

## **ANNEX B**

### **FINAL REGULATORY IMPACT ASSESSMENT**

#### **1 Title of Proposal**

- 1.1 The Food Irradiation (Scotland) Regulations 2009.

#### **2 Purpose and Intended Effect**

##### **Objective**

- 2.1 To guarantee a high level of consumer protection and to facilitate legitimate trade in irradiated foods. Food irradiation is permitted in Member States of the European Community and European Directive 1999/2/EC establishes a framework of controls on the treatment of irradiating food with ionising radiation. The intention of this Directive is the harmonisation of national laws in different Member States.
- 2.2 The irradiation of food has been shown to be a safe and effective method of preserving food. However, restrictions are in place to ensure high international standards are met and to enable consumer choice at point of sale.
- 2.3 Amendments to Scottish legislation in 2000 were intended to fully implement the requirements of Directive 1999/2/EC. However, a further intervention is now necessary because these amendments did not adequately address the national procedures relating to food irradiation facilities in non-European countries (so called "third countries"). Hence, a further intervention is now required in order to alter national rules. The specific concern is the recognition of third country food irradiation facilities. Only irradiated food treated at facilities approved by the European Community as meeting the necessary standards is allowed into the UK. Current domestic legislation states that it is the Food Standards Agency who may recognise legitimate food irradiation facilities in third countries but it does not require that these facilities are first approved by the European Community. Although Directive 1999/2/EC has not been breached in this way, intervention is required as there is a risk that the UK could allow imports of food that had been treated at a third country food irradiation facility when the standards and controls at that facility had not been considered by the European Community as a whole. There is therefore a potential risk to food standards which are designed to protect consumers.
- 2.4 Clarity and better regulation could also be addressed by an additional intervention in order to simplify food irradiation regulations and ensure that they remain up to date. There are no risks to public health or standards associated with this intervention. Examples of simplifying measures include: renaming the "spices and condiments" description of food as "dried herbs, spices and vegetable seasonings", to match the description in Directive 1999/3/EC; removing the definition of "cereals" as it is now redundant; and altering the basis for collecting fees in respect of official controls (the basis for such fees now falls under Commission Regulation 882/2004). A further intervention will be that an applicant for a food irradiation licence must show the methods they will use to ensure food is in a suitably wholesome state. This will replace the existing requirement that they specify what microbiological criteria and the type and frequency of microbiological examination they will use. This more accurately reflects the requirements of Directive 1999/2/EC and the modern horizontal approach to food hygiene.
- 2.5 The Food Standards Agency believes that intervention in this case is appropriate. The Food (Control of Irradiation) Regulations 1990 which are currently in place are almost 20 years old and have been amended several times; they predate European Directive 1999/2/EC and although amended with the intention of implementing this

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Directive in full, they do not adequately transpose the procedures dealing with third country food irradiation facilities into domestic law. The Food (Control of Irradiation) Regulations as amended are also in need of a consolidation in the interests of clarity and better regulation. It should be noted that the Agency does not propose to dilute the controls on food irradiation nor alter the continued need for labelling and traceability of irradiated foods to support consumer choice.

- 2.6 The Agency proposal is in the interests of consumers, enforcement authorities and industry. Failure to intervene would mean that there will continue to be a risk of the UK allowing food from a third country food irradiation facility where standards and controls have not been considered by the European Community as a whole. This would not meet the procedure in Directive 1999/2/EC, which is designed to ensure consumer protection and facilitate legitimate trade. Failure to correctly implement Directive 1999/2/EC would also leave the UK open to infraction proceedings from the European Commission.

### Intended Effect

- 2.7 The intended effect is to correctly introduce measures that require third countries (non-EU countries) exporting irradiated foods to the EC to ensure their irradiation facilities comply with the high standards set by the European Community. The intention is also to take this opportunity to revise the regulations; to state them in a more clear and concise manner.
- 2.8 The goal is to achieve the following three aims;
- Correctly implement Article 9 of Directive 1999/2/EC into national legislation. Article 9 requires the European Community's prior approval of food irradiation facilities in third countries (national legislation should not allow or require national authorities to separately recognise or approve third country irradiation facilities).
  - Ensure that food irradiation regulations meet the legal basis for the financing of official controls (Article 27 of Regulation 882/2004).
  - Update and consolidate The Food (Control of Irradiation) Regulations as amended, in the interests of clarity and simplification.
- 2.9 It is not intended to alter labelling requirements for irradiated foods, which are contained in food labelling regulations.

