

Statutory Instrument 1990 No. 2490

The Food (Control of Irradiation) Regulations 1990

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STATUTORY INSTRUMENTS

1990 No. 2490

FOOD

The Food (Control of Irradiation) Regulations 1990

Made

10th December 1990

Laid before Parliament

11th December 1990

Coming into force

for purposes relating to food
other than poultry

1st January 1991

for purposes relating to poultry

13th February 1991

The Minister of Agriculture, Fisheries and Food, the Secretary of State for Health and the Secretary of State for Wales, acting jointly, in relation to England and Wales, and the Secretary of State for Scotland in relation to Scotland, in exercise of the powers conferred on them by sections 4(1), 6(4), 16(1) and (3), 18(1), 19(1)(b), 26, 45 and 48(1) of, and paragraphs 1 and 4(b) of Schedule 1 to, the Food Safety Act 1990[1] and of all other powers enabling them in that behalf, hereby make the following Regulations, after consultation in accordance with section 48 of the said Act with such organisations as appear to them to be representative of interests likely to be substantially affected by the Regulations:—

Title and commencement

1. These Regulations may be cited as the Food (Control of Irradiation) Regulations 1990 and shall come into force—
(a) for purposes relating to food other than poultry, on 1st January 1991, and
(b) for purposes relating to poultry, on 13th February 1991.

Interpretation

2.—(1) In these Regulations, except where the context requires otherwise—
"the Act" means the Food Safety Act 1990;

"food" has the meaning which it has in section 16(5)(a) of the Act;

"ionising radiation" means any gamma rays, X rays or corpuscular radiations which are capable of producing ions either

directly or indirectly other than—

(a) those rays or corpuscular radiations—

(i) which are emitted by measuring or inspection devices,

(ii) which are emitted at an energy level no higher than the

appropriate maximum level, and

(iii) the dose of energy imparted by which does not exceed 0.5 Gy,
and

(b) those rays or corpuscular radiations applied in respect of food prepared under medical supervision for patients requiring sterile diets, and for the purposes of this definition the appropriate maximum level is 10 MeV in the case of X rays and 5 MeV otherwise;

"irradiation licence" means a licence to subject food of a particular description to treatment by ionising radiation;

"licensing authority" means—

(a) in relation to premises in England and Wales—
(i) except in respect of the recovery of charges, the Minister of Agriculture, Fisheries and Food, the Secretary of State for Health and the Secretary of State for Wales acting jointly,
(ii) in respect of the recovery of charges relating to premises in England, the Minister of Agriculture, Fisheries and Food, and
(iii) in respect of the recovery of charges relating to premises in Wales, the Secretary of State for Wales, and
(b) in relation to premises in Scotland, the Secretary of State for Scotland;

"official authorisation" means authorisation granted by a competent authority in a member State of the European Economic Community other than the United Kingdom to subject food of a particular description to treatment by ionising radiation in a particular plant;

"sell" includes possess, offer, expose and advertise for sale, and "sale" shall be construed accordingly.

(2) For the purposes of these Regulations—

(a) "properly irradiated food" means food—
(i) which falls within one of the seven permitted descriptions of food,
(ii) which, when subjected to treatment by ionising radiation, either was so subjected alone or was so subjected as part of a batch each item of food comprised in which was food which fell within the same permitted description of food, and
(iii) which has not been over-irradiated,
and "proper irradiation" shall be construed accordingly;
(b) food falls within one of the seven permitted descriptions of food when (excluding the weight of any added water) no less

than 98 per cent of it by weight falls within that description, and "item", in relation to a batch of food, means each item within that batch intended to be capable of being sold individually;

(c) the seven permitted descriptions of food are—

- (i) fruit,
- (ii) vegetables,
- (iii) cereals,
- (iv) bulbs and tubers,
- (v) spices and condiments,
- (vi) fish and shellfish, and
- (vii) poultry;

(d) in those seven permitted descriptions of food—

- (i) "fruit" includes fungi, tomatoes and rhubarb,
- (ii) "vegetables" excludes fruit, cereals, bulbs and tubers and spices and condiments but includes pulses,

(Delegation) Regulations 1972[2];

- (iv) "bulbs and tubers" means potatoes, yams, onions, shallots and garlic,
- (v) "spices and condiments" means dried substances normally used for

seasoning,

- (vi) "fish and shellfish" includes eels, crustaceans and molluscs, and

(vii) "poultry" means domestic fowls, geese, ducks, guinea fowls, pigeons, quails and turkeys;

(e) food has been over-irradiated when the overall average dose of ionising radiation absorbed by it, measured by the

approved method of measurement, exceeds, in the case of food falling within the permitted description of—

- (i) fruit, 2 kGy,
- (ii) vegetables, 1 kGy,
- (iii) cereals, 1 kGy,
- (iv) bulbs and tubers, 0.2 kGy,
- (v) spices and condiments, 10 kGy,
- (vi) fish and shellfish, 3 kGy, or
- (vii) poultry, 7 kGy,

or when the maximum dose of ionising radiation absorbed by it, or by any food in a batch of which it forms part, is, when so

measured, a dose of kGy higher than the lower of $3x$ and $1.5y$ where x is the minimum dose of kGy so absorbed when so

measured and y is the overall average dose of kGy specified in the paragraph of this sub-paragraph relating to that permitted

description; and

(f) the approved method of measurement relating to food subjected to treatment by ionising radiation is the method of

measuring doses of ionising radiation required by the irradiation licence or, as the case may be, official authorisation under

which that food has been subjected to that treatment.

