

SCHEDULE 1

IRRADIATION LICENCES

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.

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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 subsection 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 subsection 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

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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.