## 3 Background

- 3.1 In 1988 the European Council put forward proposals concerning foods and food ingredients treated with ionising radiation. In 1999, these proposals resulted in framework Directive 1999/2/EC and implementing Directive 1999/3/EC. These Directives create a legal framework for the single market for irradiated food. One of the key measures is intended to require third countries exporting irradiated foods to the EC to ensure their irradiation facilities comply with the high standards set by the European Community.
- 3.2 Prior to these Directives, food irradiation was permitted in Great Britain by The Food (Control of Irradiation) Regulations 1990. This domestic legislation was amended in 2000 in order to bring it into line with 1999/2/EC and 1999/3/EC. The amendments were minor as the EC Directives were based on British food irradiation legislation. However, the amendments did not adequately address procedures for dealing with third countries exporting irradiated food.
- 3.3 The proposal to alter the approval process for third country food irradiation facilities will affect the Food Standards Agency and will prevent it from acting in breach of

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European legislation. The proposal may also affect consumers, the food industry (including those who deal in imports) and the irradiation industry as it may facilitate more trade in irradiated food, a process which finds more favour outside of the European Union. However, few foods are irradiated in practice and it is unlikely that trade in irradiated food will increase in the near future.

### **Rationale for Government Intervention**

- 3.4 Intervening to alter food irradiation legislation also provides an opportunity to review the legislation, consolidate it and state the requirements more clearly. This is in line with better regulation objectives. The following changes are proposed:

#### Approval of Third Country Facilities

- 3.5 The Food (Control of Irradiation) Regulations 1990 allow the UK to "recognise" food irradiation facilities in third countries (non-EU countries), even if they are not approved by the European Community. To do so would be in breach of Article 9 of Directive 1999/2/EC. Food irradiation facilities in third countries must be approved by the Community. The current regulations are being operated in a way that ensures that the Directive is not breached and no third country food irradiation facilities have been separately "recognised" by the UK. Nevertheless, the intention of the regulations is to implement the requirements of the Directive in full.

#### Approval of UK Facilities

- 3.6 Directive 1999/2/EC requires that food irradiation facilities in Member States are approved by their National Competent Authority and in the UK this is the Food Standards Agency. Prior approval of UK facilities is implemented by a licensing system under which a licence is issued that reproduces conditions detailed in the regulations. An improvement would be to simplify the format of the licence document so that it is concise and where appropriate refers to the regulations on food irradiation without unnecessary duplication of text.

#### Removal of Inspection and Approval fees

- 3.7 The Food (Control of Irradiation) Regulations 1990 as amended include measures to collect fees to cover the costs occasioned by official food irradiation controls such as applying for prior-approval, varying existing approvals and the inspection of irradiation facilities. However, Official Food and Feed Controls under European Regulation 882/2004 came into force on the 1<sup>st</sup> January 2007 and Article 27 of Regulation 882/2004 establishes the legal basis for the financing of all official food controls. In order to comply with Article 27 the Agency proposes to no longer collect fees to cover the costs of food irradiation controls. However, this should not exclude the collection of fees where additional expenses exceed normal enforcement activities (in line with Article 28 of Regulation 882/2004).
- 3.8 This proposal will affect the irradiation industry and the Food Standards Agency. There is one authorised food irradiation facility in the UK (based in England) and removing licensing and inspection fees is a transfer of costs to the Agency.

#### General Update to the Regulations

- 3.9 Definition of cereals – The current Regulations refer to the 'Intervention Functions (Delegation) Regulations 1972' and as these are no longer in force this definition should be removed.
- 3.10 Dried herbs, spices and vegetable seasonings – One of the permitted categories of food that can be allowed to be irradiated is 'spices and condiments'. In the interests of clarity this category should be altered to 'dried aromatic herbs, spices and

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vegetable seasonings', so as to meet the exact description in the Annex of Directive 1999/3/EC.

- 3.11 Food must be in a suitably wholesome state – The current national regulations focus on microbiological safety, for example an applicant for a food irradiation licence must specify what microbiological criteria and type and frequency of microbiological examination they will use. The proposed intervention changes this so that the applicant must show the methods they will use to ensure food is in a suitably wholesome state. This more accurately reflects the requirements of Directive 1999/2/EC and the modern horizontal approach to food hygiene. It is broader than solely microbiological criteria, but it will also allow for a more flexible and pragmatic approach to be used by the irradiation facility. There are no risks to public health or standards associated with this intervention as the irradiation facility will still have to demonstrate they have the necessary procedures in place to ensure food that is to be irradiated is of a suitable quality.
- 3.12 These general improvements to the food irradiation regulations will not unduly affect consumers, industry or enforcement authorities. They will state the requirements more clearly and concisely and in this way aid the reader. The regulations will be understood more readily which will assist the food industry by helping it to comply with the law. It will aid enforcement authorities who police the regulations and it is in the interests of consumers who wish to understand the law better.