Prohibition on treatment without licence

3.—(1) No person shall in the preparation of any food for sale subject it or any part of it to treatment by ionising radiation

unless—

- (a) he holds a current irradiation licence,
- (b) the food so subjected is food which he is authorised by that irradiation licence to subject to that treatment, and
- (c) that treatment is carried out in accordance with the conditions of that irradiation licence.

(2) Each person who in the preparation of food for sale subjects it or any part of it to treatment by ionising radiation shall, on expiry of his irradiation licence, retain such records relating to that food as he is required by the licence to keep throughout its currency until five years have passed from the date of that treatment.

(3) Schedule 1 below shall have effect in relation to the grant of irradiation licences by the licensing authority, the terms and conditions, variation, withdrawal, suspension and extension of those irradiation licences and publication and charges payable to the licensing authority relating to those matters and the specification of things done by the licensing authority in respect of which such charges are payable.

Restriction on importation

4.—(1) No person shall import into Great Britain for the purpose of sale any food which has been subjected to treatment by ionising radiation unless that food is properly irradiated food, is of a recognised appropriate origin and is accompanied by appropriate documentation.

(2) Schedule 2 below shall have effect in relation to the recognition and withdrawal of recognition of appropriate origins and specification of appropriate documentation.

(3) This regulation applies to food which has (as well as food which has not) become an ingredient of other food before importation.

Restriction on storage

5.—(1) No person shall store or transport for the purpose of sale any food which has been subjected to treatment by ionising radiation unless either he is the holder of the irradiation licence relating to that food or that food is stored or, as the case may be, transported in accordance with the requirements of Schedule 3 below.

(2) This regulation applies to food which (as well as food which has not) become an ingredient of other food before storage or, as the case may be, transportation.

Restriction on sale

6. No person shall sell any food which or any part of which has been subjected to treatment by ionising radiation unless—

(a) either—

(i) that treatment took place in Great Britain in accordance with regulation 3 above and all requirements of the

irradiation licence relating to that food have been observed, or

(ii) that food was imported in circumstances in which compliance with regulation 4 above was observed, and

(b) any storage or transportation of that food was carried out in circumstances in which compliance with regulation 5 above was observed.

Activities taking place in Northern Ireland

7. In relation to food which has been subjected to treatment by ionising radiation, compliance with any provision

(corresponding to a provision of these Regulations) of legislation having effect in Northern Ireland which regulates the subjection to

treatment by ionising radiation, importation, storage and transport of that food shall, in respect of any activity which took place in

Northern Ireland, be treated for the purposes of these Regulations as if it were compliance with corresponding provision of these Regulations.

Defence in relation to exports

8.—(1) In any proceedings for an offence under these Regulations it shall be a defence for the person charged to prove—

(a) that the food, in respect of which the offence is alleged to have been committed, was intended for export to another

member State of the European Economic Community and that the food complied with that member State's domestic food

legislation relevant to the alleged offence; or

(b) that the food, in respect of which the offence is alleged to have been committed, was intended for export to a country

which is not a member of the European Economic Community for sale to the ultimate consumer within that country.

(2) In this regulation "ultimate consumer" has the meaning which it has in the Food Labelling Regulations 1984[3].

Penalties, enforcement and functions of licensing authority

9.—(1) If any person contravenes or fails to comply with any of the foregoing provisions of these Regulations or, for the purposes of these Regulations, makes any false statement or uses any document containing a false statement either recklessly or

knowing it to be false, he shall be guilty of an offence and shall be liable—

(a) on summary conviction to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding six months or both; and

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both.

(2) If any person who holds an irradiation licence contravenes or fails to comply with any condition of that irradiation licence other than the condition required to be included by paragraph 17 of Part II of Schedule 1 below he shall be guilty of an offence and shall be liable—

(a) on summary conviction to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding six months or both; and

(b) on conviction or indictment, to a fine or to imprisonment for a term not exceeding two years or both.

(3) The licensing authority shall enforce the provisions of these Regulations in so far as they fall to be observed by the holder of a current irradiation licence and (without prejudice to any power conferred on it by the Act or these Regulations) shall, so far as is reasonably practicable, carry out regular inspections during the currency of an irradiation licence for the purpose of examining whether it should in relation to that irradiation licence exercise any power available to it under paragraphs 1 to 3 of Part IV of Schedule 1 below.

(4) The licensing authority and each food authority within its area shall severally enforce the provisions of regulation 3 above in so far as they fall to be observed by any person other than the holder of a current irradiation licence.

(5) Each food authority shall enforce within its area the provisions of these Regulations save in so far as they fall to be enforced under paragraph (3) or (4) above.

(6) Each authority concerned in the administration of these Regulations shall give to each other authority so concerned such assistance and information as that other authority may reasonably require for the purpose of its duties under these Regulations.

(7) In this regulation "food authority" does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple).

(8) Where any charge under these Regulations or under an irradiation licence granted by the licensing authority falls to be paid to the licensing authority but remains outstanding, that charge shall be recoverable by the licensing authority as a civil debt.

Application of various provisions of the Food Safety Act 1990

10.—(1) The following provisions of the Act shall apply for the purposes of these Regulations as they apply for the purposes of section 8, 14 or 15 of the Act and, unless the context otherwise requires, any reference in them to the Act shall be construed for

the purposes of these Regulations as a reference to these Regulations—

- (a) section 2 (extended meaning of "sale" etc.);
- (b) section 3 (presumption that food is intended for human consumption);
- (c) section 20 (offences due to fault of another person);
- (d) section 21 (defence of due diligence);
- (e) section 22 (defence of publication in the course of business);
- (f) section 30(8) (which relates to documentary evidence);
- (g) section 33 (obstruction etc. of officers);
- (h) section 36 (offences by bodies corporate);
- (i) section 44 (protection of officers acting in good faith);
- (j) section 58(1) (which relates to territorial waters).

