EXECUTIVE NOTE TO

THE FOOD LABELLING (DECLARATION OF ALLERGENS) (SCOTLAND) REGULATIONS 2008
SSI/2008/180

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 this instrument is to implement, in Scotland, Commission Directive 2007/68/EC, amending Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council, permanently excluding certain food ingredients or substances derived from these ingredients from the list in Annex IIIa.

Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling and 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 2008 further amends the Food Labelling Regulations 1996 in Scotland by substituting a new Schedule AA1.

Schedule AA1 lists those allergens and their derivatives that must be indicated in the labelling of food. It also lists ingredients derived from allergenic ingredients which are permanently exempt from allergen labelling, because, as a result of processing, they no longer contain the allergenic component.

The Instrument provides a transitional period for foods that are marked, labelled or sold before 31 May 2009 and makes various other minor and consequential amendments.

The instrument will ensure that consumers are properly informed about the presence of allergens in the prepacked foods they buy.

Policy Background

The Food Labelling Regulations 1996 (as amended) 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 requirement to label allergenic ingredients in prepacked food was introduced in 2004. The Food Labelling Amendment (No.2) (Scotland) Regulations amended the Food Labelling Regulations 1996 to include a list of 12 allergens that must be indicated on the food product whenever they or their derivatives are used as deliberate ingredients in prepacked food, including alcoholic drinks.

In 2005, the Food Labelling Regulations 1996 were amended, implementing Commission Directive 2005/26/EC, as corrected by Commission Directive 2005/63/EC, which granted a provisional exemption from allergen labelling to certain specified derived ingredients, which due to processing no longer contain the allergenic component. These exemptions expired in November 2007. The Commission has taken advice from the European Food Safety Authority on the applications for permanent exemptions and has published Commission Directive 2007/68/EC.

The area of food information and food labelling is currently the subject of a fundamental review by the European Commission. The Commission published a proposal for a Regulation on the provision of food information to consumers on 30 January 2008. The proposal consolidates general and nutrition labelling and recasts a number of other labelling Directives. It is expected that the outcome of the review will produce a single directly applicable EC Regulation. Therefore, it is considered appropriate that the Food Labelling Regulations 1996 are further amended instead of consolidated at this stage.

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. This Instrument was not made in urgency and therefore public consultation was undertaken as follows.

The Food Standards Agency Scotland consulted publicly with a total of 611 stakeholders (industry, consumer groups, and enforcement authorities) on the new instrument. The consultation documents were also made available on the Food Standards Agency website. A total of three responses were received but no comment was made on the draft instrument. The instrument will not impact directly on the work of the Scottish Government; however they were consulted during its development.

Financial Implications

The instrument will impact upon all food manufacturers engaged in the production of prepacked foods. Although most of the ingredients previously provided with temporary exemption have been given permanent exemption there are a few cases where permanent exemption has not been given.

In these instances labels and/or ingredients will have to be amended to indicate the specified allergens, or product formulations changed. This is not considered to have a significant impact on Scottish businesses. The transition period until 31 May 2009 will allow changes to the labels of prepacked foods to be made within the manufacturers' existing labelling cycles.

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FINAL REGULATORY IMPACT ASSESSMENT

1. TITLE OF THE PROPOSAL

THE FOOD LABELLING (DECLARATION OF ALLERGENS) (SCOTLAND) REGULATIONS 2008

2. PURPOSE AND INTENDED EFFECTS OF THE MEASURE

(i) Objective

The proposed Regulation will implement into Scottish Law Commission Directive 2007/68/EC which amends Annex IIIa to 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 2008 are:

- to further amend the Food Labelling Regulations 1996 by introducing a new Schedule AA1.

- to ensure that consumers are properly informed about the presence of allergens in the pre-packed foods they buy.

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

(ii) Background

Scottish Position:

Food labelling in Scotland is principally governed by the Food Labelling Regulations 1996 (as amended) and certain provisions of the Food Safety Act 1990. Both the 1996 Regulations and the 1990 Act apply throughout Great Britain. 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 prepacked 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 (as amended).