## 4 Consultation

### Government Consultation

- 4.1 The Agency has kept Scottish Government informed through the consultation process; and BERR, DEFRA and DoH have been informed through parallel consultations elsewhere in the UK.

### Industry Consultation

- 4.2 The Agency has conducted a preliminary informal consultation with the single current UK food irradiation facility (based in England) and their views have been considered in developing these policy options.

### Public Consultation

- 4.3 A full 12 week public consultation has been undertaken on the draft Scottish Statutory Instrument (SSI). During this time, the Agency also engaged with stakeholders on a less formal basis.
- 4.4 No substantive comments were received during the consultation exercise in Scotland. All responses, on this and parallel consultations elsewhere in the UK will be published on the Agency's website at:  
[www.food.gov.uk/consultations/consulteng/2009/draftfoodirradiationregs09](http://www.food.gov.uk/consultations/consulteng/2009/draftfoodirradiationregs09)

## Options

### Option 1: No intervention

- 5.1 This option would not mitigate the risks to food standards which are designed to protect consumers (i.e. Article 9 of Directive 1999/2/EC would not be correctly implemented) and would not be in line with the Government's better regulation objectives. Government policy is to fully implement European Directives and not doing so would leave the UK open to infraction proceedings.

### Option 2: Amending the existing (previously amended) regulations

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- 5.2 This would involve producing new regulations to amend further The Food (Control of Irradiation) Regulations 1990 and thereby mitigate the potential risk to food standards which are designed to protect consumers (i.e. Article 9 of Directive 1999/2/EC would be correctly implemented). However, a further amendment would result in regulations that are difficult to understand and so hinder both industry and enforcement bodies. This would not be in line with the Government's better regulation objectives.

### Option 3: Introduce new consolidated regulations

- 5.3 This option would involve revoking existing regulations and amendments and remaking them so that food irradiation regulations are consolidated into a single Scottish Statutory Instrument (SSI). It would mitigate the potential risk to food standards by correctly implementing Article 9 of Directive 1999/2/EC (and therefore serve to ensure that consumer standards are maintained to the same standard as those in the European Community). In addition, having food irradiation regulations consolidated in one SSI would clearly state the legal requirements and aid both the industry and enforcement authorities.
- 5.4 Option 3 is the Agency's preferred option. It fully meets the policy objectives and endorses better regulation values.

### **Option 1: No intervention**

#### Costs and Benefits

- 5.5 There would be no additional costs or benefits to consumers or industry of no intervention.
- 5.6 No intervention would result in financial penalties being imposed on the UK Government by the European Court for the UK being in breach of its treaty obligations. The court would decide the penalty, which would be significant and probably in the form of a lump sum payment plus a daily penalty for the duration of the infringement. This cost has not been monetised; however, following infraction Greece recently received a lump sum penalty of 3 million euro plus a penalty of 32,000 euro for each day infringement continued thereafter.
- 5.7 The cost of licence application and consideration charges for a new entrant would remain at £5000 per application to irradiate a single food category, with a further £1500 for every additional food category contained in the application. It has been estimated that there will be one new entrant over the next five years. The cost of inspection visits would remain at £750 per visit. [Note that these costs remain in options 2 and 3, but are transferred from the irradiation industry to the Food Standards Agency]. There would continue to be a cost to industry of undertaking microbiological testing at the irradiation stage, which may duplicate testing carried out elsewhere in the supply chain and could delay processing by around three weeks. This cost is both the monetised cost of the testing (£1,500 assuming one consignment processed each year for five years) as well as the non-monetised costs associated with the long turn-around time.
- 5.8 No other financial, social or environmental costs are thought to be associated with this option.

### **Option 2: Amending the existing (previously amended) regulations**

#### Option 2 - Costs

- 5.9 Incremental costs are anticipated by further amending existing regulations due to the time taken for industry and enforcement bodies to familiarise themselves with and understand the revised requirements.

