

## FOOD STANDARDS AGENCY CONSULTATION

Title: The Food Irradiation (England)(Amendment) Regulations 2010

### CONSULTATION SUMMARY PAGE

<b>Date consultation launched:</b>	<b>Closing date for responses:</b>
25 <sup>th</sup> June 2010	6 <sup>th</sup> August 2010

#### Who will this consultation be of most interest to?

The proposed Regulations are relevant to irradiation facilities, importers of the seven permitted categories of food or manufacturers of products using these ingredients, enforcement authorities and consumer interest groups.

#### What is the subject of this consultation?

The Food Irradiation (England) (Amendment) Regulations 2010, amending the The Food Irradiation (England) Regulations 2009. To make statutory provision to implement Commission Decision 2010/172/EU, which adds three food irradiation facilities in India to the list of approved third-country (non-EU) food irradiation facilities. The list of approved EU Member State facilities will also be updated to reflect the recent changes.

#### What is the purpose of this consultation?

To seek views on the proposed amending Regulations, to make businesses and enforcement authorities aware of the new facilities and to provide opportunity for interested parties to comment on the proposals.

#### Responses to this consultation should be sent to:

Name Christopher Thomas  
Division/Branch Chemical Contaminants  
and Novel Foods Division / Policy 3  
FOOD STANDARDS AGENCY  
Tel: 020 7276 8728  
Fax: 020 7276 8446

Postal address:  
4<sup>th</sup> Floor, Aviation House  
125 Kingsway  
London. WC2B 6NH  
Email: [christopher.thomas@foodstandards.gsi.gov.uk](mailto:christopher.thomas@foodstandards.gsi.gov.uk)

**Is an Impact Assessment included  
with this consultation?**

Yes ☐

No ☒ See Annex A for reason.



INVESTOR IN PEOPLE

If you would prefer to receive future FSA consultations by e-mail,  
or if you no longer wish to receive information on this subject please  
notify the named person in this consultation.



# **The Food Irradiation (England)(Amendment) Regulations 2010**

## **DETAIL OF CONSULTATION**

### **Introduction**

1. We would welcome your comments on the proposed Food Irradiation (England) (Amendment) Regulations 2010, enclosed as Annex B. The proposed Regulations will implement Commission Decision 2010/172/EU (“the EU Decision”), regarding the approved list of food irradiation facilities outside the European Union (EU). This Decision amends Decision 2002/840/EC by adding the three facilities in India to the list of approved facilities. The EU Decision requires immediate implementation.
2. The EU Decision has been in force since 29<sup>th</sup> March 2010. We are conducting a six week consultation to seek comments from interested parties to ensure that the EU decision is implemented as soon as possible. We welcome your comments on the way in which the proposed Food Irradiation (England) (Amendment) Regulations 2010, will implement these provisions. A further delay could result in the UK Government being cited for infraction proceedings. But we will try to accommodate those needing more time if it is essential.
3. The Food Standards Agency in Scotland, Wales, and Northern Ireland will each consult on parallel but separate Regulations that will apply in their territories.

### **Abbreviations**

EU – European Union  
OJ – Official Journal  
SI – Statutory Instrument

4. The process of treating food with ionising radiation (X-rays, gamma rays or beams of electrons) (referred to as “food irradiation”) has been permitted in the UK since 1991. Food Irradiation and the importation and sale of food so treated (referred to as “irradiated food”) are currently controlled under European Directive 1999/2/EC relating to foods and food ingredients treated with ionising radiation. The provisions of Directive 1999/2/EC are fully implemented in England by The Food Irradiation (England) Regulations 2009 (SI 2009/1584).
5. Article 9 of Directive 1999/2/EC states that irradiated food must not be imported from a third-country (non-EU) unless it originates from a facility approved by the European Community. Article 9 also includes the procedures by which new facilities can be approved. In 2008, three facilities in India were inspected under these procedures. Commission Decision 2010/172/EU, which amends Decision 2002/840/EC as regards the list of approved food irradiation facilities outside the European Union, was published on the 23 March 2010 and added the three facilities to the list of approved facilities. These proposed Regulations provide for the implementation in England of Commission Decision 2010/172/EU.
6. Although food irradiation is not widely utilised in the UK, it is gaining favour in parts of the world, such as the USA, India and the Far East. It is therefore

important that we ensure our procedures for accepting food irradiated outside the European Union meet the legal standards set in EU legislation.