The requirement to label certain specified allergenic ingredients when used in prepacked food was introduced in 2004 through the Food Labelling Amendment (No.2) (Scotland) Regulations 2004. In addition, the Food Labelling Amendment (No.3) (Scotland) Regulations 2005 provided temporary exemptions for a number of products derived from the specified allergenic ingredients identified in the Food Labelling Amendment (No.2) (Scotland) Regulations 2004 for the period from November 2005 until November 2007.

EU Position:

Directive 2000/13/EC (as amended) of the European Parliament and of the Council of 20 March 2000, on the approximation of the laws of Member States relating to the labelling, presentation and advertising of foodstuffs, requires labelling of a specified list of allergenic ingredients.

Commission Directive 2005/26/EC, as corrected by Commission Directive 2005/63/EC, established a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC.

A number of applications for permanent exemption from the labelling requirement were submitted to the European Food Safety Authority (EFSA). On the basis of EFSA opinions and other available information, it was concluded that certain ingredients are not likely to cause adverse reactions in susceptible individuals and as such those ingredients should therefore be permanently exempted from Annex IIIa of Directive 2000/13/EC.

This resulted in Commission Directive 2007/68/EC of 27 November 2007, which amends Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council, and sets out certain food ingredients or substances derived from these specified allergenic ingredients that are not likely to cause adverse reactions in susceptible individuals.

(iii) Rationale for Government Intervention

EU legislation aims to ensure that those consumers with allergies are properly informed about the allergens in the prepacked 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. By implementing the

exemption list into Scottish law, consumer choice will not be restricted by the unnecessary labelling of products derived from allergenic substances that have been processed and are no longer allergenic. Some allergenic ingredients that have been covered by the temporary exemption have not been granted permanent exemptions and will now require allergen labelling. The new Regulations will clarify which foods are, and which foods are not, allergenic and increase the foods available to allergic consumers. In addition, the proposal will prevent unnecessary allergen labelling requirements for prepacked products that contain ingredients on the exemption list.

(iv) Risk Assessment

There are three options for the implementation of the provisions of Commission Directive 2007/68/EC. These are:

Option 1: Do nothing
Option 2: Implement EC requirements by further amending the Food Labelling Regulations 1996
Option 3: Revoke the Food Labelling Regulations 1996 (as amended) and introduce new legislation consolidating the existing food labelling rules and the new European requirements within a single set of Regulations.

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 lead to over-labelling of ingredients that are no longer allergenic. This option would also risk infraction proceedings from the European Commission. Option 1 is therefore not a practical 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 and allow UK manufacturers to operate freely and competitively within the single market. It would also maintain the exemption from allergen labelling requirements for products that contain many of the ingredients that were on the temporary exemption list (i.e. ingredients that, due to processing, are no longer allergenic) although a number of temporarily exempt derived products did not gain permanent exemption.

Option 3: To revoke the Food Labelling Regulations 1996 (as amended) and introduce new legislation consolidating the existing food labelling rules and the new European Requirements within a single set of Regulations.

The area of food information and labelling is currently the subject of a fundamental review by the European Commission. It is expected that the outcome of the review will produce a single consolidated piece of legislation on food labelling in the form of a directly applicable EC Regulation. Therefore,

it would be pragmatic to wait for the outcome of the European review before undertaking any exercise to consolidate all UK food labelling legislation.

3. CONSULTATION

Before Directive 2007/68/EC was published the Food Standards Agency alerted businesses to the proposal and contacted both consumer and business stakeholders to obtain their opinions on the proposal. This ensured that the Agency negotiated with the Commission in the areas that would have the biggest impact on UK consumer groups and businesses.

The responses received from stakeholders fell broadly into two categories:

- The wine producing industry was concerned that no fining agent would receive permanent exemption. This would mean that a bottle of wine would have to declare the allergenic food source of the fining agent used in this process i.e. egg, milk or fish. However, the Food Standards Agency worked with the Commission and the wine industry and obtained a permanent exemption for using Isinglass as a fining agent in wine making, as well as beer production.
- Industry was concerned that they would only receive six months to implement any label changes. An additional six months was negotiated, so that label changes will now have to be in place by 31 May 2009.

