SCOTTISH STATUTORY INSTRUMENTS

2000 No. 309

FOOD

The Food Irradiation Provisions (Scotland) Regulations 2000

Made - - - - 5th September 2000
Laid before the Scottish
Parliament - - - 8th September 2000
Coming into force - - 20th September 2000

The Scottish Ministers, in exercise of the powers conferred on them by sections 6(4), 16(1) and (3), 17(1), 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 and having had regard in accordance with section 48(4A)(2) of that Act to relevant advice given by the Food Standards Agency and after consultation in accordance with section 48(4) and (4B)(3) of that Act, hereby make the following Regulations:

Citation, commencement and extent

- 1.—(1) These Regulations may be cited as the Food Irradiation Provisions (Scotland) Regulations 2000 and shall come into force on 20th September 2000.
 - (2) These Regulations extend to Scotland only.

Amendments to the Food (Control of Irradiation) Regulations 1990

- **2.** The Food (Control of Irradiation) Regulations 1990(**4**) shall be amended in accordance with regulations 3 to 16 below.
 - **3.** In paragraph (1) of regulation 2 (interpretation)—
 - (a) there shall be inserted after the definition of "the Agency" the following definitions— "the Directives" means Directive 1999/2 and Directive 1999/3;

^{(1) 1990} c. 16; section 6(4) was amended by the Deregulation and Contracting Out Act 1994 (c. 40), Schedule 9, paragraph 6 and by the Food Standards Act 1999 (c. 28), Schedule 5, paragraph 10(3); sections 16(1), 18(1), 19(1), 45 and 48(1) were amended by the Food Standards Act 1999, Schedule 5, paragraph 8; section 17(1) was also amended by that Act, Schedule 5, paragraphs 8 and 12. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c. 46).

⁽²⁾ Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the Food Standards Act 1999.

⁽³⁾ Section 48(4B) was inserted by paragraph 21 of Schedule 5 to the Food Standards Act 1999.

⁽⁴⁾ S.I. 1990/2490, amended by S.S.I. 2000/62.

- "Directive 1999/2" means the European Parliament and Council Directive 99/2/EC on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation(5);
- "Directive 1999/3" means the European Parliament and Council Directive 99/3/EC on the establishment of a Community list of foods and food ingredients treated with ionising radiation(6);"; and
- (b) in the definition of "ionising radiation", for the words "0.5 Gy" in sub paragraph (a)(iii) there shall be substituted the words "0.01 Gy in the case of inspection devices which utilise neutrons and 0.5 Gy otherwise" and for the words "and 5 MeV otherwise" there shall be substituted the words ", 14 MeV in the case of neutrons and 5 MeV otherwise".
- **4.** In paragraph (1) of regulation 4 (restriction on importation) for the words "Great Britain" there shall be substituted the word "Scotland".
- **5.** In regulation 6 (restriction on sale), for the words "Great Britain" there shall be substituted the word "Scotland".
 - **6.** After regulation 6 there shall be inserted the following regulation—

"Labelling of non consumer foods

- **6A.**—(1) In the case of foods subject to treatment by ionising radiation not intended for sale to the ultimate consumer or catering establishments—
 - (a) the word "irradiated" or the words "treated with ionising radiation" shall be indicated on the documents which accompany or refer to those foods; and
 - (b) either the identity and address of the facility which carried out the irradiation, or the official reference number, shall be indicated on the documents referred to in sub paragraph (a) above.
- (2) In this regulation "ultimate consumer" and "catering establishment" have the meaning given in regulation 2(1) of the Food Labelling Regulations 1996(7); and "the official reference number" is that referred to in Article 7.1 of Directive 99/2.".
- 7. In regulation 7 (activities taking place in Northern Ireland) after the words "Northern Ireland" there shall in each case be inserted the words ", England or Wales, as the case may be".
 - 8. For regulation 8 (defence in relation to exports) there shall be substituted—
 - "In any proceedings for an offence under these Regulations it shall be a defence for the person charged to prove that 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 Community, that the country had legislation analogous to these Regulations and that the food complies with such legislation."
 - 9. In Schedule 1, Part I (grant of irradiation licences), in paragraph 1–
 - (a) the words "and how that would benefit consumers" shall be inserted at the end of sub paragraph (f)(i);
 - (b) the following sub paragraph shall be inserted between sub paragraphs (f) and (g):-
 - "(ff) in respect of each description of food specified pursuant to sub paragraph (e) above, particulars demonstrating that his operation will be in conformity with Annex III to Directive 1992/2 and the Joint FAO/WHO Codex Alimentarius

⁽⁵⁾ O.J. No. L 66, 13.3 99, p.16.