(2) Section 8(3) (which makes presumptions in the case of batches etc. of food) of the Act shall apply to food which it is an offence to sell under these Regulations as it applies to food which fails to comply with food safety requirements.

(3) Section 9 (inspection and seizure of suspected food) of the Act shall apply for the purposes of these Regulations as if food which it were an offence to sell under them were food which failed to comply with food safety requirements.

(4) Section 34 (which relates to time limits for the beginning of prosecutions) of the Act shall apply in relation to offences under these Regulations as it applies to offences punishable under section 35(2) of the Act.

Revocation of existing regulations

11.—(1) The Food (Control of Irradiation) Regulations 1967[4] and the Food (Control of Irradiation) (Amendment) Regulations 1972[5] are hereby revoked.

(2) The Food (Control of Irradiation) (Scotland) Regulations 1967[6] and the Food (Control of Irradiation) (Scotland) (Amendment) Regulations 1972[7] are hereby revoked.

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 7th December 1990.

John Selwyn Gummer

Minister of Agriculture, Fisheries and Food

Stephen Dorrell

Parliamentary Under Secretary of State for Health

10th December 1990

David Hunt

Secretary of State for Wales

7th December 1990

Strathclyde

Parliamentary Under Secretary of State, Scottish Office

10th December 1990

Notes:

[1] 1990 c. 16. back

[2] S.I. 1972/1679, amended by S.I. 1988/1000. back

[3] S.I. 1984/1305, to which there are amendments not relevant to these Regulations. back

[4] S.I. 1967/385; the relevant amending instrument is S.I. 1972/205. back

[5] S.I. 1972/205. back

[6] S.I. 1967/388 (S.29); the relevant amending instrument is S.I. 1972/307 (S.21).
back

[7] S.I. 1972/307 (S.21). back

SCHEDULE 1

Regulation 3

IRRADIATION LICENCES

PART I

GRANT OF IRRADIATION LICENCES

Application for an irradiation licence

1. Any person who seeks to be granted an irradiation licence shall apply for its grant by sending to the licensing authority the

following particulars in writing—

(a) his name,

(b) his address,

(c) an identification of the premises at which he proposes to subject food to treatment by ionising radiation,

(d) details of any licence or registration under other legislation which enables him to use ionising radiation at those premises

in circumstances where, but for that licence or registration, that use would be unlawful,

(e) each description of food which he proposes, subject to paragraph (ii) of sub-paragraph (f) below, to subject to

treatment by ionising radiation,

(f) in respect of each description of food specified pursuant to sub-paragraph (e) above—

(i) the purpose for which he proposes to subject that description of food to treatment by ionising radiation,

(ii) whether or not he proposes to use microbiological criteria in deciding whether or not to subject that description of

food to treatment by ionising radiation and, where he proposes to use them, the type and frequency of microbiological

examination which he proposes is to be used in assisting him to reach that decision and the qualifications of any

person who he proposes will undertake that examination,

(iii) the overall average dose, maximum dose and minimum dose of ionising radiation which, subject to paragraph (ii)

above, he proposes to apply to that description of food,
(iv) the method (including instrumentation and frequency) by which he proposes to measure any dose of ionising radiation and the dosimetry standard which he proposes to use to calibrate the dose meters used to measure it,
(v) whether or not he proposes, subject to paragraph (ii) above, to subject that description of food to treatment by ionising radiation in packaging in contact with the food and, if so, a specification of the packaging which he proposes to use, and
(vi) whether or not he proposes, subject to paragraph (ii) above, to apply temperature control to that description of food in conjunction with subjecting it to treatment by ionising radiation and, if so, a specification of the temperature at which he proposes to keep the food during the application of that temperature control,
(g) a statement of the practices which he proposes to apply, and of the minimum qualifications (whether they are formal or are derived from skill, training or experience) of persons who will be involved in applying those practices, in order to eliminate any significant risk of breach of any condition of an irradiation licence,
(h) the date from which he wishes the irradiation licence to run, and
(i) any other particulars which he wishes the licensing authority to consider in deciding whether to grant an irradiation licence.

Functions of licensing authority on application for irradiation licence

2. On receipt of the particulars required by paragraph 1 above it shall be the function of the licensing authority to decide whether to grant or to refuse to grant an irradiation licence to the applicant.

3.—(1) In deciding whether to grant or to refuse to grant an irradiation licence the licensing authority shall consider whether it is satisfied—

(a) that it is not unlawful, otherwise than for want of an irradiation licence, for the applicant to subject food of any description specified by virtue of paragraph 1(e) above to treatment by ionising radiation at the premises specified by virtue of paragraph 1(c) above,
(b) that each description of food specified by virtue of paragraph 1(e) above is, or falls within, one of the seven permitted descriptions of food,
(c) that each purpose specified by virtue of paragraph 1(f)(i) above is a legitimate purpose and that the applicant proposes

to use microbiological criteria in deciding whether or not to subject any food to treatment by ionising radiation where the purpose so specified in relation to that food falls within or partly within subparagraph (2)(b)(i) below,

(d) that either the descriptions of food specified by virtue of paragraph 1(e) above do not give rise to any significant risk or the factors specified by virtue of paragraph 1(f)(ii) above eliminate any significant risk that, during the currency of the licence applied for, the applicant will subject to treatment by ionising radiation food which either—

(i) is, for microbiological reasons, incapable of complying with food safety requirements, or

