

1992 No. 172

FOOD

**Food (Control of Irradiation) Regulations
(Northern Ireland) 1992**

Made 30th March 1992

Coming into operation 4th May 1992

Whereas, in accordance with Article 18(2) of the Food Safety (Northern Ireland) Order 1991(a) (“the Order”) it appears to the Department of Agriculture and the Department of Health and Social Services acting jointly as the Department concerned, to be necessary or expedient—

(a) for the purpose of securing that food complies with food safety requirements or in the interests of the public health; or

(b) for the purpose of protecting or promoting the interests of consumers, to make provision for the issue by the Department of Agriculture of licences in respect of the use of premises for the purposes of certain food businesses, and for prohibiting the use for those purposes of any premises except in accordance with such a licence;

And whereas, in accordance with Article 47(1) of the Order, provision in the following Regulations is made for prohibiting or regulating the carrying out of commercial operations in relation to food or contact material insofar as it relates to importation with a view to the prevention of disease (including the protection of human health) or with respect to services in connection with, or the regulation of, the quality, transport, marketing or identification of the food or contact material;

Now therefore the said Department concerned, in exercise of the powers conferred on it by Articles 15(1) and (3), 17(1), 18(1), 25, 26(3), 44 and 47(2) of, and paragraphs 1 and 4 of Schedule 1 to, the Order and of every other power enabling it in that behalf, after consultation in accordance with Article 47(3) of the Order with such organisations as appear to it to be representative of interests likely to be substantially affected thereby, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Food (Control of Irradiation) Regulations (Northern Ireland) 1992 and shall come into operation on 4th May 1992.

Interpretation

2.—(1) In these Regulations—

“the Order” means the Food Safety (Northern Ireland) Order 1991;

“alteration agreement charge” shall be construed in accordance with paragraph 1(1) of Part III of Schedule I;

“applicant” means a person who has applied for an irradiation licence and includes such a person after the licence has been issued to him;

“application consideration charge” shall be construed in accordance with paragraph 3(2) of Part I of Schedule 1;

“food” means food intended for sale for human consumption;

“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 0.5Gy,
or

(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;

“inspection charge” shall be construed in accordance with paragraph 2 of Part VI of Schedule I;

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

“licensing authority” means the Department of Agriculture;

“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;

(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;

(b) food falls within one of the seven permitted descriptions of food when (excluding the weight of any added water) not 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,
 - (iii) "cereals" has the meaning which it has in the Intervention Functions (Delegation) Regulations 1972(a),
 - (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) A person shall not, 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) Schedule 1 shall have effect in relation to—
- (a) the issue of irradiation licences;
- (b) the periods for which and the conditions subject to which the licences may be issued;
- (c) the alteration of those conditions;
- (d) the cancellation, suspension or revocation of the licences; and
- (e) the charges payable to the licensing authority for things done by it under the Schedule.

Restriction on importation

4.—(1) A person shall not import into Northern Ireland from any place outside the United Kingdom 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) For the purposes of paragraph (1), Schedule 2 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 and transport

5.—(1) A person shall not 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 under which the food was so treated, or that food is stored or, as the case may be, transported in accordance with the requirements of Schedule 3.

(2) This regulation applies to food which has (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. A person shall not 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 the United Kingdom in accordance with regulation 3 and all requirements of the irradiation licence under which that food was so treated have been observed, or
- (ii) that food was imported from any place outside the United Kingdom in compliance with regulation 4; and

(b) any storage or transportation of that food in the United Kingdom was carried out in compliance with regulation 5.

Activities taking place in Great Britain

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 for the time being having effect in Great Britain 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 Great Britain, be treated for the purposes of these Regulations as if it were compliance with the 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 (Northern Ireland) 1984(a).

Penalties, enforcement and functions of licensing authority

9.—(1) If any person contravenes 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 £2,000 or to imprisonment for a term not exceeding six months or both; and

(a) S.R. 1984 No. 407 to which there are amendments not relevant to these Regulations.

