Summary: Intervention & Options

Department /Agency:	Title:
Food Standards Agency	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*:

X ..... Date: X 24/6/09

* 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	
One-off (Transition)	**Yrs**
£ 3,300	5
Average Annual Cost (excluding one-off)	
£ 1,525	

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

Total Cost (PV) **£ 23,700**

Other **key non-monetised costs** by 'main affected groups'

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ 0	5
Average Annual Benefit (excluding one-off)	
£ 1,825	

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.

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**

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**	Large **0**
Are any of these organisations exempt?	No	No	N/A	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 <u>not</u> 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 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.

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	***Results in Evidence Base?***	***Results annexed?***
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

Annexes

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.

The Food Irradiation (England) Regulations 2009 (DRAFT) SUMMARY REPORT OF RESPONSES TO CONSULTATION FROM STAKEHOLDERS

The Food Irradiation (England) Regulations 2009 (DRAFT) consultation was issued on 29 January 2009 and closed on 27 April 2009. The Food Irradiation (England) Regulations 2009, which will replace The Food (Control of Irradiation) Regulations 1990, as amended, in as far as they apply in relation to England. The purpose of this consultation was to seek views and comments on the new Regulations governing the irradiation of food in England. Parallel regulations are also being produced in Scotland, Wales and Northern Ireland and consultations on these ran concurrently.

1 The FSA is grateful to those stakeholders who responded and sets out in the table below responses in order of the issues considered.

2 The key proposals on which the consultation sought views were:

- To amend the procedures for the approval of third country facilities to fully implement Directive 1999/2/EC.
- To replace the current licensing system with a simpler system and a shorter style licence where most of the legal requirements are contained in the Statutory Instrument, rather than the licence.
- To discontinue charging for routine official controls e.g. fees for licence applications, variations and for inspections.
- To consolidate the existing Regulations and amendments and make various drafting improvements.

3 The Food Standards Agency's considered responses to stakeholders' comments are given in the last column of the table. A summary of changes to the original proposal(s) resulting from stakeholder comments is set out in the final table.

4 A list of stakeholders who responded can be found at the end of the document.

Issue: Food must be in a suitably wholesome state

Respondent	Comment	Response
Dieter A.E. Ehlermann	The operator of an irradiation facility just sells dose. As an 'applicant' such operator would never be in a position to show and to apply methods to ensure that the food in a 'suitable wholesome state'. It would be consequent and prudent to put the burden to proof that a food is in a 'suitable wholesome state' with the owner of the food. In particular its microbial status should be considered; otherwise the allegation could arise, that the production was done negligent, the inspection system was not tight enough, and the final irradiation step is only used to clean-up ('zap') the product.	**Why is this requirement placed on the irradiation facility?** The requirement that food is in a suitably wholesome state before irradiation ensures that food is not placed on the market using irradiation treatment as a false reassurance of safety. This requirement is placed on the irradiation facility as it is the facility that is licensed to irradiate food and can be held accountable under these regulations. However, the person who ultimately places the food on the market would, as in any situation, be bound by the requirements of general food law to ensure the food they sell is safe. **This requirement does not appear in other member states regulations?** This requirement is contained in the European Directive 1999/2/EC upon which the regulations of all European Union countries are based. **What method needs to be used to determine food is suitably wholesome?** The draft regulations require that the applicant for an irradiation licence must employ some method to ensure the food they treat is suitably wholesome. This method will not necessarily require testing by the irradiation facility, but could, if appropriate, form part of a formal agreement with the person who presents the food to be
Isotron Ltd (John Harries)	Concerned there is still a requirement to undergo some testing to ensure the food is in a suitably wholesome state. We have found this requirement has significantly contributed to the lack of adoption of food irradiation in the UK. There appears to no such requirement in the reminder of the European Union including some of the countries in which we operate. The change proposed is welcome in the respect that the applicant now has the responsibility for proving that the food is in a wholesome state but we are concerned at the lack of clarity in the nature of what evidence of the wholesome state of the food prior to irradiation would be required. This is not required with any other type of product that we process including critical medical devices and pharmaceutical products.	

Respondent	Comment	Response
The Panel on Gamma and Electron Irradiation (Cathie Deeley)	Food must be in a suitably wholesome state – some of our members with plant operating in mainland Europe comment that there appears to be no such requirement applied in the remainder of the European Union. Food must be in a suitably wholesome state – the proposed change in legislation placing responsibility for the wholesomeness of the food product with the producer is welcomed by plant operators. However, they are concerned by the lack of clarity about what evidence will be required to confirm the wholesome state of the food prior to irradiation.	irradiated. The method that is deemed to be appropriate will depend on several factors including the purpose of treatment and the type and nature of the food. Consideration may also be made to other legislative requirements, for example hygiene or microbiological standards.