(ii) is capable of complying with food safety requirements, but only because any lawful method of causing it to avoid

failure for microbiological reasons to comply with food safety requirements would necessarily comprise or include its subjection to treatment by ionising radiation,

(e) that any qualifications specified by virtue of paragraph 1(f)(ii) above are no less than the requisite qualifications referred

to in the definition of "food examiner" in subsection (9) of section 30 (analysis of samples) of the Act,

(f) that the overall average dose specified in relation to each description of food by virtue of paragraph 1(f)(iii) above is

consistent with each purpose specified in respect of that description of food by virtue of paragraph 1(f)(i) above,

(g) that the factors specified by virtue of paragraph 1(f)(iv) above eliminate any significant risk that, during the currency of

licence applied for, the overall average dose as measured in accordance with those factors will on any occasion deviate to a

significant extent from the true overall average dose or that there will be a failure to record any maximum or minimum dose,

(h) that the factors specified by virtue of paragraph 1(f) above eliminate any significant risk that food subjected to treatment

by ionising radiation will, following that treatment and use of any packaging specified by virtue of paragraph 1(f)(v) above

and application of any temperature control specified by virtue of paragraph 1(f)(vi) above, fail to comply with food safety

requirements, and

(i) that the applicant will, by applying the practices proposed (and involving in applying those practices persons with

qualifications no less than those specified) in the statement made by virtue of paragraph 1(g) above, eliminate any significant

risk that there will be any breach of any condition of the irradiation licence,

and on completion of that consideration the licensing authority shall notify the applicant that it has completed that consideration and

of the amount of the application consideration charge, the applicant shall, no later than twenty-eight days after that notification, pay the application consideration charge to the licensing authority and, on receipt of that payment, the licensing authority shall, if it is satisfied of the matters specified in paragraphs (a) to (i) above, grant an irradiation licence to the applicant, but if it is not so satisfied the provisions of paragraph 4 below shall apply.

(2) For the purpose of this paragraph and the preceding paragraphs of this Part—

(a) "unlawful" means unlawful for want of registration, licence or similar authority, but that shall not affect the meaning of

"lawful";

(b) "legitimate purpose" means any of the following purposes—

(i) elimination or reduction of pathogenic organisms in food;

(ii) reduction, by the retardation or arresting of decay processes and destruction of spoilage organisms, of spoilage of food;

(iii) reduction of waste of food resulting from premature ripening, germination or sprouting;

(iv) disinfection of food from infestation by organisms harmful to plants or plant products;

(c) a true overall average dose, (specified in this paragraph as "D") is defined by the following integral over the total volume

of food in respect of which that overall average dose is calculated:

$$D =$$

$$\frac{1}{M}$$

$$\int$$

$$\rho(x,y,z)d(x,y,z)dV$$

where—

(i) M=the total mass of that food,

(ii) ρ =the local density at the point (x, y, z),

(iii) d=the local absorbed dose at the point (x, y, z),

(iv) dV=the volume element represented by each of the volume fractions which between them comprise the entire volume of that food, and

(v) each such volume element is infinitesimal; and

(d) "practices" includes layout of premises, method of subjecting food to treatment by ionising radiation, type of ionising radiation used and design and construction of the facility for subjecting food to that treatment as well as practices of business control and organisation.

(3) Nothing in this paragraph or the preceding paragraph shall be taken to prohibit the applicant for an irradiation licence from withdrawing his application and substituting a fresh application before the licensing authority has completed the consideration of the application and in such circumstances the function of the licensing authority under paragraph 2 above shall be exercised by reference to the fresh application rather than the original application.

4.—(1) Where the provisions of this paragraph apply the licensing authority shall give to the applicant a written statement of the reasons why it considers that it should not grant the irradiation licence applied for to him and shall in that statement invite the applicant to make written representations to the licensing authority within a time limit specified in that statement and expiring no earlier than twenty eight days after the date on which the statement is sent.

(2) If no such representations are received by the licensing authority within the time limit so specified, the licensing authority shall notify the applicant in writing that his application is refused but need not include any statement of reasons for the refusal.

(3) If such representations are received, the licensing authority shall consider them and—

(a) if those representations satisfy the licensing authority that all of the reasons specified in the written statement no longer apply, and the licensing authority considers that there are no other reasons why it should not grant an irradiation licence, it shall grant an irradiation licence to the applicant;

(b) in any other case the licensing authority—
(i) if it considers that there are other reasons why it should not grant an irradiation licence, shall give to the applicant the statement required by sub-paragraph (1) above (whereupon the provisions of this paragraph 4 shall apply as they apply when the original statement is given), and
(ii) otherwise shall notify the applicant in writing that his application is refused and shall include in the notification a statement of reasons for the refusal.

PART II

TERMS AND CONDITIONS OF IRRADIATION LICENCES

Introductory

1.—(1) The following paragraphs of this Part state the terms and conditions which are to be included in the irradiation licence.

(2) In this Part of this Schedule "licence" means an irradiation licence, and "licensee" means the person to whom it is granted.

Person to whom licence is granted, reference and date

2.—(1) The licence shall specify the applicant as the licensee and shall specify that, subject only, where the licence is granted to an individual, to the provisions of section 43 of the Act (continuation on death), the licence is not transferable.

(2) The licence shall include a reference provided by the licensing authority by which that licence can be identified.

(3) The licence shall specify the date on which it commences, being a date no earlier than the date specified by virtue of paragraph 1(h) of Part I above.

Premises to which licence applies

3. The licence shall specify the premises identified by virtue of paragraph 1(c) of Part I above as the premises to which the licence applies and shall prohibit the licensee from subjecting food to treatment by ionising radiation at any other premises.

