

**Explanatory Memorandum**  
**The Food Irradiation (Wales) Regulations 2009**

**This Explanatory Memorandum has been prepared by the Food Standards Agency Wales and is laid before the National Assembly for Wales in accordance with Standing Order 24.1.**

**1. Description**

- 1.1 These Regulations update and consolidate existing Regulations on food irradiation. These Regulations restrict 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.

**2. Matters of special interest to the Subordinate Legislation Committee**

- 2.1 None.

**3. Legislative Background**

- 3.1 The process of treating food with ionising radiation is currently regulated under The Food (Control of Irradiation) Regulations 1990. 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 two European Directives (1999/2/EC and 1999/3/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 meet 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 before irradiation takes place.

- 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. An additional alteration is to remove the provision for charging fees for routine official controls, e.g. fees for licence applications, variations, and inspections. This change meets with charging requirements under Article 27 of the Official Food and Feed Controls Regulations (EC Regulation 882/2004).

**4. Purpose and intended effect of the legislation**

- 4.1 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.

- 4.2 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.
- 4.3 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.
- 4.4 During a 12-week public consultation throughout the UK on these Regulations, a total of six responses were received. Due to the minimal use of this technology, mainstream media attention in the UK is currently low.
- 4.5 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.
- 4.6 This instrument consolidates and revokes the Food (Control of Irradiation) Regulations 1990 (in so far as they apply to Wales) and revokes regulations 2 to 16 of the Food Irradiation Provisions (Wales) Regulations 2001.

## **5. Implementation**

- 5.1 It is intended that these Regulations should come into force on 31st July 2009. Parallel legislation is also being made to come into force in England, Scotland and Northern Ireland.
- 5.2 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.

## **6. Consultation**

- 6.1 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.
- 6.2 A full 12-week public consultation was undertaken between the 29 January and 27 April 2009. There were no responses received within Wales. Across the UK a total six stakeholders responded to the public consultation process. Three of these responses from bodies representing enforcement authorities and one was from the single UK licensed food irradiation facility. The final two responses were from a body and an individual who both represent expertise in irradiation processing.
- 6.3 The general response was in favour of the policy objectives to update the regulations and remove the charging of fees. Some comments were received

regarding the underlying European Directives, which have been shared with the Commission

## **7. Regulatory Impact Assessment**

### **8. Options**

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

This option would not mitigate the risks to food standards which are designed to protect consumers (i.e. Directives 1999/2/EC and 1999/3/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.

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

This would involve producing new regulations to amend further The Food (Control of Irradiation) Regulations 1990 and thereby mitigate the potential risk to food standards which are designed to protect consumers (i.e. Directives 1999/2/EC and 1999/3/EC would not 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.

#### **8.3 Option 3: Introduce new consolidated regulations**

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 mitigate the potential risk to food standards by correctly implementing Directives 1999/2/EC and 1999/3/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.

8.4 Option 3 is the Agency's preferred option. It fully meets the policy objectives and endorses better regulation values.

### **9. Sectors and groups affected.**

9.1 The primary business sector that will be affected by the Regulations will be those that operate irradiation facilities, importers of any of the products in the seven permitted categories of food, in particular dried aromatic herbs, spices and vegetable seasonings, or manufacturers of products using these imported ingredients. However, there is only one authorised food irradiation facility within the UK. This is not in Wales.

9.2 These proposals will 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.

9.3 The impact on the public sector is negative. There will be a saving to food irradiation facilities due to the removal of fees for licensing and routine inspection. The fees for licensing and routine inspection will be transferred to the Food Standards Agency.

Local authorities and port health authorities are responsible for enforcing much of the food safety and food hygiene legislation. They are also responsible for enforcing the provisions of these proposed regulations, other than those that relate to the licensing of UK food irradiation facilities, and as such will also be affected by the proposals. It is anticipated that the proposed regulations will be easier for industry in general to use and comply with, and also make the enforcement easier for the enforcement authorities. There will be an initial outlay to business, based on the same principles as those for Local Authorities and port health authorities, due to the time taken for an officer to read and understand the new regulations and disseminate this information to key colleagues.

9.4A competition filter assessment has been carried out and 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.