### **Proposals**

7. The following section explains in detail the rationale behind the new Regulations.

### **Implement Commission Decision 2010/172/EC**

8. Article 9 of Directive 1999/2/EC states that irradiated food must not be imported from a third-country unless it originates from a facility approved by the European Community. Article 9 also includes the procedures by which new facilities can be approved. In 2008, three facilities in India were satisfactorily inspected under these procedures.
9. These Regulations will amend Schedule 4 (List of facilities outside the European Community) to the Food Irradiation (England) Regulations 2009 to include the three new facilities in India. They provide for the implementation in England of Commission Decision 2010/172/EU amending Decision 2002/840/EC as regards the list of approved facilities in third countries for the irradiation of foods.

### **Update the list of Member State facilities in Schedule 3**

10. Article 7(4) of Directive 1999/2/EC requires the European Commission to publish details of Member State facilities and any changes in their status in the Official Journal (OJ). These details were initially published in the C Series of the OJ, but since 2004 have been replaced by a list published solely on the Commission website. Schedule 3 to the Food Irradiation (England) Regulations 2009 is based on the list previously published on the Commission website and dated 3 September 2004. On 4 January 2010, the list on which Schedule 3 of the 2009 Regulations was based was replaced with the current, undated list.
11. The position of the Food Standards Agency (“the Agency”) is that the purpose of Article 7(4) is to produce a definitive list of approved Member State facilities. Although this list is now published on the Commission website and not strictly in accordance with the requirements of Article 7(4), it is clear that the Commission intends that these website lists are nevertheless treated as the definitive list according to Article 7(4). As such this list, and any changes to it, must be implemented into our national legislation by updating Schedule 3 of the 2009 Regulations.
12. If these changes were not implemented in our national legislation, irradiated food from the three newly listed Member State facilities, each approved by the relevant Member State in accordance with Article 7 of Directive 1999/2/EC, would not be permitted by the 2009 Regulations, which would obstruct legitimate free trade within the European Union.

### **Minor drafting improvement to Schedule 2 (Licences)**

13. This proposal also makes a minor drafting improvement in Schedule 2 (Licences) to The Food Irradiation (England) Regulations 2009. This amendment is in Part 3 (Requirements and prohibitions to be observed by a

licensee) of Schedule 2 and will replace the words in paragraph 9(1)(b) with “its batch number” instead of making reference to “the number given to it under paragraph 4”. This does not change the meaning of the provision but improves its clarity.

14. This proposal was recommended by the Scottish Parliament’s Subordinate Legislation Committee during scrutiny of their parallel legislation to the 2009 Regulations and is likewise being included in the English draft as the text is identical in this respect in the English Regulations.

**Key proposal(s):**

- **To implement Commission Decision 2010/172/EU by amending Schedule 4 (List of facilities in a country outside the European Community) of The Food Irradiation (England) Regulations 2009 to add three food irradiation facilities newly approved in India.**
- **To update Schedule 3 (List of approved facilities in Member States) of The Food Irradiation (England) Regulations 2009 to reflect recent changes to the equivalent list published on the European Commission website.**
- **To make a minor drafting improvement to Schedule 2 (Licences) of The Food Irradiation (England) Regulations 2009.**

**Consultation Process**

15. A full 12-week public consultation on the 2009 Regulations, which this draft SI will amend, was undertaken between the 29 January and 27 April 2009. This previous consultation and a summary of the responses can be found at : <http://www.food.gov.uk/consultations/consulteng/2009/draftfoodirradiationregs09>

This six-week public consultation provides interested parties the opportunity to comment on the proposed amending SI.

16. All responses received as part of the consultation exercise will be given careful consideration. These will be summarised and published on the Agency's website in due course.