Description of food to which licence applies

4. The licence shall specify each description of food specified by virtue of paragraph 1(e) of Part I above as a description of food to which the licence applies and shall prohibit the licensee from subjecting to treatment by ionising radiation any food which does not fall within such a description.

Conditions directly relating to licence application

5. The licence shall contain such conditions as will require the licensee, in and in connection with the subjection of any food to treatment by ionising radiation, not to deviate from any proposal which—

- (a) is specified by virtue of paragraph 1(f) of Part I above, and
- (b) relates to the description of food within which that food falls.

6. The licence shall contain such conditions as will require the licensee not to deviate from the practices specified by virtue of

paragraph 1(g) of Part I above and not to employ any person in the application of those practices unless his qualifications meet the minimum qualifications so specified.

Free standing conditions

7. The licence shall require the licensee not to subject any food which he receives from any other person to treatment by ionising radiation unless the following particulars are attached to the food or accompany the food at the time of receipt by him—

- (a) an identification of the food, including the name and address of its consignor;
- (b) a reference by which that food, or any batch, lot or consignment of food of the same description within which food falls, can be identified;
- (c) if that food is received by the licensee as a bailee—
 - (i) the name and address of the owner of the food; and
 - (ii) the reason why the owner of the food seeks the subjection of that food to treatment by ionising radiation; and
- (d) a statement as to whether the food or any part of it has been subjected to treatment by ionising radiation.

8. The licence shall require that all food which awaits subjection to treatment by ionising radiation at the premises to which the licence relates shall, while on those premises, be kept by the licensee on a part of the premises which is separated by a wall or barrier from any part of the premises where food which has been so subjected is kept by him, and that both are kept by him on parts of premises separated by a wall or barrier from any part of the premises on which food which neither awaits such subjection nor has been so subjected is kept by him in the course of his business.

9.—(1) Subject to sub-paragraph (2) below, the licence shall prohibit the licensee from subjecting to treatment by ionising radiation any food which, or any part of which, has previously been treated by ionising radiation.

(2) The licence shall specify that the removal of food from and return of the food to the facility where subjection to that treatment takes place shall, where that removal and return form part of a continuous process required by the design and construction of that facility, not be treated as a subjection required to be prohibited by sub-paragraph (1) above.

10. The licence shall require the licensee to identify by numerical reference each batch of food subjected by him to treatment

by ionising radiation in such a way as that reference is capable of being linked, where that food or any part of it has been received from any other person, to the reference specified in relation to that food or that part by virtue of paragraph 7(b) above.

11. The licence shall prohibit the licensee from subjecting any batch of food to treatment by ionising radiation from any source other than the following—

- (a) gamma rays from the radionuclide ^{60}Co ;
- (b) gamma rays from the radionuclide ^{137}Cs ;
- (c) X rays generated from machine sources operated at or below an energy level of 5 MeV;
- (d) electrons generated from machine sources operated at or below an energy level of 10 MeV.

12. The licence shall require the licensee to apply proper irradiation, and only proper irradiation, to any food subjected by him to treatment by ionising radiation.

13. The licence shall require the licensee to maintain such controls as shall at all times ensure that any treatment by ionising radiation is consistent with the method of measurement specified by virtue of paragraph 1(f)(iv) of Part I above.

14.—(1) The licence shall require the licensee to maintain such recording devices as shall at all times ensure that there is recorded, in relation to each batch of food subjected to treatment by ionising radiation, the following information—

- (a) where the facility for that subjection is a radionuclide facility—
 - (i) in relation to each source configuration of ionising radiation available for use in the facility, such information as to its position as shows whether, and if so when, that batch of food was exposed to it, and
 - (ii) either the speed at which the batch travels through the facility and the route which the batch travels while passing through it or the time which the batch spends in the facility;
- (b) where the facility for that subjection involves a machine source—
 - (i) the energy level of the machine source;
 - (ii) the electron current of the machine source;
 - (iii) the scanner width of the machine source;
 - (iv) unless the machine source has a scattering device, the frequency with which the beam from the machine source scans the batch; and
 - (v) the speed at which the batch travels through the facility.

(2) The licence shall require the licensee to ensure that there is recorded (whether by means of recording devices or otherwise)—

- (a) in relation to each batch of food—
 - (i) to which sub-paragraph (1)(a) above applies, and
 - (ii) in respect of which there is recorded the speed at which it travels through but not the time which it spends in the facility referred to therein, the route which it travels while passing through that facility, and
- (b) in relation to each batch of food to which sub-paragraph (1)(b) above applies, the characteristics of the beam referred to therein.

15. The licence shall require the licensee, throughout the currency of the licence, to keep records showing for each batch of

- food subjected by him to treatment by ionising radiation—
 - (a) the description and quantity of the food in that batch,
 - (b) the numerical reference by which that batch can be identified,
 - (c) the name and address of each consignor, and of each consignee, of food within that batch,
 - (d) the date on which that treatment took place,
 - (e) any microbiological information relating to food in that batch,
 - (f) the type of packaging used in contact with the food in that batch during that treatment,
 - (g) where temperature control has been applied in conjunction with that treatment, the temperature of the food in that batch immediately before that food was subjected to that treatment,
 - (h) the overall average dose of ionising radiation, and the maximum and minimum such dose, applied to that batch in that treatment, and
 - (i) the type of ionising radiation used in that treatment,
 - (j) the data used for control of that treatment including the following:—
 - (i) the positioning of dose meters within the batch and the doses of ionising radiation recorded by them,
 - (ii) previous tests used for the purpose of validating that positioning, and
 - (iii) the method (including instrumentation and frequency) used for measuring the doses of ionising radiation applied in that treatment, and in those previous tests, and the dosimetry standard used to calibrate the dose meters used to measure those doses, and
 - (k) the particulars required to be recorded by the provision required to be included in the licence by paragraph 14 above, and shall prohibit the licensee from consigning food within that batch to any other person unless that food is accompanied by a statement of the licensee's name, the premises to which his licence relates, the reference by which his licence can be identified, the

reference by which the batch can be identified and the overall average dose specified in sub-paragraph (h) above.