Issue: Approval of third country facilities

Respondent	Comment	Response
Dieter A.E. Ehlermann	Approval now of third country facilities only and directly by the EC is an improvement. The transition question would be whether there are presently any 3rd-country facilities recognized by UK but not by the EC.	No third-country facilities have been recognised by the UK which have not first been approved by the European Commission.

Respondent	Comment	Response
The Panel on Gamma and Electron Irradiation (Cathie Deeley)	Approval of third country facilities – experience has shown that the application route for licensing through the European system is often tortuous for plant operators of third country facilities. The concern is that a plant operator who wishes to irradiate fruit for export to the UK under the maintained UK approvals will find the European licensing system impossible to initiate.	The approval of third country food irradiation facilities by the European Community is for the approval of the facility itself and is not related to the type of food. Facilities with existing European approval will not need to be re-approved to import foods other than dried aromatic herbs, spices and vegetable seasonings into the UK, but in addition to having European approval they must comply with the conditions in Regulation 5(e)(ii) of the draft regulations. These additional conditions are maintained as existing national restrictions on trade as permitted by Article 4(7) of Directive 1999/2/EC.
East of England Trading Standards Association (Marie Hill)	Including the list of approved facilities in Schedule 3 and 4 are very useful but will need to be kept up-to-date.	Noted.

Issue: Approved categories of food

Respondent	Comment	Response
Dieter A.E. Ehlermann	Highlights different approaches to dose limits for certain categories in different member states, for example potatoes and onions.	The permitted dose for bulbs and tubers (which includes potatoes and onions) in the UK is 0.2 kGy, which is based on the recommendation in the Report of the Scientific Committee of Food (Eighteenth Series) published in 1986.
	'Cereals' may need an explanation, not necessarily a definition. The terminology 'cereals' should be replaced by 'corn and grain' in order to be clear and understandable. Or is their any EC-definition in English which could be referenced?	'Cereals' is the term used in the Report of the Scientific Committee of Food (Eighteenth Series) published in 1986. We consider that the ordinary meaning of 'cereals' is sufficiently clear and does not require further clarification.

Respondent	Comment	Response
	In the UK only the seven categories of food (as considered by the SCF in 1986) have been implemented in the present regulation. However, this list was supplemented by SCF in 1992 and 1998; the UK has not yet implemented all of the items with a SCF-recommendation. For this reason it would be quite appropriate to follow the lead of Belgium (cf. OJ of the EU (12.5.2006) C 112/6 - C 112/7) and to complete (expand the list of permitted items to contain any other item already permitted in another EU Member State).	The seven categories are based on the recommendations in the Report of the Scientific Committee of Food (Eighteenth Series) published in 1986. Until the finalisation of the EU wide positive list and as the Agency is not aware of any demand from the food industry to permit the irradiation of additional food categories, we do not consider it is appropriate to extend the list at this time. Should there be any requests to irradiate a food not within one of the existing seven categories; the Agency would give consideration to that request based on the best available evidence and in line with the provisions of Article 4 of Directive 1999/2/EC.
	In detail no.12 [paragraph inviting comments from importers and manufacturers] it is not appropriate to restrict the expected comments to the 'seven permitted categories'; EC has now a single market! It would be an unnecessary bureaucratic burden and a discrimination against EC-competitors if UK-companies would have to obey to such unjustified restrictions.	No interest was shown by food industry stakeholders to include additional categories to the permitted list of irradiated foods. The consultation was sent to a range of stakeholders, not just those with an interest in one of the seven permitted food categories, and was openly available on the FSA website.
	NOTE: I count less than seven categories in the list for UK as published in the OJ! The present list of national clearances is not in congruence with the categories used by the SCF and the EC.	The seven approved categories match the descriptions used in the original Report of the Scientific Committee of Food (Eighteenth Series) published in 1986. The Official Journal list of Member States' authorisations referred to (OJ of the EU (12.5.2006) C 112/6 - C 112/7) includes all seven UK categories.
East of England Trading Standards Association (Marie Hill)	What is a 'vegetable seasoning'? Is it any seasoning which is used to flavour vegetables and therefore based on its use rather than its nature, ie if the same seasoning is used to flavour another (non vegetable food) is it still a vegetable seasoning?	A vegetable seasoning is a seasoning whose ingredients consist wholly of vegetable matter.

