WELSH STATUTORY INSTRUMENTS

2005 No. 3292 (W.252) FOOD, WALES

The Food Hygiene (Wales) Regulations 2005

Made - - - - 29 November 2005 Coming into force - - 1 January 2006

The National Assembly for Wales, being designated(1) for the purposes of section 2(2) of the European Communities Act 1972(2) in relation to measures relating to food (including drink), including the primary production of food, in exercise of the powers conferred by that section, and in exercise of the powers conferred by sections 16(1)(e) of the Food Safety Act 1990(3) and now vested in it(4), having had regard in accordance with section 48(4A) of the Food Safety Act to relevant advice given by the Food Standards Agency and after consultation both as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(5), makes the following Regulations:

PART I

PRELIMINARY

Title, commencement and application

1. The title of these Regulations is the Food Hygiene (Wales) Regulations 2005, they come into force on 1 January 2006 and they apply in relation to Wales.

Interpretation

2.—(1) In these Regulations —
"the Act" ("y Ddeddf") means the Food Safety Act 1990(6);

- **(1)** S.I. 2005/1971.
- (2) 1972 c. 68.
- (3) 1990 c. 16.
- (4) Functions of the Secretary of State under the Food Safety Act 1990, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the Food Standards Act.
- (5) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (OJ No. L245, 29.9.2003, p.4).
- (6) 1990 c. 16.

"the Agency" ("yr Asiantaeth") means the Food Standards Agency;

"authorised officer" ("swyddog awdurdodedig"), in relation to an enforcement authority, means any person (whether or not an officer of the authority) who is authorised by them in writing, either generally or specially, to act in matters arising under the Hygiene Regulations;

"the Community Regulations" ("*Rheoliadau'r Gymuned*") means Regulation 852/2004, Regulation 853/2004 and Regulation 854/2004;

"enforcement authority" ("awdurdod gorfodi") means the authority which, by virtue of regulation 5, is responsible for enforcing and executing the Hygiene Regulations;

"food authority" ("awdurdod bwyd") has the meaning that it bears by virtue of section 5(1A) of the Act;

"the Hygiene Regulations" ("y Rheoliadau Hylendid") means these Regulations and the Community Regulations;

"premises" ("mangre") includes any establishment, any place, vehicle, stall or moveable structure and any ship or aircraft; and

"Regulation 178/2002" ("Rheoliad 178/2002"), "Regulation 852/2004" ("Rheoliad 852/2004"), "Regulation 853/2004" ("Rheoliad 853/2004"), "Regulation 854/2004" ("Rheoliad 854/2004") and "Regulation 882/2004" ("Rheoliad 882/2004") have the meanings respectively given to them in Schedule 1; and

"specified Community provision" ("darpariaeth Gymunedol benodedig") means any provision of the Community Regulations that is specified in column 1 of Schedule 2 and whose subject-matter is described in column 2 of that Schedule.

- (2) Subject to paragraph (3), any expression other than one defined in paragraph (1) that is used both in these Regulations and in the Act has the meaning it bears in the Act.
- (3) Any expression used both in these Regulations and in Regulation 178/2002 or the Community Regulations has the meaning it bears in Regulation 178/2002 or the Community Regulations as the case may be.
- (4) Where, apart from this paragraph, any period of less than seven days which is specified in these Regulations would include any day which is—
 - (a) a Saturday, a Sunday, Christmas Day or Good Friday; or
- (b) a day which is a bank holiday under the Banking and Financial Dealings Act 1971(7) that day is excluded from the period.

Presumptions that food is intended for human consumption

- **3.**—(1) The following paragraphs apply for the purposes of these Regulations.
- (2) Any food commonly used for human consumption must, if placed on the market or offered, exposed or kept for placing on the market, be presumed, until the contrary is proved, to have been placed on the market or, as the case may be, to have been or to be intended for placing on the market for human consumption.
 - (3) The following, namely
 - (a) any food commonly used for human consumption which is found on premises used for the preparation, storage, or placing on the market of that food; and
 - (b) any article or substance commonly used in the manufacture of food for human consumption which is found on premises used for the preparation, storage or placing on the market of that food,

will be presumed, until the contrary is proved, to be intended for placing on the market, or for manufacturing food for placing on the market, for human consumption.

