#### STATUTORY INSTRUMENTS

# 2010 No. 2312

# FOOD, ENGLAND

The Food Irradiation (England) (Amendment) Regulations 2010

Made - - - - 19th September 2010 23rd September Laid before Parliament 2010

Coming into force - - 20th October 2010

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1) and (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(1) and now vested in him(2).

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(3) 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 20th October 2010.

<sup>(1) 1990</sup> 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.

<sup>(2)</sup> 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 Scotlish Ministers by section 53 of the Scotland Act 1998 (1998 c.46) as read with section 40(2) of the 1999 Act.

<sup>(3)</sup> 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(**4**) 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.

Anne Milton
Parliamentary Under-Secretary of State,
Department of Health

19th September 2010

### 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

| Official reference number | Name and address                     |
|---------------------------|--------------------------------------|
| 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                    |
|                           |                                      |

| Official reference number | Name and address                        |
|---------------------------|---|
|                           | D-51674 Wiehl                           |
|                           | Germany                                 |
| D-BW-X-01                 | Beta-Gamma-Service GmbH & Co. KG        |
|                           | John-Deere-Strasse 3                    |
|                           | D-76646 Bruchsal                        |
|                           | Germany                                 |
| 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 dês Vallés         |
|                           | 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                         |

| Official reference number | Name and address                    |
|---------------------------|-------------------------------------|
|                           | 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 Besugárzó Részvénytársaság |
|                           | Budapest X                          |
|                           | Jászberényi út 5                    |
|                           | H-1106                              |
|                           | Hungary                             |
| 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                 |

| Official reference number | Name and address  |
|---------------------------|---|
|                           | 4879NN Etten-Leur   |
|                           | Netherlands   |
| GIS-HZ-4434-W3/MR/03      | Institute of Nuclear Chemistry and Technology   |
|                           | 16 Dorodna Str.   |
|                           | 03-195 Warsaw   |
|                           | Poland  |
| GIS-HZ-4434-W2/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<br>Development of Physics and Nuclear Engineering |
|                           | Atomistilor Street No. 407  |
|                           | PO Box MG-6   |
|                           | Magurele. Ilfov County  |
| EW/04                     | Romania   |
|                           | 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

| Official reference number | Name and address                 |
|---------------------------|----------------------------------|
| 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               |
|                           |                                  |

| Official reference number | Name and address                          |
|---------------------------|---|
|                           | TR-59500                                  |
|                           | Turkey                                    |
| EU-AIF 06-2004            | Studer Agg Werk Hard                      |
|                           | Hogenweidstrasse 2                        |
|                           | Däniken                                   |
|                           | CH-4658                                   |
|                           | Switzerland                               |
| 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 |

| Official reference number | Name and address                          |
|---------------------------|---|
|                           | 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(5) replacing Commission list of such facilities of 3 September 2004.
- 3. These Regulations amend the Food Irradiation (England) Regulations 2009 by—

<sup>(5)</sup> Published on the Commission website via 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.

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- (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.