**Questions asked in this consultation:**

- Q1: Do you have any objection to any of these facilities in the amended Schedules 3 and 4 being included as approved food irradiation facilities (for example, do you have evidence that the correct procedures for approval have not been met in any of these cases)? Please provide evidence to support your views.**
- Q2: Do you think that any aspects of the legislation will be difficult to implement or that you feel could be implemented in a more simplified, less burdensome manner? Please provide evidence to support your views.**
- Q3: Do you think that there are any alternatives to introducing legislation which could achieve the same result of ensuring irradiated food is only sold where it originates from an approved facility? Please provide evidence to support your views.**

**Q4: Do you agree with our opinion that there will be no impact to business or enforcement authorities as a result of these proposals? Please provide evidence to support your views.**

**Q5: Do you have any general comments/issues of concern with these proposals?**

17. We would welcome comments from all stakeholders, but in particular those in the irradiation industry, those who may import any of the products in the seven permitted categories of food or manufacture products using these imported ingredients and from enforcement authorities. Although the Agency does not anticipate any new or additional costs arising from the proposals discussed here, it always helps us to provide the full picture of any burdens (particularly administrative burdens) placed upon those affected by the proposals. Please send your response by email or post using the contact details on page 1.

#### **Other relevant documents**

18. Commission Directive 1999/2/EC, on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation: <http://europa.eu/scadplus/leg/en/lvb/l21117.htm>
19. Commission Decision 2010/172/EU amending Decision 2002/840/EC as regards the list of approved facilities in third countries for the irradiation of foods (OJ No. L75, 23.3.2010, p.33):  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:075:0033:0034:EN:PDF>
20. Commission Decision 2007/802/EC amending Decision 2002/840/EC as regards the list of approved facilities in third countries for the irradiation of foods (OJ No. L323, 8.12.2007, p.40):  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:323:0040:0041:EN:PDF>
21. Commission Decision 2004/691/EC amending Decision 2002/840/EC as regards the list of approved facilities in third countries for the irradiation of foods (OJ No. L314, 13.10.2004, p.14):  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:314:0014:0015:EN:PDF>
22. Commission Decision 2002/840/EC as regards the list of approved facilities in third countries for the irradiation of foods (OJ No. L287, 25.10.2002, p.40):  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:287:0040:0041:EN:PDF>
23. Final report of a mission carried out in India from 28 January to 05 February 2008 in order to evaluate food irradiation facilities:  
[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_id=1972](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=1972)
24. Commission list of approved facilities for the treatment of foods and food ingredients with ionising radiation in the Member States replacing Commission

list of such facilities of 3 September 2004:

[http://ec.europa.eu/food/food/biosafety/irradiation/approved\\_facilities\\_en.pdf](http://ec.europa.eu/food/food/biosafety/irradiation/approved_facilities_en.pdf)

available through the European Commission webpage "Food irradiation – Community Legislation":

[http://ec.europa.eu/food/food/biosafety/irradiation/comm\\_legisl\\_en.htm](http://ec.europa.eu/food/food/biosafety/irradiation/comm_legisl_en.htm)

25. The Food Irradiation (England) Regulations 2009 (SI 2009/1584):

[http://www.opsi.gov.uk/si/si2009/pdf/uksi\\_20091584\\_en.pdf](http://www.opsi.gov.uk/si/si2009/pdf/uksi_20091584_en.pdf)

26. Consultation on The Food Irradiation (England) Regulations 2009 and summary of responses:

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

27. Final Impact Assessment for The Food Irradiation (England) Regulations 2009:

<http://www.food.gov.uk/multimedia/pdfs/iafoodirradiationregs09.pdf>

## **Responses**

28. **Responses are required by close 6<sup>th</sup> August 2010.** Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

**Christopher Thomas (Food Irradiation Officer)**  
**Policy 3**  
**Chemical Contaminants and Novel Foods Division**

**Enclosed**

**Annex A: Standard Consultation Information**

**Annex B: List of interested parties**

**Annex C: The Food Irradiation (England)(Amendment) Regulations 2010 (DRAFT)**

## Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

## Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at <http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc> Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.
3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.
4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

## Further information

5. A list of interested parties to whom this letter is being sent appears in Annex B. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.
6. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.
7. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: <http://www.berr.gov.uk/files/file47158.pdf> The Consultation Criteria from that Code should be included in each consultation and they are listed below:

## The Seven Consultation Criteria

### Criterion 1 — When to consult

*Formal consultation should take place at a stage when there is scope to influence the policy outcome.*

