clinical Immunology" 2007

[6] http://www.scotpho.org.uk/web/site/home/Healthwellbeinganddisease/Allergic_conditions/Allergicconditionsdata/Allergic_conditions-secondary_care.asp

[7] http://www.dh.gov.uk/assetRoot/04/13/32/28/04133228.xls

[8] National Allergy Strategy Group (NASG) October 2006

Although, we do not have evidence on the total number of food product lines that will be affected, we would expect this to be limited. In addition, it is likely that, because of the already existing requirement to declare crustaceans, many manufacturers are already declaring molluscs or the more generic "shellfish", on the label.

There may be limited costs associated with additional checking of the composition of compound ingredients that are bought in for these two additional allergens.

Businesses will need to allow time to read and understand the new Regulations. However, due to the simplicity of these Regulations this should not be onerous. For most businesses we estimate that they would take approximately 20 minutes to read.

This option will also affect the public bodies (Local Authorities and Public Analysts) who have responsibility for implementing and enforcing legislation in this area. LACORS have estimated the cost of enforcement to be in the region of £20,000 per annum based on a notional figure of 400 samples at £50 per sample. An estimate of the cost of the time taken by local authority enforcement officers to read the legislation and guidance is £22.18.[9]

**Option 3: Extend implementation to cover non-prepacked foods**

Industry has indicated that in terms of labelling or point of sale notices, staff training and traceability procedures, the costs of introducing this option may be quite high for those businesses providing foods which are sold loose or pre-packed for direct sale and these businesses may find this cost difficult to absorb. However, the numbers of businesses affected and to what extent is not known.

## 6. SMALL FIRMS IMPACT TEST

The addition of lupin and molluscs to Schedule AA1 of the Food Labelling 1996 will affect a limited number of businesses. It is understood that many small bakers are in the process of re-formulating to remove the lupin content from their products in an effort to avoid additional labelling requirements.

However, an initial assessment of the impact to small businesses shows that the main impact will be the work needed to determine whether or not allergenic ingredients are used in part-prepared foods or ingredients that are bought in and any re-labelling cost. Businesses of all sizes which handle these ingredients are likely to incur some additional costs from setting in place these additional information checks and for re-labelling products to reflect the new requirements. These costs will be in relation to their size, turnover and number of product ranges.

Evidence from the Taskforce Report (scope is UK wide) on the burdens of food regulations on Small Businesses suggests that some small food businesses have difficulties in keeping up to date with changes in legislation and getting advice on

[9] Figure taken from the 2006 ONS Annual Survey of Hours and Earnings of Public Service Professionals of £17.06 per hour (median value) with an additional 30% to cover overheads in line with standard cost model.

legal requirements. Failure to do so can prove expensive and the cumulative effect is often significantly burdensome. To help businesses understand the changes to the legislation the Agency has produced comprehensive guidance on allergen labelling requirement.

## 7. IMPACT ON THE REGIONS

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

## 8. TEST RUN OF BUSINESS FORMS

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

## 9. COMPETITION ASSESSMENT

The results from the competition filter and new Competition Assessment Guidelines indicate that the proposed Regulations will have little impact on the competitive structure or process within the pre-packed food markets. The potential costs are those relating to the updating of labels to reflect the new requirements of disclosing lupin and molluscs ingredients in pre-packed foods. In most cases it is likely that these changes will be absorbed into the normal labelling changing cycle. All manufacturers of such products would be affected and therefore there appears to be little significant threat to competition.

## 10. SUSTAINABLE DEVELOPMENT

There may be a small impact on sustainability as some labels which remain unused by 22 December 2008 will have to be discarded at the end of this period.

There are no impacts on rural issues.

## 11. RACIAL AND GENDER EQUALITY

The FSA does not consider that the new legislation has any impact on race or gender equality as there is no evidence to suggest that any group is likely to react to either molluscs or lupin more than any other group.

## 12. ENVIRONMENTAL IMPACT

There are no environmental effects of the new legislation.

## 13. ENFORCEMENT AND SANCTIONS

Enforcement of the Regulations will be the responsibility of Local Authorities. Provision will be made in domestic legislation for execution and enforcement of the Regulation's requirements by Local Authorities, with offences and penalties applied in line with the Food Safety Act 1990.
Enforcement Authorities' representatives have been consulted on the indication of enforcement costs.