(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 a current irradiation licence contravenes any condition of that irradiation licence (other than the condition required to be included by paragraph 17 of Part II of Schedule 1) he shall be guilty of an offence and shall be liable—

(a) on summary conviction to a fine not exceeding £2,000 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 Order or these Regulations) shall, so far as is reasonably practicable, during the currency of an irradiation licence carry out regular inspections 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.

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

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

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

(7) Any charge under these Regulations payable to the licensing authority shall be recoverable by it as a civil debt.

Application of various provisions of the Food Safety (Northern Ireland) Order 1991

10.—(1) The following provisions of the Order shall apply for the purposes of these Regulations as they apply for the purposes of Articles 7, 13 or 14 of the Order as if references in them to the Order, or any provisions thereof, included references to these Regulations—

(a) Article 3 (application to food offered as prizes etc);

(b) Article 4 (presumption that food is intended for human consumption);

(c) Article 19 (defences where offences are due to fault of another person);

(d) Article 20 (defence of due diligence);

(e) Article 21 (defence of publication in the course of business);

(f) Article 30(8) (which relates to documentary evidence);

(g) Article 43 (protection of public analyst acting in good faith).

(2) Article 7(2) of the Order (which makes presumptions in the case of batches etc of food) 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) Article 8 of the Order (inspection and seizure of suspected food) 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) Article 35 of the Order (which relates to time limits for the beginning of prosecutions) shall apply in relation to offences under these Regulations as it applies to offences punishable under Article 36(2) of the Order.

Revocation of existing regulations

11. The Food (Control of Irradiation) Regulations (Northern Ireland) 1967(a) as amended by the Food (Control of Irradiation) (Amendment) Regulations (Northern Ireland) 1969(b) and the Food (Control of Irradiation) (Amendment) Regulations (Northern Ireland) 1972(c) are hereby revoked.

Sealed with the Official Seal of the Department of Agriculture on 30th March 1992.

(L.S.)

I. C. Henderson

Assistant Secretary

Sealed with the Official Seal of the Department of Health and Social Services on 30th March 1992.

(L.S.)

J. Scott

Assistant Secretary

(a) S.R. 1967 No. 51
(b) S.R. 1969 No. 226
(c) S.R. 1972 No. 68

Irradiation Licences

PART I

ISSUE OF IRRADIATION LICENCES

Application for an irradiation licence

1. A person may apply for an irradiation licence by sending to the licensing authority the following particulars in writing—

- (a) his name;
- (b) his address;
- (c) the address of the premises at which he proposes to subject food to treatment by ionising radiation;
- (d) details of any licence or registration under legislation other than these Regulations or the Order 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 to subject to treatment by ionising radiation;
- (f) in respect of each description of food specified pursuant to sub-paragraph (e)—
 - (i) the purpose for which he proposes to subject food of that description to treatment by ionising radiation;
 - (ii) whether or not he proposes to use microbiological criteria in deciding whether or not to subject food of that description 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 he proposes to apply to food of that description;
 - (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 to subject food of that description to treatment by ionising radiation in packaging in contact with the food and, if so, a description of the packaging which he proposes to use; and
 - (vi) whether or not he proposes to apply temperature control to food of that description 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 academic 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 issue an irradiation licence.

Functions of licensing authority on application for irradiation licence

2. On receipt of the particulars required by paragraph 1 the licensing authority may issue an irradiation licence to the applicant.

3.—(1) In deciding whether or not to issue 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) to treatment by ionising radiation at the premises specified by virtue of paragraph 1(c);
- (b) that each description of food specified by virtue of paragraph 1(e) is, or falls within, one of the seven permitted descriptions of food;
- (c) that each purpose specified by virtue of paragraph 1(f)(i) 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 sub-paragraph (5)(b)(i);
- (d) that either the descriptions of food specified by virtue of paragraph 1(e) do not give rise to any significant risk, or the factors specified by virtue of paragraph 1(f)(ii) 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) are no less than the requisite qualifications referred to, as the case may be, in the definition of “food examiner” in Article 30(9) or 31(3) (analysis of samples) of the Order;
- (f) that the overall average dose specified in relation to each description of food by virtue of paragraph 1(f)(iii) is consistent with each purpose specified in respect of that description of food by virtue of paragraph 1(f)(i);
- (g) that the factors specified by virtue of paragraph 1(f)(iv) 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) 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) and application of any temperature control specified by virtue of paragraph 1(f)(vi), fail to comply with food safety requirements; and
- (i) that the applicant will, by applying the practices proposed in the statement made by virtue of paragraph 1(g) (and involving in applying those practices persons with qualifications no less than those specified) eliminate any significant risk that there will be any breach of any condition of the irradiation licence.

and on completing that consideration the licensing authority shall notify the applicant that it has done so.