### Criterion 2 — Duration of consultation exercises

*Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.*

### Criterion 3 — Clarity of scope and impact



*Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.*

**Criterion 4 — Accessibility of consultation exercises**

*Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.*

**Criterion 5 — The burden of consultation**

*Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.*

**Criterion 6 Responsiveness of consultation exercises**

*Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.*

**Criterion 7 Capacity to consult**

*Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.*

8. Criterion 2 states that *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible*. This consultation is being held for six weeks because of the need to implement the Decision as soon as possible after publication. Commission Decision 2010/172/EU was published on 23 March 2010 and came into force on 29 March when it was formally notified to the UK by the Commission. It is also worth noting that a full 12-week public consultation was undertaken between the 29 January and 27 April 2009 on the 2009 Regulations, which this instrument amends.
9. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. We have not produced an Impact Assessment (IA) for this proposal because these amendments make no change to the substance of the Regulations and the market in irradiated foods is very small in the UK. On this basis, there will be no impact on business and very little, if any, on enforcement authorities. The consultation documents do however, refer to earlier consultations and IAs and our assumption that there are no new costs for business.
10. For details about the consultation process (not about the content of this consultation) please contact: [Food Standards Agency Consultation Co-ordinator](#), Room 1B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

**Comments on the consultation process itself**

11. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at <http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc>
12. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at <http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc> The questionnaire can also be used to update us about your existing contact details.



Amway Europe  
ASDA Stores Ltd  
Association of Port Health Authorities  
Association of Public Analysts  
Boots plc  
British Nutrition Foundation  
Brunel Healthcare  
Chartered Institute of Environmental Health  
Cheshire County Council  
Confederation of British Industry  
Council for Responsible Nutrition  
Department for Business Enterprise and Regulatory Reform  
Department for the Environment, Food and Rural Affairs  
Department of Health  
Devon County Council  
Eurofins  
Eurofins Laboratories  
Federation of Small Businesses  
Food and Drink Federation  
Food Commission  
Foodaware: the Consumers Food Group  
Gee Lawson Ltd  
Hampshire Trading Standards  
Health Food Manufacturers Association  
Holland and Barrett Retail Ltd  
Institute of Food Research  
Institute of Food Science and Technology  
Isotron plc  
Kent County Council  
Laboratory of the Government Chemist  
LACORS  
Law Laboratories  
Leatherhead Food Research Association  
Lincolne, Sutton and Wood  
Lincolnshire Trading Standards  
Marks and Spencer plc  
Morrison's plc  
National Consumer Council  
National Consumer Federation  
NutraTech  
Panel of Gamma and Electron Irradiation  
Quest Vitamins Ltd  
Radiological Protection Division – Health Protection Agency  
Sainsbury's Supermarket Ltd  
Seasoning & Spice Association  
Seven Seas Ltd  
Scottish Universities Environment Research Centre  
Swindon Borough Council  
Tesco Stores Ltd  
Trading Standards Institute

## LIST OF INTERESTED PARTIES

Annex B

Waitrose  
Which?

**2010 No.**

**FOOD, ENGLAND**

**The Food Irradiation (England) (Amendment) Regulations 2010**

*Made* - - - - 2010

*Laid before Parliament* 2010

*Coming into force* - - 2010

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1), 16(3), 17(1), 18(1)(c), 19(1)(b), 26 and 48(1) of, and paragraphs 1 and 4(b) of Schedule 1 to, the Food Safety Act 1990(a) and now vested in him(b).

In accordance with section 48(4A) of that Act, he has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c) there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

**Title and commencement**

**1.** These Regulations may be cited as the Food Irradiation (England) (Amendment) Regulations 2010 and come into force on [ ] 2010.

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- (a) 1990 c.16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17, 19 and 48 were amended by paragraphs 12, 14 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), “the 1999 Act”. Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act, S.I. 2004/2990 and S.I. 2004/3279.
- (b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Functions of “the Ministers” so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act, and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c.46) as read with section 40(2) of the 1999 Act.
- (c) OJ No. L31, 1.2.2002, p.1, as last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p.14).

## **Amendment of the Food Irradiation (England) Regulations 2009**

**2.** The Food Irradiation (England) Regulations 2009<sup>(a)</sup> are amended in accordance with regulations 3 to 5.

**3.** In Schedule 2 (licences) for sub-paragraph (1)(b) of paragraph 9 of Part 3 (requirements and prohibitions to be observed by a licensee) there is substituted the following sub-paragraph—

“(b) its batch number;”.

