

EXPLANATORY MEMORANDUM TO
THE FOOD IRRADIATION REGULATIONS (NORTHERN IRELAND) 2009

2009 No. 258

1. Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency Northern Ireland to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule is made under Articles 15(1) and (3), 16(1), 17(1)(c), 18(1)(b), 25, 26(3) and 47(2) of, and paragraphs 1 and 4(b) of Schedule 1 to, the Food Safety (Northern Ireland) Order 1991 and is subject to the negative resolution procedure.

2. Purpose of the Rule

2.1 The purpose of the Rule is to update and consolidate existing Regulations on food irradiation. These Regulations control the treatment of food with ionising radiation (X-rays, gamma rays or beams of electrons), referred to as food irradiation, and the importation and sale of irradiated food.

3. Legislative Background

3.1 The process of treating food with ionising radiation is currently regulated under The Food (Control of Irradiation) Regulations (Northern Ireland) 1992. These Regulations have been in place for nearly 20 years and have been amended several times. However, the current national Regulations do not correctly implement the European Directive (1999/2/EC) on Food Irradiation.

3.2 The main deficiencies in the legislation relate to the procedures by which the UK accepts irradiated food from third countries. Although food irradiation is not widely utilised in the UK, it is gaining favour in other parts of the world, such as the USA, India and in the Far East. It is therefore important that we ensure our procedures for accepting food irradiated outside the Community meets the legal standards set by the European Commission. In addition, these Regulations give effect to part of an Article requiring food to be in a suitably wholesome state.

3.3 The opportunity is also being taken to make a number of relatively minor changes intended to make the Regulations and the control system easier to understand. These include changing the licensing system and the food irradiation licence issued to irradiation facilities. Another alteration is to remove the provision for charging fees for routine official controls, e.g. fees for licence applications, variations, and inspections. These charges are not mandatory under EC legislation and this change meets with charging requirements under Article 27 of the Official Food and Feed Controls Regulations (EC Regulation 882/2004).

4. Parity or Replicatory Measure

4.1 This Rule applies to Northern Ireland only. Parallel legislation is being made in England, Scotland and Wales.

5. European Convention on Human Rights

- 5.1 As this rule is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Policy background

- What is being done and why

6.1 European Directive 1999/2/EC established a harmonised framework of controls on food irradiation. It covers areas including the conditions for treatment, the rules governing the approval and control of irradiation and the trade of irradiated foods, which are implemented in these Regulations. Irradiation can be used to reduce food-borne disease by destroying pathogenic organisms. It can also delay ripening, prevent sprouting and delay other deterioration. Finally, irradiation can be used as a phytosanitary measure. Directive 1999/2/EC also establishes the rules on labelling of irradiated food and food ingredients, but these are implemented in the UK by the Food Labelling Regulations 1996 (as amended), as regards products ready for the final consumer.

6.2 European Directive 1999/3/EC established an initial positive list of foods that could be irradiated in accordance with Directive 1999/2/EC and freely traded within the European Union. Until a final positive list is established, Directive 1999/2/EC permits member states to maintain pre-existing national authorisations of food which may be treated with ionising radiation. These Regulations maintain a further six categories of food, in addition to the Community wide category of dried aromatic herbs, spices and vegetable seasonings.

6.3 The treatment and sale of irradiated food has not been widely adopted in the UK; there is a single licensed facility in the UK, which is licensed to irradiate a variety of herbs and spices and few irradiated foods are on sale on the UK market. However, it is gaining favour in other parts of the world, such as the USA, India and in the Far East.

6.4 Changes to the Regulations are necessary at this time to correct deficiencies in the current Regulations which do not correctly implement the European Directive, as laid out in paragraph 3.2 of this memorandum.

- Consolidation

6.5 This rule will revoke and re-enact in consolidated form the provisions of the Food (Control of Irradiation) Regulations (Northern Ireland) 1992 and Regulations 2 to 12 of the Food Irradiation Provisions Regulations (Northern Ireland) 2000.

7. Consultation

7.1 The Agency has conducted a preliminary informal consultation with the single current food irradiation facility and their views have been considered in developing these policy options.

7.2 A full 12-week public consultation was undertaken in Northern Ireland between the 4 February 2009 and 1 May 2009. No responses were received.

8. Guidance

- 8.1 As this is predominantly a consolidation and updating of existing legislation and the market in irradiated foods is small, no specific guidance has been produced to accompany this legislation.
- 8.2 Existing guidance on importing irradiated foods, which is available on the Food Standards Agency website, will be updated to reflect the changes caused by these Regulations. District Councils will be notified of this revised guidance.