⁽⁶⁾ O.J. No. L 66, 13.3.99, p.24.

⁽⁷⁾ S.I. 1996/1499, to which there are amendments not relevant to these definitions.

Commission Recommended International Code of Practice for the operation of irradiation facilities used for the treatment of foods ("the Code of Practice") (reference FAO/WHO/CAC, vol. XV, edition 1),".

- (c) the following sub-paragraph shall be inserted between sub-paragraphs (g) and (h)-
 - "(gg) details of the person who has been designated to be responsible for compliance with the conditions necessary for application of the practices referred to in subparagraph (g) above,".
- **10.** In Schedule 1, Part I, in paragraph 3(1)–
 - (a) the following sub-paragraph shall be inserted between sub-paragraphs (a) and (b)-
 - "(aa) that the irradiation will be performed in conformity with the Code of Practice,";
 - (b) in sub paragraph (g), after "paragraph 1(f)(iv) above" there shall be inserted "are in conformity with Annex III to Directive 1999/2 and";
 - (c) in sub paragraph (h) the word "and" at the end shall be omitted;
 - (d) after sub paragraph (i) there shall be added the following-

"and

- (i) that the irradiation will be of benefit to the consumer,"; and
- (e) for "paragraphs (a) to (i) above" there shall be substituted "paragraphs (a) to (j) above".
- 11. In Schedule 1, Part II (terms and conditions of irradiation licences)—
 - (a) in paragraph 9(1) there shall be inserted at the beginning the words "The licence shall prohibit the licensee from subjecting any food to treatment by ionising radiation in combination with any chemical treatment having the same purpose as that treatment.";
 - (b) in paragraph 15 before "The licence" insert "(1)" and there shall be added at the end the following sub paragraph:—
 - "(2) The licence shall require the licensee to preserve the records referred to in sub paragraph (1) for a period of 5 years after making.";
 - (c) for paragraph 16(1) there shall be substituted the following:-
 - "(1) The licence shall require the licensee to send to the licensing authority within twenty eight days after each anniversary of the date from which the licence runs a written return in respect of the year ending with that anniversary."; and
 - (d) for paragraph 18 (duration) there shall be substituted the following:-

"Duration

- **18.** The licence shall, subject to Part III below, continue in effect unless withdrawn or suspended in accordance with the provisions of Part IV below or surrendered by the licensee to the licensing authority; and existing licenses shall be construed accordingly.".
- **12.** In Schedule 1, Part III (variation of irradiation licence), for paragraph 1(1) there shall be substituted the following:–
 - "(1) The licensing authority and the licensee may, subject to paragraph 2 below, agree between themselves, on payment by the licensee to the licensing authority of the appropriate variation agreement charge, to vary—
 - (a) the term of the licence inserted by virtue of paragraph 4 of Part II above, but only if the licence will, if so varied, apply to the same one of the seven permitted descriptions of food that it did prior to the variation; and in deciding whether or not to agree to vary

that term the licensing authority shall consider whether it is satisfied that the conditions of the licence inserted by virtue of paragraph 5 or 6 of Part II above are appropriate to the new description of food, or should be varied, and whether any new conditions should be inserted;