9.5 These proposals have no particular impact on charities or voluntary bodies, nor on rural areas or members of any particular racial group.

## **10. Benefits**

### Option 1

10.1 There would be no additional costs or benefits to consumers or industry of no intervention. However, the UK Government could be open to financial penalty from the European Courts for not fully implementing the Directive previously mentioned. Assuming that the European Courts do not impose a fine for the UK being in breach of its treaty obligations, the base line cost is estimated as zero.

10.2 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.

10.3 No other financial, social or environmental costs are thought to be associated with this option.

### Option 2

10.4 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.

10.5 The non monetised benefits are:

- The amendments may facilitate trade in irradiated foods (although few irradiated foods are currently imported or exported).
- The amendments will reduce turn-around time from up to 25 days to 3 or 4 days by removing duplicated microbiological testing at the irradiation stage. This will lead to a reduction in storage costs and the potential for increased business by removing one of the barriers to competition with other processing industries.
- The amendments will ensure that consumer protection in irradiated food is maintained.

### Option 3

10.6 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.

10.7 The non monetised benefits are:

- The regulations will be easier for industry in general to use and comply with, and also make enforcement easier for the enforcement authorities.
- It potentially facilitates more trade in irradiated foods (although few irradiated foods are currently imported or exported)
- 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.

## **11. Costs**

11.1 **Option 1:** See Paragraphs 10.1 to 10.3 above.

11.2 **Option 2:** 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.

### **Administrative Costs**

11.3 There will be a small one-off cost to businesses and enforcement authorities for reading and familiarising themselves with the new Regulations.

## Costs to Enforcement Authorities

- 11.4 There are 22 Local Authorities (LAs) in Wales. 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 £1,300
- 11.5 There is 1 Port Health Authorities (PHA) in Wales. It is estimated that one enforcement officer 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 the PHA of £60.

## Costs to Industry

- 11.6 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 the UK. 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.
- 11.7 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.
- 11.8 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.
- 11.9 In total, option 2 is estimated to lead to one-off costs of approximately £1,300 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.

- 11.10 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.
- 11.11 **Option 3:** As with Option 2, there are 22 Local Authorities (LAs) in Wales. 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 two hours to do so. Their time is valued at £19.42 per hour (based on the 2008 Annual Survey of Hours and Earnings (ASHE) data for environmental health officers (EHOs) uprated by 30% to include overheads). This equates to an approximate one-off cost to LAs of £1,300.
- 11.12 There is 1 Port Health Authorities (PHA) in Wales. It is estimated that one enforcement officer in the PHA 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 the PHA of £60.
- 11.13 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 the UK. It is assumed that one person in the company would need to read and understand the regulation and disseminate this information to key staff in the organisation and that it would take them two hours to do so. Their time is valued at £24.32 per hour (based on the 2008 Annual Survey of Hours and Earnings (ASHE) data for Production Managers uprated by 30% to include overheads). This equates to an approximate one-off cost to industry of £50.
- 11.14 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.
- 11.15 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.

## **12. Guidance on the proposed Regulations**

- 12.1 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. Port Health Authorities will be notified of this revised guidance.

## **13. Consultation**

- 13.1 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.
- 13.2 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.
- 13.3 All responses received during the consultation exercise were given careful consideration and the Regulatory Impact Assessment has been amended as necessary. The responses, and the Agency's comments on issues raised, have been published on the Agency's website:

<http://www.food.gov.uk/consultations/consulteng/2009/draftfoodirradiationregs09>

## **14. Enforcement**

- 14.1 This will not alter so far as facilities in the UK are concerned where the Food Standards Agency will remain the licensing and inspection authority. Local Authorities 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.

## **15. Implementation and Review**

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

## **16. Summary and recommendations**

- 16.1 The Agency believes that the advantages of full implementation of the proposals that are the subject of this Regulatory Impact Assessment will benefit industry, enforcement authorities and consumers.
- 16.2 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, (although few irradiated foods are currently traded). There may also be a reduction in turn-around time due to removal of duplicated microbiological testing, and it will maintain consumer protection. **Option 3 is therefore recommended as a means of achieving this.**