## 13. IMPLEMENTATION AND DELIVERY PLAN

On 26 June 2006 the Standing Committee on the Food Chain and Animal Health, General Food Law section (SCOFCAH) discussed a draft Directive amending Directive 2000/13/EC by adding molluscs and lupin to Annex IIIa of the Directive.

On 28 June 2006 the Food Standards Agency issued an Interested Parties letter explaining to stakeholders the timing of the proposed Directive and informing them that there would most likely be a vote on this on 17 July 2006.

SCOFCAH actually met on 19 July 2006 when agreement was reached on the draft Directive amending Annex IIIa of Directive 2000/13/EC (allergenic ingredients) to include two additional food allergens. The Directive was agreed by Qualified Majority Vote, with the Netherlands abstaining.

The Agency issued a second Interested Parties letter on 24 July 2006 reporting the outcome of the SCOFCAH meeting.

A Directive to amend Annex IIIa of Directive 2000/13/EC, which lists the allergenic foods that have to be labelled whenever they are used in pre-packed foods, was published in the Official Journal on 23 December 2006. The Agency issued a third Interested Parties letter about this in January 2007 The letter also stated that Member States had to implement national legislation by 23 December 2007 and that Industry would have a further 12 months (that is, until 23 December 2008) to comply with the labelling provisions, although products produced and labelled before that time could continue to be sold whilst stocks last.

The Agency in Scotland published a consultation package on 22 June 2007. Interested parties were given 12 weeks to comment on the draft Scottish Statutory Instrument (SSI) and accompanying documentation.

The publication of the new SSI will be communicated to stakeholders by a further Interested Parties letter.

## 14. MONITORING AND REVIEW

The effectiveness of the Regulations will be monitored through feedback from stakeholders. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys and general enquiries from the public.

Guidance notes on the application of the new requirements have been drawn up in full consultation with stakeholders and their impact will be kept under regular review.

## 15. POST- IMPLEMENTATION REVIEW

The agency will consider this legislation as part of the ongoing EU food labelling review and will also monitor stakeholder meetings and general enquiries from the public to inform discussion 12 months post implementation.

## 17. SUMMARY AND RECOMMENDATIONS

The proposals here provide for new legislation amending the list of ingredients.

| | Costs | Benefits |
|---|---|---|
| Option 1 | No direct costs, but by not complying with the new EU provisions on allergen labelling, manufacturers would risk losing EU markets. Would not provide adequate protection to the health of consumers who are allergic or intolerant to lupin or molluscs. Would also risk infraction proceedings from the Commission | The current rules would remain unchanged. Food manufacturers would continue to indicate the presence of the existing specified allergens. |
| Option 2 | Could result in additional costs to certain food manufacturers if they decide to reformulate.<br><br>Potential cost of re-labelling some products is estimated at £1000 per product.<br><br>There may be a limited cost associated with checking the composition of ingredients that are bought in. | Would deliver full benefits to manufacturers and food allergic consumers offering them an increased protection and choice from allergenic labelling of food products. |
| Option 3 | The costs of introducing this option are thought to be quite high for those businesses providing foods which are sold loose or pre-packed for direct sale and these businesses may find this cost difficult to absorb. | Consumers may benefit, as more comprehensive information on all of the ingredients in Schedule AA1 of the Food Labelling Regulations 1996 will be available to them not just on pre-packed foods, but also from all outlets where foods are sold other than pre-packed, for example bakeries and restaurants. |

**Option 2 is recommended**. This option will deliver the full health protection benefits of the Directive. It will also fulfil the UK's obligations by providing for the Directive's enforcement.

## 18. DECLARATION AND PUBLICATION

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

**Signed**:……..

**Date**:……..

**Minister's Name, and Title:**

Shona Robison, Minister for Public Health, Scottish Government

**Contact point for enquiries and comments**

Christine Green
6th Floor
St.Magnus House
25 Guild Street
Aberdeen
AB116NJ
Telephone: 01224 285165
Email: christine.green@foodstandards.gsi.gov.uk

**Appendix 1**

## THE INGREDIENTS LISTED IN SCHEDULE AA1 – FOOD LABELLING REGULATIONS 1996

- The following cereals containing gluten: wheat, rye, barley, oats, spelt, kamut and their hybridised strains)
- Crustaceans
- Eggs
- Fish
- Peanuts
- Soybeans
- Milk
- The following nuts: Almond, Hazelnut, Walnut, Cashew, Pecan nut, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut)
- Celery
- Mustard
- Sesame seeds
- Sulphur dioxide and sulphites at levels above 10mg/kg or 10mg/litre expressed as SO2