(2) The licensing authority may make a charge (hereinafter referred to as "the application consideration charge") for considering any application under this Part.

(3) The notification under paragraph (1) shall specify the amount of the application consideration charge determined under Part VI and the applicant shall, no later than twenty-eight days after that notification, pay the application consideration charge to the licensing authority.

(4) On receipt of the payment in respect of the application consideration charge the licensing authority shall, if it is satisfied of the matters specified in sub-paragraphs (1)(a) to (i), issue an irradiation licence to the applicant, but if it is not so satisfied the provisions of paragraph 4 shall apply.

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

- (a) "unlawful" in relation to any act means unlawful for want of registration, licence or similar authority issued under any legislation, 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:

$$D = \frac{1}{M} \int P_{(x,y,z)} d_{(x,y,z)} dV$$

where—

- (i) M = the total mass of that food,
- (ii) P = 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.

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

4.—(1) Where the licensing authority considers that it should not issue an irradiation licence to any applicant it shall give to the applicant a written statement of

the reasons for that view 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 representations are received by the licensing authority in pursuance of sub-paragraph (1) within the time limits therein specified, that 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 representations are received by the licensing authority in pursuance of sub-paragraph (1) that authority shall consider them and—

- (a) if those representations satisfy the licensing authority that none of the reasons specified in the written statement sent to the applicant under sub-paragraph (1) apply or apply any longer, and the licensing authority considers that there are no other reasons why it should not issue an irradiation licence, it shall issue such a licence to the applicant;
- (b) in any other case the licensing authority shall—
 - (i) if it considers that there are reasons (other than those it has already given) why it should not issue an irradiation licence, give to the applicant the written statement required by sub-paragraph (1) (whereupon the provisions of this paragraph shall apply as they apply when the original statement is given); or
 - (ii) otherwise 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

CONDITIONS OF IRRADIATION LICENCES

Introductory

1.—(1) Each irradiation licence (hereinafter referred to as “the licence”) shall contain the conditions required by the following provisions of this Part.

Person to whom licence is issued, reference and date

2.—(1) The licence shall specify the applicant as the licensee and shall specify that, subject only (where the licence is issued to an individual) to the provisions of Article 42 of the Order (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.

Premises to which licence applies

3. The licence shall specify the premises specified by virtue of paragraph 1(c) of Part I as the premises to which the licence applies and shall prohibit the applicant 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 as a description of food to which the licence applies and shall prohibit the applicant 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 applicant, 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; and
- (b) relates to the description of food within which that food falls.

6. The licence shall contain such conditions as will require the applicant not to deviate from the practices specified by virtue of paragraph 1(g) of Part I and not to employ any person in the application of those practices unless that person's qualifications meet the minimum qualifications so specified.

Free standing conditions

7. The licence shall prohibit the applicant from subjecting 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 applicant 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 previously 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 applicant 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) the licence shall prohibit the applicant 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 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).

10. The licence shall require the applicant 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).

11. The licence shall prohibit the applicant 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; or
- (d) electrons generated from machine sources operated at or below an energy level of 10 MeV.

12. The licence shall require the applicant 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 applicant 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.

14.—(1) The licence shall require the applicant 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 applicant 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) 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) applies, the characteristics of the beam referred to therein.

15. The licence shall require the applicant, 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;
- (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;
 - (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 by the licence to be recorded in pursuance of paragraph 14,

and shall prohibit the applicant from consigning food within that batch to any other person unless that food is accompanied by a statement of the applicant'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).