Respondent	Comment	Response
	This is an ideal opportunity to include herbal remedies, along side food supplements, in the list of products which cannot be irradiated. Sampling surveys have shown that herbal remedies from Asia are frequently irradiated but since they fall outside of food controls there is nothing enforcement agencies can do to ensure the integrity of the irradiation process nor the labelling of the treatment to inform consumer choice. A consumer does not differentiate between herbal remedies and food supplements, both are ingested and both need regulating in the same way with regards to irradiation. See Imported food survey of Foods from Asia, funded by the FSA, Norfolk CC 07/08 for examples.	Certain herbal remedies can fall under the category of medicinal products. These draft Food Irradiation (England) Regulations are to be made under the Food Safety Act 1990, which does not cover medicinal products.
	Can you clarify whether herbs, spices or vegetable seasonings used as ingredients within Food Supplements are permitted to be irradiated.	It is our opinion that a product which falls under the definition of a dried aromatic herb, spice or vegetable seasoning could be irradiated before being included as an ingredient in another food product, including food supplements, provided that the irradiation has been carried out in accordance with the regulations. Any product containing this irradiated ingredient would have to be labelled such that the name of the ingredient is accompanied by the word "irradiated" or the words "treated with ionising radiation", as required by the Food Labelling Regulations 1996.

Issue: Other comments

Respondent	Comment	Response
Trading Standards South East - Mrs Kathryn Heirons	The Partnership has concerns that the time taken to disseminate information to staff within enforcement authorities has not been taken into account in the consultation. In the recent Contaminants in Food consultation, time was mentioned as a factor as follows, 'In addition we have estimated that each person uses a further hour for dissemination to key staff within the organisation.' The Partnership is of the opinion that this statement should also be included for this consultation.	We have assumed 2 hours in Option 3 (3 hours in Option 2) to read and understand the regulations and this time includes the time to disseminate the information as required. The time of 2 hours is equal to the total time in the Contaminants in Food consultation. The Impact Assessment will be amended to clarify that the time to disseminate information has been taken into account in our cost analysis.
Dieter A.E. Ehlermann	Should be part of a broader EU debate on food irradiation including finalizing the EC-directives on food irradiation and adapting a 'final' positive list. EC Directives and the draft regulations do not meet the 2003 Codex Alimentarius standard on irradiated food, which allows for irradiation of any food at any dose. The terminology of 'overall average dose' should be removed without any replacement, as reflected in the 2003 Codex Alimentarius. The present labelling regulations relating to irradiated food are quite unnecessary and an unjustified and bureaucratic burden for food control, causing also avoidable costs: The point is that labelling of ingredients is required down to the last molecule of an ingredient which had been irradiated, even in cases where the counterpart below a certain level of content treated by some other method as e.g. chemical fumigation needs not to be labelled at all.	The UK must comply with the present EC Directives and these regulations have been drafted accordingly. We note these concerns and have advised the Commission of these comments. As noted by the respondent, the labelling regulations are beyond the scope of this consultation. However, these comments have been noted.

Respondent	Comment	Response
	The present draft of the (UK) regulations is lacking any provisions according to art.7 no.3 of the EC directives in particular about - checks in licensed facilities - checks at the market level - reports about the methods used for detection and the assessment of their usability	It is not necessary to specify responsibilities of the UK authorities of this kind in legislation since the obligations in question that the Directive imposes have direct effect on the Member States, and it is up to those States to determine in whatever way they chose any division of responsibilities.
LACORS (Les Bailey)	Support proposed Option 3 – No additional comments.	Noted
East of England Trading Standards Association (Marie Hill)	It would be beneficial for enforcement agencies to have powers to detain product as well as seize it, similar to those in Products Of Animal Origin legislation. This would be particularly beneficial where suspected illegally irradiated product is found e.g. at retail/wholesale level and we await documentation which has been requested e.g. from the importer. Accompanying guidance notes would also be beneficial. We agree with the time estimated.	The Food Safety Act 1990, under which these regulations are to be made, does not include powers to detain products. We do not consider that it would be appropriate to invoke powers in addition to those that parliament has seen fit to provide in this Act. Noted. Noted.
The Panel on Gamma and Electron Irradiation (Cathie Deeley)	The Panel supports option 3. To revoke existing regulations and amendments and remake a new Statutory Instrument that fully implements the Directives and consolidates existing food irradiation regulations.	Noted.

SUMMARY OF CHANGES MADE:

ACTIONS TO BE IMPLEMENTED:
• Impact assessment amended to clarify that the time taken to disseminate information to staff within enforcement authorities has been assessed.

List of Respondents:

		Method of Response	Date Received
1.	Trading Standards South East - Mrs Kathryn Heirons	Email	07/04/2009
2.	Dieter A.E. Ehlermann	Email	16/04/2009
3.	LACORS (Les Bailey)	Letter	17/04/2009
4.	Isotron (John Harries)	Email	17/04/2009
5.	East of England Trading Standards Association (Marie Hill)	Email	20/04/2009
6.	The Panel on Gamma and Electron Irradiation (Cathie Deeley)	Email	27/04/2009