Public Consultation
In addition, the Agency held a public consultation between 4 February and 17 March 2008 to allow all those interested in food and allergen labelling to contribute to the development of the domestic Regulations. Directive 2007/68/EC requires Member States to have national legislation in place by the end of May 2008. In order to comply with this timing, the consultation was for a shortened period of six weeks.

The Agency in Scotland consulted with a total of 611 stakeholders from industry, consumer groups and enforcement. Three responses were received, which included a nil comment. The only substantive response came from a consumer who commented on the guidance notes. These comments fed into the redrafting work on the guidance.

Within Government
The new Regulations do not impact directly on the work of other Government Directorates; however, they have been informed of the new Regulations and given the chance to be involved in their development.

4. OPTIONS

There are three options for transposing the provisions of Directive 2007/68/EC. These are:

Option 1: Do nothing

Do not implement Directive 2007/68/EC into Scottish Law. However, this option could lead to consumer confusion due to over-labelling of ingredients that are no longer allergenic. It would also create differences within the UK and between Member States and lead to barriers to trade within the single European market. 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 2007/68/EC into Scottish 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.

As mentioned previously this option would fulfil the UK's obligation under the EC Treaty, ensure consistent labelling rules across the UK, and allow manufacturers to operate freely and competitively within the single European market.

Option 3: Extend implementation to revoke the Food Labelling Regulations 1996 (as amended) and introduce new legislation consolidating the existing food labelling rules and the new European Requirements within a single set of Regulations.

This option would go beyond the provisions of Directive 2007/68/EC by requiring a large scale review of the Food Labelling Regulations 1996. This would delay the implementation of this Directive, which would risk infraction proceedings as discussed above. It would not be pragmatic to undertake a review at this time, given that the EU review of food labelling is well underway.

5. COSTS AND BENEFITS

(i) Sectors and Groups affected

The groups affected would be all food manufacturers engaged in the production of prepacked foods.

(ii) Benefits

Option 1: Do nothing

Under this option, the temporary exemption granted between November 2005 and November 2007 would remain expired, which would require the labelling of all ingredients derived from allergenic foods. There are no benefits of not implementing this legislation.

Option 2: Implement EC requirements
Implementing the Directive would fulfil the UK's obligation under the EC Treaty ensuring consistent labelling of prepacked foods across the EU. Under this option most of the ingredients previously given temporary exemptions from labelling would be confirmed as exempt. Although there are a number of cases where permanent exemptions were not given (see option 2 costs) this is not considered to have a significant impact on UK businesses as a result of the extended transition time until 31 May 2009 that was negotiated.

Consumers will benefit from the new rules, as more comprehensive labelling will increase information and choice, and potentially further protect health.

In the absence of implementation, many products, which currently contain ingredients that are given exemption by the new Directive, would have to be labelled in future - even though that ingredient no longer has the potential to cause an allergic reaction. It is therefore entirely possible that consumers with allergies will assume that, if they eat these foods that are labelled as containing an allergenic ingredient and do not react, they have overcome their allergy. They may then start to eat other foods which contain the allergen and could suffer severe adverse reactions. It is therefore an advantage for the allergic consumer for these ingredients that do not pose an allergic risk, to be exempt from the allergen labelling legislation. In addition, implementing the Directive will improve consumer choice, as the ingredients that should be exempt would not have to be labelled.

It is further the case that by not implementing this Directive many more prepacked foods will be subject to the allergen labelling legislation than would be required by implementing it. It is therefore to the advantage of the food industry to implement this Directive.

Option 3: Extend implementation to revoke the Food Labelling Regulations 1996 (as amended) and introduce new legislation consolidating the existing food labelling rules and the new European Requirements within a single set of Regulations.

The benefits set out under option 2 would apply here.

(iii) Costs

Option 1: Do nothing
Under this option all manufacturers of prepacked foods currently taking advantage of the temporary labelling exemptions, which expired in November 2007, would have to immediately start labelling ingredients derived from allergenic food. As well as the costs of designing and printing new labels, this would result in unnecessary labelling of certain derived ingredients that EFSA have concluded are not likely to cause adverse reactions.