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- 5.10 There are 32 Local Authorities (LAs) in Scotland. It is estimated that one enforcement officer in each LA will need to read and understand the regulation and disseminate this information to key staff in the organisation and that it will take them three hours to do so. Their time is valued at £19.42 per hour (based on the 2008 Annual Survey of Hours and Earnings (ASHE) data for environmental health officers (EHOs) uprated by 30% to include overheads). This equates to an approximate one-off cost to LAs of £1870 (£59 per LA).
- 5.11 Currently there are no approved food irradiation facilities in Scotland (and only one in the UK, in England). However, there will be a cost to a new entrant, should one apply for an approval to irradiate food, as it will take them longer to read and understand the regulations. It is estimated that there will be one new entrant in the next five years. It is assumed that one person from the company would read and understand the amendments and that it will take them three hours to do so. Their time is valued at £24.32 (based on the 2008 Annual Survey of Hours and Earnings (ASHE) data for Production Managers uprated by 30% to include overheads). This equates to an approximate cost of £70 to new firms over the 5 years.
- 5.12 The proposed amendment would remove fees for applications (£5,000) and routine inspections (£750). Note that this is a transfer of costs from the irradiation industry to the Food Standards Agency. This transfer balances an additional cost to the enforcement agency with an equal benefit to the industry. The total transfer is £5,750 for each new entrant in current figures. It is assumed that there will be one new entrant over the next five years, so the figure is discounted for 2.5 years (to reflect the average expected time of entry), giving a present value of approximately £5,300. There will also be a transfer of £1,875 (£750 x 2.5) from the incumbent firm for bi-annual routine inspections, giving a present value of approximately £1,700. This gives a total transfer of £7,625 in current figures, or £7,000 in present value terms.
- 5.13 A further, non monetised, cost associated with producing a further amendment to existing regulations is that it may result in regulations that are difficult to understand and so could hinder both industry and enforcement bodies. No further financial, social or environmental costs are thought to be associated with this option.

### Option 2 - Benefits

- 5.14 Option 2 has a number of benefits over option 1; however, these could mostly not be monetised. One monetised benefit is the reduced cost to industry from the removal of fees, explained above. A second is the removal of duplicated microbiological testing at the irradiation stage, which is estimated at a saving of £1,500 (assuming one consignment processed per year for five years), which equates to approximately £1,380 in present value terms. In total, option 2 is estimated to lead to benefits of approximately £9,125 (present value £8,400) from the transfer of fees and the removal of duplicated testing over a five-year period.
- 5.15 The non monetised benefits are:
- The amendments may facilitate trade in irradiated foods (although few irradiated foods are currently imported or exported).
  - The amendments will reduce turn-around time from up to 25 days to 3 or 4 days by removing duplicated microbiological testing at the irradiation stage. This will lead to a reduction in storage costs and the potential for increased business by removing one of the barriers to competition with other processing industries.
  - The amendments will ensure that consumer protection in irradiated food is maintained.

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### Option 3: Introduce new consolidated regulations

#### Option 3 - Costs

- 5.16 There are 32 Local Authorities (LAs) in Scotland. It is estimated that one enforcement officer in each LA will need to read and understand the regulation and disseminate this information to key staff in the organisation and that it will take them two hours to do so. Their time is valued at £19.42 per hour (based on the 2008 Annual Survey of Hours and Earnings (ASHE) data for environmental health officers (EHOs) uprated by 30% to include overheads). This equates to an approximate one-off cost to LAs of £1250 (£39 per LA).
- 5.17 Currently there are no approved food irradiation facilities in Scotland (and only one in the UK, in England). However, there would be a one-off cost to new entrants arising from reading and familiarising themselves with the proposed regulations. It is assumed that one person in the company would need to read and understand the regulation and disseminate this information to key staff in the organisation and that it would take them two hours to do so. Their time is valued at £24.32 per hour (based on the 2008 Annual Survey of Hours and Earnings (ASHE) data for Production Managers uprated by 30% to include overheads). This equates to an approximate one-off cost to industry of £50.
- 5.18 The proposed new consolidated regulations would remove fees for applications (£5,000) and routine inspections (£750). Note that this is a transfer of costs from the irradiation industry to the Food Standards Agency. It is assumed that there will be one new entrant over the next five years, so the figure is discounted for 2.5 years (to reflect the average expected time of entry), giving a present value of approximately £5,300. There will also be a transfer of £1,875 (£750 x 2.5) from the incumbent firm for bi-annual routine inspections, giving a present value of approximately £1,700. This gives a total transfer of £7,625 in current figures, or £7,000 in present value terms.
- 5.19 In total, option 3 is estimated to lead to one-off costs of just over £16,650 from the costs of reading and understanding the amendment, and recurring costs of approximately £7,625 (present value £7,000) from the transfer of fees, over a five-year period. No further financial, social or environmental costs are thought to be associated with this option.