**4.** For Schedule 3 (list of approved facilities in member States) there is substituted the Schedule set out in Schedule 1.

**5.** For Schedule 4 (list of facilities in a country outside the European Community) there is substituted the Schedule set out in Schedule 2.

Signed by authority of the Secretary of State for Health

Date

*Name*  
Parliamentary Under Secretary of State,  
Department of Health

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<sup>(a)</sup> S.I. 2009/1584.

## SCHEDULE 1

Regulation 4

### SCHEDULE SUBSTITUTED FOR SCHEDULE 3 TO THE FOOD IRRADIATION (ENGLAND) REGULATIONS 2009

“SCHEDULE 3 Regulations 3(1) and 5(1)(b)(i)

#### LIST OF APPROVED FACILITIES IN MEMBER STATES

<i>Official reference number</i>	<i>Name and address</i>
2110/91/0004	Sterigenics SA Zoning Industriel B-6220 Fleurus Belgium
01/23.05.2008	BULGAMMA SOPHARMA Ltd Iliensko Shosse Str.16 Sofia Bulgaria
IR-02-CZ	BIOSTER a.s. Tejny 621 664- 71 Veverska Bityska Czech Republic
SN 01	Gamma-Service Produktbestrahlung GmbH Juri—Gagarin Strasse 15 D-01454 Radeberg Germany
BY FS 01/2001	Isotron Deutschland GmbH Kesselbodenstrasse 7 D-85391 Allershausen Germany
NRW-GM 01 and NRW-GM 02	BSG Beta-Gamma-Service GmbH & Co. KG Fritz-Kotz-Str.16 D-51674 Wiehl Germany
D-BW-X-01	Beta-Gamma-Service GmbH & Co. KG John-Deere-Strasse 3 D-76646 Bruchsal Germany

<i>Official reference number</i>	<i>Name and address</i>
500001/CU	Ionmed Esterilización, SA Santiago Rusiñol 12. Madrid Antigua Cntra Madrid-Valencia KM 83.7. Tarancón Cuenca Spain
5.00002/B	ARAGOGAMMA S.A. Salvador Mundi 11, bajo. 08017 Barcelona Carretera Granoolers a Cardedeu km 3,5. 08520 Les Franqueses dèl Vallès Barcelona Spain
13055 F	Isotron France SAS Rue Jean Queillau Marché des Arnavaux F-13014 Marseille Cedex 14 France
01 142 F	Ionisos SA Zone Industrielle les Chartinières F-01120 Dagneux France
72 264 F	Ionisos SA Zone Industrielle de l'Aubrée F-72300 Sablé-sur-Sarthe France
85 182 F	Ionisos SA ZI Montifaud F-85700 Pouzauges France
10 093 F	Ionisos SA Zone Industrielle F-10500 Chaumesnil France
EU-AIF-04-2002	AGROSTER Besugárho Részvénytársaság Budapest X Jászberényi út 5 H-1106 Hungary

<i>Official reference number</i>	<i>Name and address</i>
RAD 1/04 IT	GAMMARAD ITALIA SPA Via Marzabotto, 4 Minerbio (BO) Italy
GZB/VVB-991393 Ede	Isotron Nederland BV Morsestraat 3 6716AH Ede Netherlands
GZB/VVB-991393 Etten-Leur	Isotron Nederland BV Soevereinsestraat 2 4879NN Etten-Leur Netherlands
GIS-HZ-4434-W.-3/MR/03	Institute of Nuclear Chemistry and Technology 16 Dorodna Str. 03-195 Warsaw Poland
GIS-HZ-4434-W.-2/MR/03	Institute of Applied Radiation Chemistry Technical University of Lodz 15 Wróblewskiego Str. 39-590 Lodz Poland
RG016/2008	Multipurpose Irradiation Facility IRASM Technological Irradiations Department Horia Hulubei National Institute for Research and Development of Physics and Nuclear Engineering Atomistilor Street No. 407 PO Box MG-6 Magurele, Ilfov County Romania
EW/04	Isotron Limited Moray Road Elgin Industrial Estate Swindon Wilts SN2 8XS United Kingdom.”