- (b) any condition of a licence inserted by virtue of paragraph 5 or 6 of Part II above.".
- **13.** In Schedule 1, in Part IV (withdrawal, suspension and extension of irradiation licence) paragraphs 4 and 5 shall be revoked.
 - 14. In Schedule 1, Part VI (charges)-
 - (a) for paragraph 2 there shall be substituted the following:-
 - "2. For the purposes of this Schedule-
 - (a) the amount of the application consideration charge is £5,000 plus—
 - (i) if more than one description of food is specified by virtue of paragraph 1(e) of Part I above, a sum (fixed at the discretion of the licensing authority) no greater than £1,500 × A where A is one less than the number of descriptions of food so specified; and
 - (ii) if the application (however many descriptions of food the application relates to) falls within paragraph 3(3) of Part I above, a sum (fixed at the discretion of the licensing authority) no greater than the sum which would otherwise have been payable in respect of the original application;
 - (b) the amount of the inspection charge is £750 for each inspection carried out in respect of which an inspection charge is payable;
 - (c) the amount of the variation agreement charge is-
 - (i) in the case of a variation pursuant to paragraph 1(1)(a) of Part III above whereby the licence, if varied, will apply to a description of food not specified in the term of the licence inserted by virtue of paragraph 4 of Part II above which specifies each description of food to which the licence applies, a sum (fixed at the discretion of the licensing authority) no greater than £1,500 × (B C) where B is the number of descriptions of food to which the licence, if varied, will apply and C is the number of descriptions of food specified in the term; and
 - (ii) £500 in any other cases.";
 - (b) in paragraph (b) of paragraph 3-
 - (i) for the words "other than a pure continuation licence, £1,800" in sub paragraph (i) there shall be substituted ", £1,500"; and
 - (ii) for "£2,700" in sub-paragraph (ii) there shall be substituted "£2,250".
 - 15. For Schedule 2 (importation of food) ther e shall be substituted the following-

"SCHEDULE 2

Regulation 4

IMPORTATION OF FOOD

PART I

IMPORTATION FROM OTHER MEMBER STATES

1. This Part applies to the importation of food irradiated in other member States.

- 2. For the purposes of regulation 4–
 - (a) "recognised appropriate origin" means origin in a plant, authorised by the competent authority of that member State, which is listed in the Official Journal of the European Communities pursuant to Article 7.4 of Directive 1999/2; and
 - (b) "appropriate documentation" means documentation containing the information referred to in regulation 6A(1)(b).

PART II

IMPORTATION FROM THIRD COUNTRIES

- **1.** This Part applies to the importation of food irradiated in a country (or territory) outside the European Community.
 - 2. In the case of herbs and spices, for the purposes of regulation 4–
 - (a) "recognised appropriate origin" means origin in a plant approved pursuant to Article 9 of Directive 1999/2, and listed in the Official Journal of the European Communities pursuant to that Article; and
 - (b) "the appropriate documentation" means the documents referred to in the second indent of paragraph 1 of the said Article 9.
 - 3. In the case of food other than herbs and spices—
 - (a) recognition of appropriate origin shall be effected by publication by the Agency of a notice in the Edinburgh Gazette declaring that an origin is an appropriate origin for the purposes of these Regulations.
 - (b) "Origin" means, in relation to a country or territory specified in the notice, origin in that country or territory.
 - (c) recognition of appropriate origin may not be effected by the Agency in respect of any country unless it is satisfied—
 - (i) 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;
 - (ii) 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
 - (iii) 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.
 - (d) if the Agency ceases to be satisfied of the matters specified in sub paragraphs (i), (ii) and (iii) of paragraph (c) above in respect of an origin in a country it may publish in the Edinburgh 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.
 - (e) appropriate documentation for food to which this paragraph applies 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—

- (i) a copy of all the particulars a copy of which, by virtue of paragraphs (a) to (d) of paragraph 15(1) 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; and
 - (ii) confirmation from the holder of the irradiation licence in the country in which the food was subjected to treatment by ionising radiation that an irradiation licence was in effect in relation to the food at the time at which that treatment took place.".
- **16.** In Schedule 3 (requirements for storage and transportation)—
 - (a) in paragraphs 2 and 4, for "Great Britain" there shall be substituted in each case "Scotland"; and
 - (b) in paragraph 4, after "Northern Ireland" there shall be inserted ", England and Wales".

