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WELSH STATUTORY INSTRUMENTS

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**2001 No. 1232 (W.66)**

**FOOD, WALES**

**The Food Irradiation Provisions (Wales) Regulations 2001**

*Made* - - - - 22nd March 2001

*Coming into force* - - 1st May 2001

The National Assembly for Wales in exercise of the powers conferred on it by sections 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), having had regard in accordance with section 48A of that Act to relevant advice given by the Food Standards Agency and after consultation in accordance with section 48(4) and (4B) of that Act makes the following Regulations:

**Title, application and commencement**

1. These Regulations may be cited as the Food Irradiation Provisions (Wales) Regulations 2001; they apply to Wales only and shall come into force on 1 May 2001

**Amendments to the Food (Control of Irradiation) Regulations 1990**

2. The Food (Control of Irradiation) Regulations 1990 (2) shall be amended insofar as they apply to Wales in accordance with regulations 3 to 16 below.

3. In paragraph (1) of regulation 2 (interpretation)—

(a) there shall be inserted immediately after the definition of “the Agency” the following definitions—

“Directive 1999/2” means the European Parliament and Commission Directive [1999/2/EC](#) on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation (3);

“Directive 1999/3” means the European Parliament and Commission Directive [1999/3/EC](#) on the establishment of a Community list of foods and food ingredients treated with ionising radiation (4); and

(b) in the definition of “ionising radiation”, for the words “0.5 Gy” in subparagraph (a)(iii) there shall be substituted the words “0.01 Gy in the case of

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(1) 1990 c. 16

(2) [SI 1990/2490](#), amended by [SI 2000/656](#).

(3) OJ No. L66, 13.3.1999, p.16

(4) OJ No. L66, 13.3.1999, p.24

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 “Wales”.

5. In regulation 6 (restriction on sale), for the words “Great Britain” there shall be substituted the word “Wales”.

6. After regulation 6 there shall be inserted the following regulation—

**“Labelling of non-consumer foods**

(a) **6A.** (1) In the case of foods subject to treatment by ionising radiation not intended for sale to the ultimate consumer or catering establishments the word “irradiated” or the words “treated with ionising radiation” shall be indicated on the documents which accompany or refer to those foods.

(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 **(5)**; and “the official reference number” is that referred to in Article 7.1 of Directive 1999/2.”.

7. In regulation 7 (activities taking place in Northern Ireland)—

(a) for the heading there shall be substituted “Activities taking place in Northern Ireland, Scotland and England”; and

(b) after the words “Northern Ireland” there shall in each case be inserted the words “,Scotland or England”.

8. For the text of 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 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 Community, that that country had legislation analogous to these Regulations and that the food complies with such legislation.”.

9. In Schedule 1 (irradiation licences), in 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 1999/2 and the Joint FAO/WHO Codex Alimentarius Commission Recommended International Code of Practice **(6)** 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,”; and

**(5)** SI 1996/1499; relevant amending instruments are SI 1998/1398, SI 1999/747, SI 1999/1483 and SI 2000/768.

**(6)** A copy of the said Code of Practice may be obtained from the Codex Alimentarius Commission, Food and Agriculture Organisation of the United Nations, Viale della Terme di Caracalla, 0010, Rome, or may be viewed at or downloaded from the website [www.foa.org/WAICENT/FAOINFO/ECONOMIC/ESN/Codex/STANDARD/standard.htm](http://www.foa.org/WAICENT/FAOINFO/ECONOMIC/ESN/Codex/STANDARD/standard.htm).

- (c) the following sub-paragraph shall be inserted between sub-paragraphs (g) and (h)—
- “(gg) the identity, qualifications and position in his management structure 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 (g) above.”.

**10.** In Schedule 1, in Part I, in paragraph 3(1)—

- (a) immediately before sub-paragraph (b) there shall be inserted the following sub-paragraph—
- “(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
- (j) that the irradiation will be of benefit to the consumer.”; and
- (e) in the full-out words, for “paragraphs (a) to (i) above” there shall be substituted “sub-paragraphs (a) to (j) above”.

**11.** In Schedule 1, in 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) the contents of paragraph 15 shall be numbered “(1)” and there shall be added 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, in 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(7), but only if the licence will if so varied apply to the same one or more of the seven permitted

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(7) Paragraph 4 requires the irradiation licence to specify each description of food to which it applies.

