

## SCHEDULE 2

### LICENCES

#### PART 1

##### Grant of Licence

###### **Application for licence**

1. A person seeking a licence to irradiate food (“the applicant”) shall apply by sending to the Agency an application in writing containing—

- (a) the applicant’s name;
- (b) the applicant’s address;
- (c) the address of the facility at which the applicant proposes to irradiate food;
- (d) details of any licence or registration under any other legislation which enables the applicant to use ionising radiation at the facility in circumstances where, but for that licence or registration, that use would be unlawful;
- (e) a description of each food which the applicant proposes to irradiate which is sufficient to show that it falls within a permitted category of food;
- (f) in respect of each food described pursuant to sub-paragraph (e)—
  - (i) the purpose for which the applicant proposes to irradiate the food and how that would benefit consumers;
  - (ii) the method by which the applicant will ensure that the food is in a suitably wholesome state before irradiation;
  - (iii) the overall average dose, maximum dose and minimum dose of ionising radiation which the applicant proposes to apply to the food;
  - (iv) the method (including instrumentation and frequency) by which the applicant proposes to measure any dose of ionising radiation and the dosimetry standard which the applicant proposes to use to calibrate the dose meters used to measure it;
  - (v) whether or not the applicant proposes to irradiate the food in packaging in contact with the food and, if so, the packaging which the applicant proposes to use; and
  - (vi) whether or not the applicant proposes to apply temperature control to the food while irradiating it and, if so, the temperature at which the applicant proposes to keep the food during the application of temperature control;
- (g) in respect of each food described under sub-paragraph (e), particulars demonstrating that the irradiation will be in conformity with Schedule 1 and the Joint FAO/WHO Codex Alimentarius Commission Recommended International Code of Practice for the operation of irradiation facilities used for the treatment of foods (in this Part of this Schedule referred to as “the Code of Practice”), reference FAO/WHO/CAC, vol XV, edition 1(1);
- (h) a plan of the layout of the facility, details of its design and construction and a statement of the practices which the applicant proposes to apply, including—
  - (i) the proposed method of irradiating food;
  - (ii) the type of radiation to be used;

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(1) A copy of the Code of Practice may be obtained from the Codex Alimentarius Commission, Food and Agriculture Organisation of the United Nations, Vialle della Terme di Caracalla, 0010, Rome.

*Status: This is the original version (as it was originally made).*

- (iii) the proposed methods of business control and organisation, including the minimum qualifications (whether they are formal or are derived from skill, training or experience) of persons who will be involved in applying the practices;
- (i) the identity and qualifications of the person who has been designated to be responsible for compliance with the conditions necessary for application of the practices referred to in sub-paragraph (h) and that person's position within the applicant's management structure;
- (j) the date from which the applicant wishes the licence to run; and
- (k) any other particulars which the applicant wishes the Agency to consider in deciding whether to grant a licence.

### **Consideration of the application**

2. The Agency may grant a licence where it is satisfied that—
  - (a) the facility specified in the application satisfies the requirements of the Code of Practice;
  - (b) the food described in the application falls within a permitted category;
  - (c) there is a reasonable technological need;
  - (d) the irradiation would present no health hazard and would be carried out under the conditions described in the application;
  - (e) the irradiation would be of benefit to the consumer;
  - (f) the irradiation would not be used as a substitute for hygiene and health practices or for good manufacturing or agricultural practice;
  - (g) the purposes of irradiation are only—
    - (i) to reduce the incidence of food-borne disease by destroying pathogenic organisms;
    - (ii) to reduce spoilage of foodstuffs by retarding or arresting decay processes and destroying spoilage organisms;
    - (iii) to reduce loss of foodstuffs by premature ripening, germination or sprouting; or
    - (iv) to rid foodstuffs of organisms harmful to plants or plant products;
  - (h) where the purposes of irradiation include reducing the incidence of food-borne disease by destroying pathogenic organisms, the applicant will use microbiological criteria in deciding whether to irradiate food;
  - (i) there is no significant risk that the applicant may irradiate food which for microbiological reasons cannot comply with food safety requirements, or cannot comply without being irradiated;
  - (j) every method specified under paragraph 1(f)(ii) is adequate to enable the applicant to ensure that the food is in a suitably wholesome state before irradiation;
  - (k) the overall average dose specified under paragraph 1(f)(iii) in relation to each description of food is consistent with each purpose specified in respect of that description of food under paragraph 1(f)(i);
  - (l) the method and standard specified under paragraph 1(f)(iv)—
    - (i) comply with Schedule 1; and
    - (ii) eliminate any significant risk that the overall average dose, measured by that method, will deviate significantly from the overall average dose as defined under paragraph 1 of Schedule 1;

- (m) the factors specified under paragraph 1(f) eliminate any significant risk that food, irradiated in any packaging specified under paragraph 1(f)(v), and at any temperature specified under paragraph 1(f)(vi), will fail to comply with food safety requirements; and
- (n) the practices and qualifications specified in the statement under paragraph 1(h) are adequate for ensuring that the requirements of these Regulations and of any conditions of the licence will not be breached.

**3.** Where the Agency believes that—

- (a) it ought to take account of the practical operation of the facility before it finally determines the application; and
- (b) it would not prejudice safety if food was irradiated at the facility for the time being,

it may grant a licence for a period, or further period, not exceeding 6 months in total to enable it to take such account.

**Refusal of application**

**4.—(1)** Where the Agency refuses to grant a licence, it shall give to the applicant a statement in writing of its reasons for doing so and shall invite the applicant to make representations to it in writing within 28 days after the statement is sent.

(2) After considering any such representations, the Agency—

- (a) may, if satisfied as to the matters specified in paragraph 2, grant a licence; or
- (b) shall give to the applicant a statement in writing of its reasons for continuing to refuse the licence.

**Duration**

**5.—(1)** Subject to sub-paragraph (2), a licence continues in effect unless cancelled or suspended in accordance with the provisions of Part 5 or surrendered by the licensee to the Agency.

(2) A licence under paragraph 3 shall continue in effect until—

- (a) the expiration of the period for which it was granted; or
- (b) the refusal by the Agency of a licence on its final determination of the application,

unless cancelled or suspended in accordance with the provisions of Part 5 or surrendered by the licensee to the Agency.