Under this option, consumers would receive inaccurate labelling information. In addition, the cost to allergic consumers would be in terms of a reduction in

the foods available to them to consume, as ingredients that are in practice no longer allergenic, would still be labelled with reference to the source allergenic food. There are unlikely to be any costs passed onto the NHS as a result of doing nothing as it is unlikely that there will be an increase in hospital admissions or fatalities.

There would be costs to the UK Government if infraction proceedings were taken by the European Commission because of non-implementation.

Option 2: Implement fully the provisions of Directive 2007/68/EC

Although most of the temporary exemptions from labelling were confirmed as permanently exempt, there are a few cases where permanent exemptions from labelling were not given, these are:

- egg albumin fining agent for wine and cider,
- isinglass fining agent for cider (manufacturers did not supply a further dossier to support an exemption for this use),
- milk (casein) fining agent for wine and cider,
- almonds/walnuts to flavour spirits,
- celery – in any form,
- mustard – in any form.

In these instances labels and/or ingredient lists will have to be amended to indicate the specified allergens, or product formulations changed to remove or replace them with non-allergenic materials. This is not considered to have a significant impact on UK businesses.

As there is a transition period until 31 May 2009, it is anticipated that changes to the labels of prepacked foods can be made within manufacturers' existing labelling cycles. Any costs arising should therefore be minimal. The British Retail Consortium has estimated the costs of re-labelling at approximately £1000 per product. However, the twelve months transitional period will cushion this effect by minimising any extra costs that might be incurred as a result of having to print new labels out of the commercial cycle or remove products from sale whilst the labels are changed, and so the overall costs of any new labelling required is likely to be insignificant.

Businesses will need to allow time to read and understand the Regulations. However, due to the simplicity of the Regulations this should not be onerous. For most businesses we estimate that this would take approximately 30 minutes to read, at a rate of £11.19 (2006 Annual Survey of Hours and Earnings (ASHE) analysis by industry) based on 2 people to read the new legislation. There are approximately 18,000 UK manufacturers who may need to understand these Regulations, thus yielding a gross one-off administrative cost of £403,000.

There are 469 local authorities in the UK and, based on allowing 2 people 30 minutes to read the new legislation at a rate of £9.95, it would cost £9333.

Source – 2006 Annual Survey of Hours and Earnings analysis by Government Office by occupation.

The Agency considers that many firms will have an existing understanding of the composition of their ingredient inputs and therefore normal commercial sourcing practices are likely to inform producers of the likely allergenic make up of their product inputs. Even if clarification of the potential allergenic nature of upstream supplies is required this is not expected to involve significant cost.

Option 3: Extend implementation to revoke the Food Labelling Regulations 1996 (as amended) and introduce new legislation consolidating the existing food labelling rules and the new European Requirements within a single set of Regulations.

The costs set out under option 2 would apply here. However option 3 would require a significant review and consolidation of the Food Labelling Regulations 1996, which would delay the implementation of this Directive. In addition, it would not be sensible to undertake such a review and consolidation of the domestic Regulations at a time when the Commission proposal for updating and consolidating EC general labelling rules is currently in progress.

Questions raised during the public consultation:

Can you provide any figures on the costs/benefits of the Regulation to your sector?

Do you foresee any additional costs/benefits not already identified in the partial Regulatory Impact Assessment?

No responses to these questions were received

6. SMALL FIRMS IMPACT TEST

An initial assessment of the impact to small businesses shows a potential impact via the need 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 may incur some additional cost from setting in place these information checks and be in relation to their size, turnover and number of product ranges, but as noted are not expected to be significant in nature.

Evidence from the Taskforce Report 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 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 requirements.

In addition, the Agency negotiated for a twelve month period to implement any label changes, which should help small businesses to reduce the cost by working these changes into their normal label review process.

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 new Competition Assessment Guidelines indicate that the proposed Regulations will have little impact on the competitive structure or process within the prepacked food markets. The potential costs are those relating to the updating of labels to reflect the new requirements of those ingredients that were not permanently exempt from labelling requirements in prepacked foods. In almost all cases it is likely that these changes will be absorbed into the normal labelling change 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 small numbers of labels which remain unused by 31st May 2009 will have to be discarded at the end of this period. There will be a positive benefit for consumers with allergies in clearly identifying processed allergenic ingredients.