16.—(1) The licence shall require the applicant 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) The return of an applicant relating to a period shall state—

- (a) the name of the applicant;
- (b) the reference referred to in paragraph 2(2);
- (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 applicant 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 applicant to send to the licensing authority, no later than twenty-eight days after the date of any inspection within regulation 9(3) 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 applicant shall not contravene 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 from the date specified in accordance with paragraph 2(3).

PART III

ALTERATION OF CONDITIONS OF IRRADIATION LICENCE

1.—(1) The licensing authority and the applicant may, subject to paragraph 2, and to payment by the applicant to the licensing authority of a charge therefor (hereinafter referred to as “an alteration agreement charge”), agree to alter any condition of a licence inserted by virtue of paragraph 5 or 6 of Part II.

(2) The licence shall be altered in accordance with any such agreement as is mentioned in sub-paragraph (1) with effect from such time as payment of the alteration agreement charge is received by the licensing authority or (if later) such time as is specified in the agreement.

2.—(1) The licensing authority shall not in pursuance of paragraph 1 agree any alteration which permits any act or omission a proposal for which would, had it been made in the initial application for the licence, have caused the licensing authority to refuse to issue the licence.

(2) For the purposes of sub-paragraph (1) the licensing authority, in considering whether or not to agree any alteration of the conditions of a licence, 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

CANCELLATION, SUSPENSION AND EXTENSION OF IRRADIATION LICENCE

Cancellation 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 issue the irradiation licence, to refuse to do so, it may give notice to the applicant—

- (a) specifying those circumstances; and
- (b) informing him that, unless he satisfies it within a period specified in the notice (not being less than twenty-eight days from the date of the notice) that those circumstances either do not exist or should not have had the persuasive effect referred to in this paragraph, the licence will be cancelled.

2. If, by the end of the period so specified in the notice referred to in paragraph 1(a), or such longer period as is agreed by the licensing authority and the applicant for the purposes of this Part, the applicant has not satisfied the licensing authority that the circumstances referred to in paragraph 1 either do not exist or should not have had the persuasive effect referred to therein, the licensing authority shall give a further written notice to the applicant that the licence is cancelled as from a date specified in that notice and shall state why the licensing authority is not so satisfied, and when such a notice is given the licence shall be cancelled 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 applicant 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), 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) the suspension shall, subject to sub-paragraph (3), 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 applicant under paragraph 1; or
- (b) if such notice has been so served—
 - (i) at the time when cancellation 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 cancel the licence.

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

Extension

4. Where the holder of an existing licence applies under paragraph 1 of Part I no later than fifty-six days before the end of the period of the three year currency of that licence for 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 issue the licence applied for, it may by notice in writing to the applicant extend the currency of the 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 for a licence the terms and conditions of which would, if issued, differ from those of his existing licence.

(2) If the licence applied for under sub-paragraph (1) is issued with effect from a date which falls within the currency of the applicant's existing licence, then the existing licence shall, by virtue of the issue of that licence terminate at the end of the day before that date.

PART V

PUBLICATION

1. The licensing authority shall publish in the Belfast Gazette notice of—
 - (a) each irradiation licence issued;
 - (b) each suspension of an irradiation licence;

- (c) each cancellation of an irradiation licence; and
- (d) each alteration of the conditions of an irradiation licence.

2. Any notice published under paragraph 1 shall specify the name of the applicant or former licensee, the premises to which the licence relates or related and the reference provided in compliance with paragraph 2(2) of Part II and shall state in outline the effect of the matter to which it relates.