## SCHEDULE 2

Regulation 5

### SCHEDULE SUBSTITUTED FOR SCHEDULE 4 TO THE FOOD IRRADIATION (ENGLAND) REGULATIONS 2009

#### “SCHEDULE 4

Regulation 5(1)(b)(ii)

#### LIST OF FACILITIES IN COUNTRIES OUTSIDE THE EUROPEAN UNION

<i>Official reference number</i>	<i>Name and address</i>
EU-AIF 01-2002	HEPRO Cape (Pty) Ltd 6 Ferrule Avenue Montague Gardens Milnerton 7441 Western Cape Republic of South Africa
EU-AIF 02-2002	Gammaster South Africa (Pty) Ltd PO Box 3219 5 Waterpas Street Isando Extension 3 Kempton Park 1620 Johannesburg Republic of South Africa
EU-AIF 03-2002	Gamwave (Pty) Ltd PO Box 26406 Isipingo Beach Durban 4115 Kwazulu-Natal Republic of South Africa
EU-AIF 05-2004	Gamma-Pak As Yünsa Yolu N: 4 0SB Cerkezköy/TEKIRDAG TR-59500 Turkey
EU-AIF 06-2004	Studer Agg Werk Hard Hogenweidstrasse 2 Däniken CH-4658 Switzerland

<i>Official reference number</i>	<i>Name and address</i>
EU-AIF 07-2006	Thai Irradiation Centre Thailand Institute of Nuclear Technology (Public Organisation) 37 Moo 3, TECHNOPOLIS Klong 5, Klong Luang Pathumthani 12120 Thailand
EU-AIF 08-2006	Isotron (Thailand) Ltd Bangpakong Industrial Park (Amata Nakorn) 700/465 Moo 7, Tambon Donhuaroh, Amphur Muang, Chonburi 20000 Thailand
EU-AIF 09-2010	Board of Radiation and Isotope Technology Department of Atomic Energy BRIT/BARC Vashi Complex Sector 20, Vashi Navi Mumbai – 400 705 (Maharashtra) India
EU-AIF 10-2010	Board of Radiation and Isotope Technology ISOMED Bhabha Atomic Research Centre South Site Gate, Refinery Road Next to TATA Power Station, Trombay Mumbai – 400 085 (Maharashtra) India
EU-AIF 11-2010	Microtrol Sterilisation Services Pvt. Ltd Plot No. 14 Bommasandra- Jigani Link Road Industrial Area KIADB, Off Hosur Road Hennagarra Post Bengalooru – 562 106 (Karnataka) India.”

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

1. These Regulations amend the Food Irradiation (England) Regulations 2009 (S.I. 2009/1584).
2. These Regulations give effect to the provisions of—
  - (a) Commission Decision 2010/172/EU amending Decision 2002/840/EC as regards the list of approved facilities in third countries for the irradiation of foods (OJ No. L75, 23.3.2010, p.33); and
  - (b) undated Commission list of approved facilities for the treatment of foods and food ingredients with ionising radiation in the member States<sup>(a)</sup> replacing Commission list of such facilities of 3 September 2004.
3. These Regulations amend the Food Irradiation (England) Regulations 2009 by—
  - (a) substituting for sub-paragraph (1)(b) of paragraph 9 of Part 3 (requirements and prohibitions to be observed by a licensee) of Schedule 2 (licences) a revised sub-paragraph (1)(b) (*regulation 3*);
  - (b) substituting for Schedule 3 (list of approved facilities in member States) a revised Schedule 3 containing a modified list of approved facilities in member States (*regulation 4*); and
  - (c) substituting for Schedule 4 (list of facilities in a country outside the European Community) a revised Schedule 4 adding three new facilities to the list of the approved facilities in countries outside the European Union (*regulation 5*).
4. A full impact assessment has not been produced for this instrument as no impact on the public or voluntary sectors is foreseen.

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<sup>(a)</sup> Published on the Commission website via [http://ec.europa.eu/food/food/biosafety/irradiation/comm\\_legisl\\_en.htm](http://ec.europa.eu/food/food/biosafety/irradiation/comm_legisl_en.htm). A hard copy may be obtained from the European Commission, Directorate General for Health and Consumers, B-1049 Brussels, Belgium.