9. Equality Impact

- 9.1 These regulations will apply in equal measure to all Section 75 groups. It is not expected that any of these changes will impact differentially across any of the section 75 groups.

10. Impact

- 10.1 The impact on business is positive. There will be a saving to food irradiation facilities due to the removal of fees for licensing and routine inspection. There will be no impact on charities or voluntary bodies.
- 10.2 The impact on the public sector is negative. The fees for licensing and routine inspection will be transferred to the Food Standards Agency. There will also be an initial outlay to food enforcement bodies due to the time taken for an officer to read and understand the new Regulations and disseminate this information to key colleagues.
- 10.3 An Impact Assessment is attached to this memorandum. This IA has been prepared by FSA colleagues in England but it is believed to be equally representative of the situation in Northern Ireland.

11. Regulating small business

- 11.1 The legislation applies to small business. 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.

12. Contact

Mervyn Briggs at the Food Standards Agency NI, Tel: 028 9041 7742,

Email: mervyn.briggs@foodstandards.gsi.gov.uk or

Esther Chartres, Tel: 028 9041 7737

Email: esther.chartres@foodstandards.gsi.gov.uk

Summary: Intervention & Options

Department /Agency: Food Standards Agency	Title: Impact Assessment of The Food Irradiation (England) Regulations 2009	
Stage: Final	Version: #2	Date: 19 June 2009
Related Publications: Food Irradiation - Consumer Committee Report - 2 March 2004 (http://www.food.gov.uk/multimedia/pdfs/cc_foodirradiation.pdf)		

Available to view or download at:

<http://www.food.gov.uk>

Contact for enquiries: Christopher Thomas

Telephone: 020 7276 8728

What is the problem under consideration? Why is government intervention necessary?

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.

Differences between national laws relating to food irradiation (and its conditions of use) hinder the free movement of foods in the European Union and may create unequal competition, directly affecting the operation of the internal market. Intervention is necessary in order to remove these differences between Member States and guarantee a high level of consumer protection.

What are the policy objectives and the intended effects?

The policy objectives are to: correctly implement Article 9 of European Directive 1999/2/EC into domestic law; simplify domestic food irradiation regulations; and update regulations where necessary (e.g. the arrangements for charging fees for official controls are now covered by Commission Regulation 882/2004). The intended effect is to correctly introduce measures aimed at both maintaining consumer protection and facilitating the smooth operation of the market.

What policy options have been considered? Please justify any preferred option.

[1] Do nothing.

[2] Produce a further amendment to existing regulations in order to alter domestic regulations.

[3] Revoke existing regulations and amendments and remake a new Statutory Instrument that fully implements the Directives and consolidates existing food irradiation regulations.

Option [3] is preferred; it is the one that best meets the policy objective of correctly implementing European Directives and simplifying current regulations. This option is in line with the Government's better regulation agenda.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? July 2012

Ministerial/CEO Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister/Chief Executive*:

.....Date:

* for Impact Assessments undertaken by non-ministerial departments/agencies and NOT being considered by Parliament

Summary: Analysis & Evidence

Policy Option: 3

Description: Revoke existing regulations and amendments and remake a new statutory instrument

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups' One-off cost borne by Local Authorities: ≈ £15,100; One-off cost borne by Port Health Authorities ≈ £1,500; One-off cost to incumbent firm: ≈ £50; Additional cost to enforcement authority due to removal of licensing and inspection fees: ≈ £ 7,625
	One-off (Transition)	Yrs	
	£ 3,300	5	
	Average Annual Cost (excluding one-off)		
	£ 1,525		Total Cost (PV) £ 23,700
Other key non-monetised costs by 'main affected groups'			

BENEFITS	ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups' Removal of licensing and inspection fees reduced cost to firms ≈ £ 7,625 (note this is a transfer of costs from industry to the Agency). Removal of duplicated microbiological testing at the irradiation stage ≈ £1,500.
	One-off	Yrs	
	£ 0	5	
	Average Annual Benefit (excluding one-off)		
	£ 1,825		Total Benefit (PV) £ 8,400
Other key non-monetised benefits by 'main affected groups' The regulations will be easier for industry to use and comply with, it will also make enforcement easier and avoid infraction. Consolidation will reduce the time for a new firm to read the regulations. It may also facilitate trade in irradiated foods (however few irradiated foods are currently traded). There may be a reduction in turn-around time due to removal of duplicated microbiological testing. It will maintain consumer protection.			