Amendments to the Food Labelling Regulations 1996

- 17. The Food Labelling Regulations 1996(8) shall be amended in accordance with regulations 18 to 24 below.
 - **18.** In paragraph (1) of regulation 2 (interpretation)—
 - (a) after the definition of "Directive 94/54" there shall be inserted the following definition—
 ""Directive 99/2" means European Parliament and Council Directive 99/2/EC on
 the approximation of the laws of the member States concerning foods and food
 ingredients treated with ionising radiation;"; and
 - (b) in the definition of "ionising radiation", for the words "0.5 Gy" in sub paragraph (c) there shall be substituted the words "0.1 Gy in the case of inspection devices which utilise neutrons and 0.5 Gy otherwise", and for the words "and 5 MeV otherwise" there shall be substituted the words ", 14 MeV in the case of neutrons and 5 MeV otherwise".
- **19.** In paragraph (1)(iv) of regulation 3 (exemptions), for the words "and Directive 94/54" there shall be substituted the words ", Directive 94/54 and Directive 99/2".
 - 20. For paragraph (4)(b) of regulation 15 (compound ingredients) there shall be substituted—
 - "(b) the compound ingredient constitutes less than 25 per cent of the finished product, except that—
 - (i) subject to regulation 17, any additive which is an ingredient of such a compound ingredient shall be named in the list of ingredients in accordance with paragraph (2) of this regulation; and
 - (ii) where an ingredient of such a compound ingredient has been irradiated the name of that ingredient and the words required by paragraph 2 of Schedule 2 shall be given, except in the case of food which is prepared for patients requiring sterile diets under medical supervision."
- **21.** The following paragraph shall be inserted after paragraph (4) of regulation 26 (small packages and certain indelibly marked bottles)—
 - "(4A) Any food which-
 - (a) by virtue of paragraph (1) or (3) of this regulation is exempted from the requirement to be marked or labelled with a list of ingredients;
 - (b) contains any ingredient which has been irradiated; and
 - (c) is not prepared for patients requiring sterile diets under medical supervision,

shall be marked or labelled with an indication that it contains that ingredient and in such a case the reference within that indication to that ingredient shall include or be accompanied by the word "irradiated" or the words "treated with ionising radiation"."

- **22.** In regulation 35 (general requirement as to the manner of marking or labelling of food other than food to which regulation 23, 27 or 31 applies)—
 - (a) before the words "When any" insert "(1)";
 - (b) after the words "such particulars may" there shall be inserted the words "(except as provided in paragraph (2) of this regulation)"; and
 - (c) there shall be inserted after paragraph (1) the following paragraph—
 - "(2) In the case of food to which paragraph (1) of this regulation applies which has been irradiated, other than food which is prepared for patients requiring sterile diets under medical supervision, the alternative provided in that paragraph shall not apply as regards the particulars specified in regulation 14(2) and 26(4A) and paragraph 2 of Schedule 2, and the word "irradiated" or the words "treated with ionising radiation" shall in all cases appear on the commercial documents relating to such food."
- **23.** In regulation 36 (manner of marking or labelling of food to which regulation 23 or 27 applies)—
 - (a) after paragraph (1) there shall be inserted the following paragraph—
 - "(1A) Paragraphs (2) to (4) of this regulation shall apply only to food which is prepared for patients requiring sterile diets under medical supervision.";
 - (b) in paragraph (5)(c) there shall be inserted at the beginning the phrase "(except as provided in paragraph (6) of this regulation)"; and
 - (c) there shall be inserted at the end the following paragraphs-
 - "(6) Notwithstanding the foregoing paragraphs of this regulation (but subject to paragraph (7) below), in the case of the sale of food to which regulation 23 or 27 applies which has been irradiated—
 - (a) the word "irradiated" or the words "treated with ionising radiation" shall in all cases appear on the commercial documents relating to such food; and
 - (b) sub paragraph (c) of paragraph (5) of this regulation shall not apply as regards the particulars specified in regulations 14(2), 25(1) and 27(3) and (4) and paragraph 2 of Schedule 2.
 - (7) Paragraph (6) of this regulation shall not apply in relation to food which is prepared for patients requiring sterile diets under medical supervision.".
- **24.** In regulation 47(b) (defence in relation to exports), for the words "and Directive 94/54" there shall be substituted the words ", Directive 94/54 and Directive 99/2".

St. Andrew's House, Edinburgh 5th September 2000

SUSAN DEACON
A member of the Scottish Executive

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations give effect in Scotland to the provisions of-

- (a) Directive 1999/2/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation (O.J. No. L 66, 13.3.99, p.16); and
- (b) Directive 1999/3/EC of the European Parliament and of the Council on the establishment of a Community list of foods and food ingredients treated with ionising radiation (O.J. No. L 66, 13.3.99, p.24).

These Regulations give effect to the above provisions by amending the following Regulations in so far as they extend to Scotland—

- (a) the Food (Control of Irradiation) Regulations 1990 (S.I.1990/2490), as amended; and
- (b) the Food Labelling Regulations 1996 (S.I. 1996/1499), as amended.