16.—(1) The licence shall require the licensee to send to the licensing authority—

- (a) within twenty-eight days after the first anniversary of the date from which the licence runs, a written return in respect of the year ending with that first anniversary,
- (b) within twenty-eight days after the second anniversary of the date from which the licence runs, a written return in respect of the year ending with the second anniversary, and
- (c) no later than twenty-eight days before the third anniversary of the date from which the licence runs, a written return in respect of the period which commenced on the day after the date of the second anniversary of the date from which the licence runs and ended fifty-six days before that third anniversary.

(2) A return of a licensee relating to a period shall state—

- (a) the name of the licensee;
- (b) the reference referred to in paragraph 2(2) above;
- (c) the period to which the return relates and the fact that it is a return for that period;
- (d) each description of food subjected within that period by the licensee to treatment by ionising radiation; and
- (e) the quantity, in volume or in weight measurements, of each description of food so subjected.

(3) The licence shall require the licensee to send to the licensing authority, no later than twenty-eight days after the date of any inspection within regulation 9(3) above in respect of which an inspection charge is payable, a remittance for that inspection charge.

Avoidance of contravention of these Regulations

17. It shall be a condition of the licence that the licensee shall neither contravene nor fail to comply with any provision of these Regulations which falls to be complied with by him in respect of food which he subjects to treatment by ionising radiation.

Duration

18. The licence shall, subject to the following provisions of this Schedule, continue in effect for a period of three years beginning with the date on which it commences.

PART III

VARIATION OF IRRADIATION LICENCE

1.—(1) The licensing authority and the licensee may, subject to paragraph 2 below, agree, subject to payment by the licensee to the licensing authority of the variation agreement charge, to vary any condition of a licence inserted by virtue of paragraph 5 or 6 of Part II above.

(2) Following such agreement the licence shall be varied in accordance therewith with effect from such time as payment of the variation agreement charge is received by the licensing authority or (if later) such time as is specified in the agreement.

2.—(1) Subject to sub-paragraph (2) below, the licensing authority shall not in pursuance of paragraph 1 above agree any variation which permits any act or omission a proposal for which would, had it been made in the initial licence application, have caused the licensing authority to refuse to grant the licence.

(2) For the purposes of sub-paragraph (1) above the licensing authority, in considering whether or not to agree such a variation, shall treat all scientific knowledge which it has at the time of that consideration as if it were scientific knowledge which it had at the time when it considered the initial licence application.

PART IV

WITHDRAWAL, SUSPENSION AND EXTENSION OF IRRADIATION LICENCE

Withdrawal and suspension

1. If the licensing authority is at a particular time of the opinion that circumstances exist which would have persuaded it, had it foreseen them (and possessed the scientific knowledge possessed by it at that particular time) at the time when it was considering whether to grant the irradiation licence, to refuse to grant it, it may give notice to the licensee—

- (a) specifying the circumstances which it considers exist, and
- (b) informing the licensee that, unless he satisfies it within a period specified in the notice (not being less than twenty-eight days) that those circumstances either do not exist or should not have had the persuasive effect specified above, the licence will be withdrawn.

2. If, by the end of the period so specified, or such longer period as is agreed by the licensing authority and the licensee for the purposes of this Part of this Schedule, the licensee has not satisfied the licensing authority that those circumstances either do not exist or should not have had the persuasive effect specified in paragraph 1 above, the licensing authority shall give written notice to the licensee that the licence is withdrawn as from a date specified in the notice and shall state why the licensing authority is not so satisfied, and when such a notice is given the licence shall terminate on the day so specified.

3.—(1) If the licensing authority is of the opinion that unless the licence is suspended there will or may be a risk of injury to health it may give written notice to the licensee suspending the licence as from a date specified in the notice for such a period as is specified in the notice, and, subject to sub-paragraphs (2) and (3) below, the licence shall have no effect for the purpose of these Regulations during that period.

(2) Where a notice is given under sub-paragraph (1) above the suspension shall, subject to sub-paragraph (3) below, cease to have effect—

(a) if more than three days have passed since the giving of that notice and no notice has been served on the licensee under

paragraph 1 above,

(b) if such notice has been so served—

(i) at the time when withdrawal of the licence takes effect, or

(ii) at the time when the licensing authority declares itself to be satisfied of those matters of which, following service of

such a notice, it is required to be satisfied in order not to withdraw the licence.

(3) The licensing authority may, by further notice in writing to the licensee, withdraw the notice suspending the licence, but shall only do so if it is of the opinion that in the absence of suspension there will not be a risk of injury to health.

Extension

4. Where the holder of an existing licence applies under paragraph 1 of Part I above no later than fifty-six days before the end

of the period of the three year currency of that licence for the grant of a further licence commencing immediately after the end of

that period but the licensing authority considers that it will not before the expiry of that period decide whether or not to grant the

licence applied for it may by notice in writing to the licensee extend the currency of that existing licence up to the date on which its

decision in relation to that application takes effect.

Application during the currency of a licence

5.—(1) A licensee may at any time during the currency of an existing licence apply under paragraph 1 of Part I above for a

licence the terms and conditions of which would, if granted, differ from those of his existing licence.