#### Option 3 – Benefits

- 5.20 Under option 3 there are various benefits which could mostly not be monetised. One monetised benefit is the reduced cost to industry from the removal of fees, explained above. A second is the removal of duplicated microbiological testing at the irradiation stage, which is estimated at a saving of £1,500 (assuming one consignment processed per year for five years), which equates to approximately £1,380 in present value terms. In total, option 3 is estimated to lead to recurring benefits of approximately £9,125 (present value £8,400) from the transfer of fees and the removal of duplicated testing over a five-year period.
- 5.21 The non monetised benefits are:
- The regulations will be easier for industry in general to use and comply with, and also make enforcement easier for the enforcement authorities.
  - It potentially facilitates more trade in irradiated foods (although few irradiated foods are currently imported or exported)

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- It will reduce turn-around time from up to 25 days to 3 or 4 days by removing duplicated microbiological testing at the irradiation stage. This will lead to a reduction in storage costs and the potential for increased business by removing one of the barriers to competition with other processing industries.
- It will ensure that consumer protection in irradiated food is maintained.
- A consolidation of the regulation may also reduce the time it takes for a new firm to read the regulation.

### **6 Administrative Burden Costs**

- 6.1 There are currently no licensed food irradiation facilities in Scotland. Preliminary informal consultation with the single licensed business in the UK (based in England) indicated there would be minimal impact. The business was made aware of the new proposals and its implications for their operation.

### **7 Economic, Social and Environmental Impact**

#### Small Firms Impact Test

- 7.1 These proposals would in principle apply to businesses of all sizes as no exemptions can be made under the European Directive 1999/2/EC. However, there are no small firms operating in the food irradiation market in the UK and the Agency is not aware of any small firms who would be likely to enter the market.

#### Competition Assessment

- 7.2 Although the proposal continues to impose certain obligations and responsibilities on businesses, it does not directly or indirectly restrict the number or range of suppliers able to operate in the market place. Any business or individual can apply for registration and provided they comply with the specific requirements and have their premises officially certified or inspected, they can market their products.
- 7.3 As one of the proposal's aims is to reduce administrative burdens on the industry, if anything it is more likely to enhance competition. This is because it will improve consistency and transparency in relation to the standards to be met.

### **8 Social Impact**

- 8.1 No negative impact health issues have been identified for this proposal which is not expected to alter the extent nor the physical process of food irradiation.
- 8.2 There are no limitations on meeting the requirements of the proposal on the grounds of race, as it does not impose any restrictions or requirements which a person of a particular racial background would find difficult to comply with.
- 8.3 There are no gender equality impacts associated with this proposal. Conditions apply equally to all individuals and businesses involved in the activities covered by the proposal.
- 8.4 There are no disability equality impacts arising from this proposal.
- 8.5 The proposal is consistent with the Human Rights Act 1998.
- 8.6 This proposal is expected to have no additional impact on rural communities. No policy adjustments are necessary to take account of rural needs or circumstances.

### **9 Environmental Impact**

- 9.1 The Food Standards Agency's remit is to protect the interest of consumers in relation to food safety, both now and in the future. In doing so, the Agency will take sustainable development into account in all of its activities and policy decisions. The



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proposal would have little, if any, impact on the delivery of the Government's five principles of sustainable development, on the environment or in relation to public health.

9.2 The proposal will have no significant effect on carbon emissions as the current nature and scale of food irradiation is likely to remain the same. The same applies to the Carbon footprint.

9.3 As the nature and scale of food irradiation is likely to remain the same, the proposal has no implications in relation to climate change, waste management, landscapes, water and floods, habitat, wildlife or noise pollution.

### **10 Enforcement, Sanctions and Monitoring**


10.1 This will not alter so far as facilities in the UK are concerned where the Food Standards Agency will remain the licensing and inspection authority. Local Authorities will enforce the provisions of the regulations other than those that relate to the licensing and inspection of UK food irradiation facilities.

### **11 Implementation and Review**

The policy is due to be implemented in July 2009 and will be reviewed three years after implementation in July 2012.

### **12 Declaration and publication**

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

Signed .....  .....

Date ..... 23/6/09 .....

SHONA ROBISON  
MINISTER FOR PUBLIC HEALTH & SPORT,  
HEALTH AND WELLBEING DIRECTORATE