Key Assumptions/Sensitivities/Risks One new entrant firm is expected over the next five years and one consignment of irradiated food processed each year.

Price Base Year 2008	Time Period Years 5	Net Benefit Range (NPV) £ -15,300	NET BENEFIT (NPV Best estimate) £ -15,300
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What is the geographic coverage of the policy/option?		England	
On what date will the policy be implemented?		31/07/09	
Which organisation(s) will enforce the policy?		Local Authorities / Port Health Authorities/ FSA	
What is the total annual cost of enforcement for these organisations?		£ 4,850	
Does enforcement comply with Hampton principles?		Yes	
Will implementation go beyond minimum EU requirements?		No	
What is the value of the proposed offsetting measure per year?		£ N/A	
What is the value of changes in greenhouse gas emissions?		£ N/A	
Will the proposal have a significant impact on competition?		No	
Annual cost (£-£) per organisation (excluding one-off)	Micro 0	Small 0	Medium £ -910
Are any of these organisations exempt?	No	No	N/A

Impact on Admin Burdens Baseline (2005 Prices)		(Increase - Decrease)	
Increase of	£ 0	Decrease of	£ 0
		Net Impact	£ 0

Key: Annual costs and benefits: Constant Prices (Net) Present Value

Evidence Base (for summary sheets)

Reason for Intervention

- 1) The rationale for intervention is 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) 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.
- 3) Amendments to English regulations 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 (referred to as “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 regulations state that it is the UK 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 the potential for inconsistent standards being applied within the Community.
- 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.
- 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 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.

- 6) The Agency's 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

- 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.
- 8) The goal is to achieve the following three aims;
- Correctly implement Article 9 of Directive 1999/2/EC into national regulations. Article 9 requires the European Community's prior approval of food irradiation facilities in third countries (national regulations 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).
 - Up-date and consolidate The Food (Control of Irradiation) Regulations as amended, in the interests of clarity and simplification.
- 9) It is not intended to alter labelling requirements for irradiated foods contained in food labelling regulations.

Background

- 10) 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.
- 11) Prior to these Directives, food irradiation was permitted in Great Britain by The Food (Control of Irradiation) Regulations 1990. The domestic regulations were amended in 2000 in order to bring them into line with Directives 1999/2/EC and 1999/3/EC. The amendments were minor as the EC Directives were based on British food irradiation regulations. However, the amendments did not adequately address procedures for dealing with third countries exporting irradiated food.
- 12) 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 the European Directives. 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.

Up-date the regulations

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

Approval of Third Country Facilities

- 14) 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

- 15) 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

- 16) 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 Regulations to give effect to European Regulation 882/2004 came into force on 1 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 no longer to 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).
- 17) This proposal will affect the irradiation industry and The Food Standards Agency. There is one authorised food irradiation facility in England and removing licensing and inspection fees is a transfer of costs to the Agency.

General Update to the Regulations

- 18) 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.
- 19) 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 vegetable seasonings', so as to meet the exact description in the Annex of Directive 1999/3/EC.
- 20) 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.

- 21) 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.

Options

Option 1: No intervention

- 22) 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. UK 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

- 23) This would involve producing new regulations to amend further The Food (Control of Irradiation) Regulations 1990 and thereby avoid infraction proceedings and 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

- 24) This option would involve revoking existing regulations and amendments and remaking them so that food irradiation regulations are consolidated into a single Statutory Instrument (SI). It would avoid infraction proceedings and 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 Statutory Instrument would clearly state the legal requirements and aid both the industry and enforcement authorities.
- 25) Option 3 is the Agency's preferred option. It fully meets the policy objectives and endorses better regulation values.

Costs and benefits of options

Option 1

- 26) There would be no additional costs or benefits to consumers or industry of no intervention..
- 27) The cost of licence application and consideration charges for a new entrant would remain at £5,000 per application to irradiate a single food category, with a further £1,500 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 routine 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.
- 28) No other financial, social or environmental costs are thought to be associated with this option.