(2) If the licence so applied for is granted with effect from a date which falls within the currency of that existing licence, then the

existing licence shall by virtue of that grant terminate at the end of the day before that date.

PART V

PUBLICATION

1. The licensing authority shall publish in the London and Edinburgh Gazettes notice of—

- (a) each irradiation licence granted;
- (b) each suspension of an irradiation licence;
- (c) each withdrawal of an irradiation licence; and
- (d) each agreed variation of the terms of an irradiation licence.

2. Any notice so published shall specify the name of the licensee or former licensee, the premises to which the notice relates

and the reference provided in compliance with paragraph 2(2) of Part II above and shall state in outline the effect of the matter to which it relates.

PART VI

CHARGES

1. This Part of this Schedule specifies the amount of each charge referred to in this Schedule, and also specifies the thing done

by the licensing authority in respect of which each such charge is payable.

2. For the purposes of this Schedule—

(a) the amount of the application consideration charge is—

(i) in the case of an application by a licensee for the grant of a pure continuation licence (that is to say a further

irradiation licence on the same terms, other than in relation to its commencement date, as those of his existing

irradiation licence), £325,

(ii) in the case of an application by a licensee for the grant of a continuation licence with type A additions (that is to say a further irradiation licence which is a pure continuation licence in relation to food to which his existing licence relates but extends to other food within the same of the seven permitted descriptions of food), a sum (fixed at the discretion of the licensing authority) no greater than $£1,500 \times A$ where A is the number of permitted descriptions of food into which the type A additions fall,

(iii) in the case of an application by a licensee for the grant of a continuation licence with type B additions (that is to say a further irradiation licence which is a pure continuation licence in relation to food to which his existing licence relates but extends to other food within other permitted descriptions of food), a sum of $£1,500 \times B$ where B is the number of other permitted descriptions of food into which the type B additions fall,

(iv) in the case of an application by a licensee for the grant of a continuation licence with type A and type B additions, the total which would be fixed and payable under paragraph (ii) above in relation to the type A additions and payable under paragraph (iii) above in relation to the type B additions, and

(v) in any other case, £6,000 plus, if the application relates to two or more of the seven permitted descriptions of food, $(£1,500 \times C)$ where C is one less than the number of permitted descriptions of food to which the application relates,

plus, if the application (however many of the seven permitted descriptions of food the application relates to) falls within paragraph 3(3) of Part I of this Schedule, a sum (fixed at the discretion of the licensing authority) no greater than the sum which would otherwise be payable in the case within which that application falls;

(b) the amount of the inspection charge is £900 for each inspection carried out in respect of which an inspection charge is payable;

(c) the amount of the variation agreement charge is £500; and

(d) an application by a licensee for a further irradiation licence which relates to food entirely within, but not comprising the entirety of, food to which his existing licence relates shall not for that reason alone be regarded as an application for a licence on terms not the same as those of his existing irradiation licence.

3. For the purposes of this Schedule—

(a) an application consideration charge is payable in respect of the exercise by the licensing authority of its functions under paragraph 3 of Part I of this Schedule relating to consideration of an application for an irradiation licence;

(b) an inspection charge is payable in respect of each inspection (referred to in regulation 9(3) above) carried out by the licensing authority except for any such inspection which would cause the total amount payable in respect of such inspections during any licence year to exceed the appropriate upper limit for that year, the appropriate upper limit being—

(i) for the first licence year in respect of an irradiation licence other than a pure continuation licence, £1,800, and

(ii) for any licence year other than a first licence year to which paragraph (i) above applies, £2,700; and

(c) a variation agreement charge is payable in respect of the exercise by the licensing authority of its functions under Part III of this Schedule of agreeing, subject to payment of that charge, the variation of any condition of a licence to which that Part of this Schedule applies.

SCHEDULE 2

Regulation 4

IMPORTATION OF FOOD

Recognition of appropriate origin and withdrawal of recognition

1.—(1) Recognition of appropriate origin shall for the purpose of these Regulations be effected by publication by the appropriate Ministers of notice in the London and Edinburgh Gazettes declaring that an origin is an appropriate origin for the purposes of these Regulations.

(2) In this Schedule—

(a) "the appropriate Ministers" means the Minister of Agriculture, Fisheries and Food, the Secretary of State for Health, the Secretary of State for Scotland and the Secretary of State for Wales acting jointly;

(b) "origin" means—

(i) in relation to a member State other than the United Kingdom, an origin in a plant therein specified in the notice,

and

(ii) in relation to any other country outside the United Kingdom specified in the notice, an origin in that country; and

(c) "country" includes territory.

2.—(1) Recognition of appropriate origin may not be effected by the appropriate Ministers in respect of any plant capable of coming within paragraph 1(2)(b)(i) above unless they are satisfied—

- (a) that there is in effect an official authorisation which applies to that plant;
- (b) that that official authorisation includes provision for an approved method of measurement relating to food to which the official authorisation relates; and
- (c) that the terms of that official authorisation, as combined with the operation of the legislation in force in the country in which that plant is situated relating to the subjecting there of food to treatment by ionising radiation, protects human health in relation to food subjected to treatment by ionising radiation in that plant to an extent not less than human health is protected by the operation of these Regulations in relation to food of a similar description when subjected in Great Britain to such treatment.

(2) Recognition of appropriate origin may not be effected by the appropriate Ministers in respect of any country capable of coming within paragraph 1(2)(b)(ii) above unless they are satisfied—

- (a) that in that country food which is subjected to treatment by ionising radiation may only be so subjected if the person who subjects it has a current irradiation licence granted, under a reference by which that licence can be identified, by a competent authority in that country,
- (b) that any irradiation licence granted in that country includes provision for an approved method of measurement relating to food to which the licence relates, and
- (c) that the operation of the legislation in force in that country relating to the subjecting there of food to treatment by ionising radiation protects human health to an extent not less than human health is protected by operation of these Regulations.