PART VI

CHARGES

1. For the purposes of this Schedule—

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

- (i) in the case of an application by the holder of an irradiation licence for the issue of a further irradiation licence on the same terms, other than in relation to its commencement date, as those of his existing irradiation licence, (hereinafter referred to as “a pure continuation licence”) £325;
- (ii) in the case of an application by the holder of an existing irradiation licence for the issue of a further irradiation licence which is a pure continuation licence in relation to the food to which his existing licence relates but extends to other food within the same of the seven permitted descriptions of food to which that existing licence applies, (such extension being hereinafter referred to as “type A extension”) 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 extension relates;
- (iii) in the case of an application by the holder of an existing irradiation licence for the issue of 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 permitted descriptions of food other than those to which the existing licence applies, (such an extension being hereinafter referred to as “type B extension”) a sum of $£1500 \times B$ where B is the number of other permitted descriptions of food into which the type B extension relates;
- (iv) in the case of an application by the holder of an existing irradiation licence for the issue of a further irradiation licence which is a pure continuation licence in relation to food to which his existing licence relates but which includes type A and type B extensions, the total which would be fixed and payable under head (ii) in relation to the type A extension and payable under head (iii) in relation to the type B extension; and
- (v) in any other case, £6,000 plus, if the application in question 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 to which it relates) falls within paragraph 3(6) of Part I, a sum (fixed at the discretion of the licensing authority) no greater than the sum which would otherwise be payable in the case of that application;

- (b) the amount of any inspection charge is £900;
- (c) the amount of any alteration agreement charge is £500; and

(d) an application by the holder of an irradiation licence 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.

2. For the purposes of this Schedule a charge (hereinafter called "an inspection charge") is payable in respect of each inspection referred to in regulation 9(3) 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—

- (a) for the first licence year in respect of an irradiation licence other than a pure continuation licence, £1,800, and
- (b) for any licence year other than a first licence year to which sub-paragraph (a) applies, £2,700.

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 Department of Agriculture of a notice in the Belfast Gazette declaring that an origin is an appropriate origin for the purposes of these Regulations.

(2) In this Schedule—

(a) “origin” means—

- (i) in relation to a Member State of the European Economic Community other than the United Kingdom, an origin in a plant 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

(b) “country” includes any territory with a country.

2.—(1) Recognition of appropriate origin shall not be effected by the Department of Agriculture in respect of any plant falling within paragraph 1(2)(a)(i) unless it is satisfied—

- (a) that there is in effect an official authorisation which applies to that plant;
- (b) that the official authorisation includes provision for an approved method of measurement in respect of food to which that 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 subjection 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 Northern Ireland to such treatment.

(2) Recognition of appropriate origin shall not be effected by the Department of Agriculture in respect of any country falling within paragraph 1(2)(a)(ii) unless it is 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 issued, under a reference by which that licence can be identified, by a competent authority in that country,
- (b) that any irradiation licence issued 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 subjection 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 Department of Agriculture ceases to be satisfied of the matters specified in heads (a), (b) and (c) of sub-paragraph (1) in respect of an origin in a plant or, as the case may be, of sub-paragraph (2) in respect of an origin in a country it may publish in the Belfast Gazette 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)(a)(i) 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, would be required to accompany any food had the official authorisation relating to the plant of that origin been an irradiation licence issued under these Regulations and had that food been consigned by the holder of such 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)(a)(ii) 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 would be required to accompany any food had it been consigned by the holder of an irradiation licence issued under these Regulations 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.

Requirements for storage and transporation

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 Northern Ireland, 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 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 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 subjection in Great Britain to treatment by ionising radiation shall be treated as if it took place in Northern Ireland and any licence having effect there shall be treated accordingly.

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations 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 regulations 2, 3, 4 and Schedules 1 and 2) where the irradiation has taken place under licence.

Where irradiation takes place in Northern Ireland the licence falls to be issued by the Department of Agriculture. Schedule 1 sets out the procedure for issue, conditions, alteration, cancellation and suspension of licences. It also provides for charges to be payable following an application for issue and agreement for alteration 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 the Department of Agriculture being satisfied that the official authorisation gives a standard of health protection equivalent to that given by an irradiation licence in Northern Ireland (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 the Department of Agriculture, and approval cannot be given unless the Department is 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 issued under Schedule 1 must include a requirement to segregate irradiated food from other food in the premises to which the licence applies (Schedule 1, Part II, paragraph 8) and a prohibition on re-irradiation (Schedule 1, Part II, paragraph 9).

These Regulations also make provision for records to be kept by the licence holder (Schedule 1, Part II, paragraph 15), 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 Great Britain (regulation 7), for a defence in relation to exports (regulation 8), for offences, penalties and enforcement (regulation 9), and for application of provisions of the Food Safety (Northern Ireland) Order 1991 where those provisions would not otherwise apply to regulations under that Order (regulation 10).