Option 2

Costs:

- 29) 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.
- 30) There are 389 Local Authorities (LAs) in England. It is estimated that one enforcement officer in each local authority 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 £22,700
- 31) There are 39 Port Health Authorities (PHAs) in England. It is estimated that one enforcement officer in each of the 39 PHAs is expected to read and understand the regulation and disseminate this information to key staff in the organisation and that it takes them 3 hours to do so. The assumption is made that their wage rates are the same as EHOs at the rate of £19.42 per hour as described above. This equates to an approximate one-off cost to PHAs of £2,300.
- 32) There will be a one-off cost to industry arising from reading and familiarising themselves with the proposed regulations. There is only one approved food irradiation facility in England. 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 three 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 £70.
- 33) There will also 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.

- 34) 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 is reflected in the figures by showing the additional cost to the enforcement agency and 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.
- 35) In total, option 2 is estimated to lead to one-off costs of just over £25,000 from the costs of reading and understanding the amendment, and costs of approximately £7,625 (present value £7,000) from the transfer of fees, over a five-year period.
- 36) 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.

Benefits:

- 37) Under option 2 there are 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.
- 38) By fully implementing the Directive, the UK Government would avoid financial penalties by the European Court for the UK being in breach of its treaty obligations (The court would decide the penalty, it 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 saving has not been monetised.
- 39) Other 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.

Option 3

Costs:

- 40) At the 389 Local Authorities (LAs) in England, it is estimated that it will take one enforcement officer in each LA 2 hours to read and understand the regulation and disseminate this information to key staff in the organisation. Based on the valuation of their

time outlined under Option 2, this equates to an approximate one-off cost to LAs of £15,100.

- 41) At the 39 Port Health Authorities (PHAs) in England, it is estimated that it will take one enforcement officer in each PHA 2 hours to read and understand the regulation and disseminate this information to key staff in the organisation. Based on the valuation of their time outlined under Option 2, this equates to an approximate one-off cost to PHAs of £1,500.
- 42) There will be a one-off cost to industry arising from reading and familiarising themselves with the proposed regulations. There is only one approved food irradiation facility in England. It is estimated that it will take one person in the company 2 hours to read and understand the regulation and disseminate this information to key staff in the organisation. Based on the valuation of their time outlined under Option 2, this equates to an approximate one-off cost to industry of £50.
- 43) 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. This transfer is reflected in the figures by showing the additional cost to the enforcement agency and 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 ($£750 \times 2.5$) 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.
- 44) 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.

Benefits:

- 45) 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.
- 46) By fully implementing the Directive, the UK Government would avoid financial penalties by the European Court for the UK being in breach of its treaty obligations (The court would decide the penalty, it 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 saving has not been monetised
- 47) Other 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)
 - 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 maintain consumer protection from irradiated foodstuffs.
- A consolidation of the regulation may also reduce the time it takes for a new firm to read the regulation.

Administrative Burden Costs

- 48) Preliminary informal consultation with the single business in England licensed to irradiate herbs and spices indicated there would be minimal impact. The business was made aware of the new proposals and its implications for their operation.

Consultation

- 49) The Agency has conducted a preliminary informal consultation with the single current food irradiation facility and their views have been considered in developing these policy options.
- 50) A full 12-week public consultation has been undertaken on the SI. During this time, the Agency has also engaged with stakeholders on a less formal basis.
- 51) All All responses received during the consultation exercise were given careful consideration and the impact assessment has been amended as necessary. The responses, and the Agency's comments on issued raised, have been summarised as an Annex to this IA and have also been published on the Agency's website:
<http://www.food.gov.uk/multimedia/pdfs/consultationresponse/consrespfoodirradregs09.pdf>

Enforcement

- 52) 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 and Port Health Authorities will enforce the provisions of the Regulations other than those that relate to the licensing and inspection of UK food irradiation facilities.

Implementation and Review

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

Specific Impact Tests: Checklist

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	Yes
Sustainable Development	No	Yes
Carbon Assessment	No	Yes
Other Environment	No	Yes
Health Impact Assessment	No	Yes
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

Competition Assessment

- 54) 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.
- 55) 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.

Small Firms Impact Test

- 56) 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.

Legal Aid

- 57) The proposal does not create new criminal sanctions or civil penalties.

Sustainable development

- 58) 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 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.

Carbon Impact Assessment

- 59) 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.

Other Environmental Issues

- 60) 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.

Health Impact Assessment

- 61) No negative health issues have been identified for this proposal which is not expected to alter the extent nor the physical process of food irradiation.

Race equality issues

- 62) 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.

Gender equality issues

63) 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.

Disability equality issues

64) There are no disability equality impacts arising from this proposal.

Human Rights

65) The proposal is consistent with the Human Rights Act 1998.

Rural Proofing

66) 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.