The substantive amendments to the Food (Control of Irradiation) Regulations 1990 are as follows-

- (a) definitions of Directives 1999/2/EC and 1999/3/EC are inserted into regulation 2(1) (regulation 3(a));
- (b) the definition of "ionising radiation" in regulation 2(1) is amended (regulation 3(b));
- (c) a new regulation, 6A, requiring the labelling of non-consumer foods which are subject to ionising radiation, is inserted (regulation 6);
- (d) the text of regulation 8 (defence in relation to exports) is revised (regulation 8). The defence now only operates in relation to food intended for export to a country which is not a member of the European Community;
- (e) the particulars specified in paragraph 1 of Part I of Schedule 1 (particulars to be sent to the licensing authority by a person applying for an irradiation licence) are amended (regulation 9);
- (f) the matters set out in paragraph 3 of Part I of Schedule 1 (matters the licensing authority has to take into account in deciding whether to grant or to refuse to grant an irradiation licence) are revised (regulation 10);
- (g) the terms and conditions set out in Part II of Schedule 1 (terms and conditions to be included in irradiation licences) are varied (regulation 11);
- (h) the licensing authority and the licensee are given the power to agree a variation of the term of an irradiation licence inserted by virtue of paragraph 4 of Part II of Schedule 1 (regulation 12);
- (i) the power to extend an irradiation licence currently found in Part IV of Schedule 1 is revoked (regulation 13);
- (j) a revised paragraph 2 of Part VI of Schedule 1 (which specifies the amount of each charge referred to in that Schedule) is substituted for the existing paragraph so numbered, which also specifies the amount of each charge referred to in Schedule 1 (regulation 14(a));
- (k) paragraph 3(b) of Part VI of Schedule 1 is amended to vary the maximum sums which fall to be paid in any one year in respect of the inspections referred to in regulation 9(3) (regulation 14(b)); and

(l) a revised Schedule 2 (relating to the import of food) is substituted for the existing Schedule so numbered (which also deals with the import of food) (regulation 15).

These Regulations also make some further consequential amendments to the Food (Control of Irradiation) Regulations 1990.

The amendments to the Food Labelling Regulations 1996 are-

- (a) a definition of Directive 1999/2/EC is inserted into regulation 2(1) (regulation 18(a));
- (b) the definition of "ionising radiation" in regulation 2(1) is amended (regulation 18(b));
- (c) the exemption in regulation 3(1) for food brought into Great Britain in certain circumstances from another member State or an EEA state is adjusted so as to require such food to comply (where applicable) with Directive 1999/2/EC(regulation 19);
- (d) a revised sub-paragraph (b) of regulation 15(4) (providing an exception to the requirement that the names of the ingredients of a compound ingredient used in the preparation of a food have to be given in the list of ingredients of the food) is substituted for the existing sub-paragraph (b) of regulation 15(4) (regulation 20);
- (e) regulation 26 (small packages and certain indelibly marked bottles) is amended to require certain food which, although exempted from the requirement to be marked or labelled with a list of ingredients, nevertheless contains an ingredient which has been irradiated, to be marked and labelled accordingly (regulation 21);
- (f) regulation 35 (which imposes a general requirement as to the manner of marking or labelling of certain food) is so amended that the alternative to that requirement contained at the end of that regulation is modified in the case of a specified category of that food which has been irradiated (regulation 22);
- (g) regulation 36 (which imposes a requirement as to the manner of marking or labelling of certain other food) is so amended that—
 - (i) the application of paragraphs (2) to (4) of that regulation (which permit the use of alternative labelling in the case of certain food which has been or contains an ingredient which has been irradiated) is restricted to food which is prepared for patients requiring sterile diets under medical supervision, and
 - (ii) in the case of the sale of food to which regulation 23 or 27 of S.I. 1996/1499 applies which has been irradiated (other than food which is prepared for patients requiring sterile diets under medical supervision)—
 - (aa) the commercial documents relating to the food must in all cases indicate that it has been irradiated, and
 - (bb) certain particulars are no longer required to appear on those documents (regulation 23); and
- (h) the defence in relation to exports (regulation 47) is updated to include a reference to Directive 1999/2/EC(regulation 24).

A Regulatory Impact Assessment in relation to these Regulations has been placed in the Scottish Parliament Information Centre and copies can be obtained from the Food Standards Agency, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.