(3) If the appropriate Ministers cease to be satisfied of the matters specified in paragraphs (a), (b) and (c) of sub-paragraph (1) above in respect of an origin in a plant or, as the case may be, of sub-paragraph (2) above in respect of an origin in a country they may publish in the London and Edinburgh Gazettes notice that, as from a date specified in the notice, that origin shall no longer be an appropriate origin for the purposes of these Regulations and, if such a notice is published, the recognition of appropriate origin shall cease to have effect on that date.

Appropriate documentation

3. Appropriate documentation for food for the purposes of these Regulations is a statement to the effect that the food has been subjected to treatment by ionising radiation together with—

(a) in relation to food from an origin within paragraph 1(2)(b)(i) above, a copy of all the particulars a copy of which, by virtue of sub-paragraphs (a) to (d) of paragraph 15 of Part II of Schedule 1 above, would be required to accompany any food had the official authorisation relating to the plant of that origin been an irradiation licence and had that food been consigned by the holder of an irradiation licence to any other person after subjection by him to treatment by ionising radiation, together with confirmation from the person authorised by virtue of that official authorisation that that official authorisation was in effect in relation to the food at the time at which that treatment took place, and

(b) in relation to food from an origin within paragraph 1(2)(b)(ii) above, a copy of all the particulars a copy of which, by virtue of sub-paragraphs (a) to (d) of paragraph 15 of Part II of Schedule 1 above, would be required to accompany any food had it been consigned by the holder of an irradiation licence to any other person after subjection by him to treatment by ionising radiation, together with confirmation from the holder of the irradiation licence in the country in which the food was subjected to treatment by ionising radiation that that irradiation licence was in effect in relation to the food at the time at which that treatment took place.

SCHEDULE 3

Regulation 5

REQUIREMENTS FOR STORAGE AND TRANSPORTATION

1. Food is stored and transported in accordance with the requirements of this Schedule where the requisite documentation accompanies the food.
2. For the purposes of this Schedule the requisite documentation, in relation to any food subjected to treatment by ionising radiation in Great Britain, is documentation containing a statement to the effect that the food has been subjected to treatment by ionising radiation together with the original or a copy of those particulars required by virtue of sub-paragraphs (a) to (d) of paragraph 15 of Part II of Schedule 1 above to accompany that food at the time of consignment.

3. For the purposes of this Schedule the requisite documentation, in relation to any food to which Schedule 2 above applies, is the original or a copy of the documentation which is the appropriate documentation for that food under that Schedule.

4. For the purposes of this Schedule subsection in Northern Ireland to treatment by ionising radiation shall be treated as if it took place in Great Britain and any licence having effect there shall be treated accordingly.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to Great Britain, revoke previous regulations which prohibited the sale of irradiated food (regulation 11), and permit the sale of specified types of irradiated food (regulation 6 as read with regulation 2, 3, 4 and Schedules 1 and 2) where the irradiation has taken place under licence.

Where irradiation takes place in England and Wales the licence falls to be granted by the Minister of Agriculture, Fisheries and Food, the Secretary of State for Health and the Secretary of State for Wales, acting jointly; in Scotland, the Secretary of State for Scotland is the licensing authority; Schedule 1 sets out the procedure for grant, terms, variation and suspension of licences.

It also provides for charges to be payable following an application for grant and agreement for variation of licences and in relation to the carrying out of inspections.

Where irradiation takes place in another EC member State, food can only be imported if the irradiation has taken place in a plant subject to official authorisation, recognition of which depends on those specified Ministers of the Crown jointly being satisfied that the official authorisation gives a standard of health protection equivalent to that given by an irradiation licence in Great Britain (Schedule 2—see in particular paragraph 2(1)).

Where irradiation takes place elsewhere overseas, food can only be imported if the exporting country is approved by those specified Ministers of the Crown acting jointly, and approval cannot be given unless those Ministers are satisfied that a

licensing system with equivalent health protection operates in the exporting country (Schedule 2—see in particular paragraph 2(2)).

The specified types of food which may be irradiated, or imported after irradiation, are fruit, vegetables, cereals, bulbs and tubers, spices and condiments, fish and shellfish and poultry (regulation 2(2) as read with regulation 3 and Schedule 1, Part II, paragraph 12 on home produced food and with regulation 4(1) in relation to imported food); regulation 2(2)(e) specifies the limits of overall average dose of ionising radiation which apply. The provisions of any licence granted under Schedule 1 must include a requirement to segregate irradiated food from other food in the premises to which the licence applies (Schedule 1, paragraph 8) and a prohibition on re-irradiation (Schedule 1, paragraph 9).

These Regulations also make provision for records to be kept by licensees (regulation 3 and Schedule 1), to be provided on import (Schedule 2), and to accompany irradiated food while it is being stored or transported (regulation 5 and Schedule 3).

They also make provision for parallel treatment of food irradiated in Northern Ireland (regulation 7), for a defence in relation to exports (regulation 8), for offences, penalties and enforcement (regulation 9), and for application (regulation 10) of provisions of the Food Safety Act 1990 where those provisions would not otherwise apply to regulations under that Act; thus no specific provision is made for a power of entry, but that power, by virtue of section 32 of the 1990 Act, applies automatically for the purposes of regulations under that Act, whereas the due diligence defence in section 21 of that Act, which would not otherwise apply to these Regulations, is specifically provided for.