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; or

(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)—

(i) in the heading “Withdrawal, suspension and extension of irradiation licence” for the words “, suspension and extension” there shall be substituted the words “and suspension”, and

(ii) paragraphs 4 and 5 shall be revoked.

**14.** In Schedule 1, in 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  $£1,500 \times A$  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; and

(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  $£1,500 \times (B - C)$  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 case.”;

(b) in sub-paragraph (b) of paragraph 3—

(i) for the words “other than a pure continuation licence, £1,800” in paragraph (i) there shall be substituted “, £1,500”, and

(ii) for “£2,700” in paragraph (ii) there shall be substituted “£2,250”.

**15.** For Schedule 2 (importation of food) there 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 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—
  - (1) Recognition of appropriate origin shall be effected by publication by the Agency of a notice in the London Gazette declaring that an origin is an appropriate origin for the purposes of these Regulations.
  - (2) “Origin” means, in relation to a country or territory specified in the notice, origin in that country or territory.
  - (3) Recognition of appropriate origin may not be effected by the Agency in respect of any country or territory 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 granted, under a reference by which that licence can be identified, by a competent authority in that country or territory,
    - (b) that any irradiation licence granted in that country or territory 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 or territory 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.

(4) If the Agency ceases to be satisfied of the matters specified in sub-paragraphs (a), (b) and (c) of sub-paragraph (2) above in respect of an origin in a country or territory it may publish in the London Gazette notice that, as from a date specified in the notice, that origin shall not 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**

(5) Appropriate documentation for food other than herbs and spices 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) a copy of all the particulars a copy of which, by virtue of sub-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
- (b) confirmation from the holder of the irradiation licence in the country in which the food was subjected to treatment by ionising radiation that the 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 “Wales”; and
- (b) in paragraph 4, after “Northern Ireland” there shall be inserted, “ Scotland and England”.

### **Amendments to the Food Labelling Regulations 1996**

**17.** The Food Labelling Regulations 1996 shall be amended insofar as they apply to Wales 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 1999/2/EC on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation;”;
- (b) in the definition of “ionising radiation”, for the words “0.5 Gy” in sub-paragraph (c) 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”.

**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 between paragraphs (4) and (5) 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 alone 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) the existing text shall be numbered “(1)”;
- (b) in the full-out words to paragraph (1), after the word “may” there shall be inserted the words “(except as provided in paragraph (2) of this regulation)”;
- (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 the full-out words to that paragraph shall not apply as regards the particulars specified in regulations 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) immediately 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), in sub-paragraph (c) there shall be inserted at the beginning the phrase “(except as provided in paragraph (6) of this regulation)”;

- (c) there shall be added at the end the following paragraphs—

“(6) Notwithstanding the foregoing paragraphs of this regulation (but subject to paragraph (7) of the same), in the case of the sale of any 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 sub-paragraph (b) of regulation 47 (defence in relation to exports), for the words “and Directive 94/54” there shall be inserted the words “,Directive 94/54 and Directive 99/2”.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998 (8)

22nd March 2001

*D. Elis Thomas*  
The Presiding Officer of the National Assembly



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## EXPLANATORY NOTE

*(This note does not form part of the Regulations)*

1. These Regulations give effect in Wales 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 (OJNo. L66, 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 (OJ No. L66, 13.3.99, p.24).
2. These Regulations give effect to the above provisions by amending the following Regulations in so far as they apply to Wales—
  - (a) the Food (Control of Irradiation) Regulations 1990 ([SI 1990/2490](#)), as amended; and
  - (b) the Food Labelling Regulations 1996 ([SI 1996/1499](#)), as amended.
3. The Food (Control of Irradiation) Regulations 1990 and the Food Labelling Regulations 1996 extend to the whole of Great Britain.
4. 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 subjected 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 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 2 of that Part, which also specifies the amount of each charge referred to in Schedule 1 (regulation 14(a));

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

- (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).
5. These Regulations also make some consequential amendments to the Food (Control of Irradiation) Regulations 1990.
6. The amendments to the Food Labelling Regulations 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 European Economic Area 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 [SI 1996/1499](#) applies which has been irradiated (other than food which is prepared for patients requiring sterile diets under medical supervision), the commercial documents relating to the food must in all cases indicate that it has been irradiated (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).
7. A regulatory appraisal for these Regulations has been prepared pursuant to section 65 of the Government of Wales Act 1998 and placed in the library of the National Assembly for Wales. Copies may be obtained from the Food Standards Agency, 1st Floor, Southgate House, Cardiff, CF10 1EN.