11. RACIAL, GENDER AND DISABILITY EQUALITY

The Food standards Agency does not consider that the proposed legislation has any impact on race or gender or disability equality as there is no evidence to suggest that any group is likely to be affected more than any other group.

12. ENFORCEMENT AND SANCTIONS

Enforcement of the Regulations will be the responsibility of Food Authorities. Provision will be made in domestic legislation for execution and enforcement of the Regulation's requirements by food authorities, with offences and penalties applied in line with the Food Safety Act 1990.

13. REVIEW

The effectiveness of the Regulations will be monitored continuously through feedback from stakeholders. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys and general enquiries from the public. The FSA will conduct a full review of the effectiveness of the Regulations by 2011.

14. GUIDANCE

Guidance notes on the application of the new requirements, linked to the revision of guidance on existing allergen information, have been drawn up following full consultation with stakeholders.

15. ADMINSTRATIVE BURDENS

There are no requirements in the proposed legislation which require additional records to be kept. Therefore, no additional administrative burdens are envisaged.

16. IMPLEMENTATION AND DELIVERY PLAN

Directive 2000/13/EC (as amended) requires labelling of a specified list of allergenic ingredients as set out in Annex IIIa of the Directive.

Directive 2005/26/EC, as corrected by Directive 2005/63/EC, established a list of food ingredients or substances provisionally excluded from Annex IIIa.

A number of applications for permanent exemptions from the allergen labelling requirement were submitted to the European Food Safety Authority (EFSA). On the basis of EFSA opinions and other available information, it was concluded that certain ingredients are not likely to cause adverse reactions in susceptible individuals and should therefore be permanently exempt from Annex IIIa.

Directive 2007/68/EC revokes Directive 2005/26/EC and replaces Annex IIIa to include certain food ingredients or substances derived from the specified allergenic list that are permanently exempt and also lists those allergens and their derivatives that must be indicated in the labelling of food.

The Agency in Scotland published a consultation package on 4 February 2008. Interested parties were given six weeks to comment on the draft

Scottish Statutory Instrument (SSI), and accompanying documents, which implement Directive 2007/68/EC.

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

17. 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 requirements have been drawn up in full consultation with stakeholders and their impact will be kept under regular review.

18. POST- IMPLEMENTATION REVIEW

The Agency will consider this legislation as part of the ongoing EU Food Labelling review.

19. SUMMARY AND RECOMMENDATIONS

The proposed Regulation implements Directive 2007/68/EC into Scottish Law and introduces a new Schedule AA1 into the Food Labelling Regulations 1996 (as amended) which gives permanent exemptions from labelling for certain products derived from allergens.

	Costs	Benefits
Option 1	Industry would have to introduce labelling for all ingredients derived from allergens. Consumers with allergies may avoid certain foods unnecessarily. The UK government would risk infraction proceedings from the European Commission.	No benefits since ingredients derived from allergenic foods would have to be labelled.

Option 2	Industry would be required to alter labels for those allergens not given permanent exemptions (estimated at £1000 per product). Product formulations may have to be changed to use non-allergenic products. Administrative costs associated with reading and understanding the Regulations for industry and Local Authorities.	The transitional period will minimise costs to industry as labelling changes can be absorbed into existing labelling cycles. Consumers will benefit from the new rules, as more comprehensive labelling will increase information and choice, and potentially further protect health. It is advantageous to the consumer with allergies for those ingredients which no longer have the potential to cause an allergic reaction to be exempt from the allergen labelling legislation. It is to the food industry's advantage to implement this Directive since it cuts down on the amount of labelling required.
Option 3	As in option 2. Additionally there would be a delay in implementing this Directive due to the time spent consolidating domestic Regulations. Also the European Commission is in the process of reviewing labelling rules.	As in option 2.

Option 2 is the recommended option.

20. 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, Title and Department:

Shona Robison, Minister for Public Health, Scottish Executive Health Directorate

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