(4) Any article or substance capable of being used in the composition or preparation of any food commonly used for human consumption which is found on premises on which that food is prepared will, until the contrary is proved, be presumed to be intended for such use.

Competent authority

4. The competent authority for the purposes of the Community Regulations is the Agency except where it has delegated competencies as provided for in those Regulations.

Enforcement

- **5.**—(1) In respect of any food business operator to whose operations Regulation 852/2004 applies but Regulation 853/2004 does not apply
 - (a) the Agency must enforce and execute the Hygiene Regulations insofar as the operator concerned is carrying out primary production and those associated operations listed in paragraph 1 of Part AI of Annex I to Regulation 852/2004 other than the associated operations described in sub-paragraphs (a) and (c) of that paragraph insofar as they concern wild game; and
 - (b) the food authority in whose area the food business operator carries out his or her operations must enforce and execute the Hygiene Regulations insofar as the operator concerned is carrying out operations which are not enforced and executed by the Agency pursuant to sub-paragraph (a).
- (2) In respect of any food business operator to whose operations both Regulation 852/2004 and Regulation 853/2004 apply
 - (a) the Agency must enforce and execute the Hygiene Regulations insofar as the operator concerned is carrying out operations in relation to the following establishments and activities
 - (i) slaughterhouses,
 - (ii) game handling establishments,
 - (iii) cutting plants placing fresh meat on the market, and
 - (iv) activities in respect of eggs set out in Chapter I of Section X of Annex III to Regulation 853/2004; and
 - (b) the Agency or the food authority in whose area the food business operator carries out his or her operations must enforce and execute the Hygiene Regulations insofar as the operator concerned is carrying out operations in relation to any establishment or activity that is not specified in sub-paragraph (a) and is regulated by Regulation 853/2004.
 - (3) In respect of
 - (a) collection centres and tanneries supplying raw material for the production of gelatine intended for human consumption pursuant to paragraph 5 of Chapter I of Section XIV of Annex III to Regulation 853/2004; and
 - (b) collection centres and tanneries supplying raw material for the production of collagen intended for human consumption pursuant to paragraph 5 of Chapter I of Section XV of Annex III to Regulation 853/2004,

the food authority in whose area the collection centre or tannery concerned is situated must enforce and execute the Hygiene Regulations.

- (4) Each food authority must enforce and execute these Regulations in its area in relation to the matters regulated by
 - (a) Schedules 3 to 5; and
 - (b) Schedule 6 insofar as it applies in relation to raw milk intended for direct human consumption other than raw cows' milk.
- (5) The Agency must enforce and execute these Regulations in relation to the matters regulated by Schedule 6 insofar as it applies in relation to raw cows' milk intended for direct human consumption.

PART II

MAIN PROVISIONS

Hygiene improvement notices

- **6.**—(1) If an authorised officer of an enforcement authority has reasonable grounds for believing that a food business operator is failing to comply with the Hygiene Regulations, the officer may by a notice served on that person (in these Regulations referred to as a "hygiene improvement notice")—
 - (a) state the officer's grounds for believing that the food business operator is failing to comply with the Hygiene Regulations;
 - (b) specify the matters which constitute the food business operator's failure to comply;
 - (c) specify the measures which, in the officer's opinion, the food business operator must take in order to secure compliance; and
 - (d) require the food business operator to take those measures, or measures which are at least equivalent to them, within such period (not being less than 14 days) as may be specified in the notice.
- (2) Any person who fails to comply with a hygiene improvement notice will be guilty of an offence.

Hygiene prohibition orders

7.—(1) If—

- (a) a food business operator is convicted of an offence under these Regulations; and
- (b) the court by or before which the operator is so convicted is satisfied that the health risk condition is fulfilled with respect to the food business concerned,

the court will by an order impose the appropriate prohibition.

- (2) The health risk condition is fulfilled with respect to any food business if any of the following involves risk of injury to health (including any impairment, whether permanent or temporary), namely
 - (a) the use for the purposes of the business of any process or treatment;
 - (b) the construction of any premises used for the purposes of the business, or the use for those purposes of any equipment; and
 - (c) the state or condition of any premises or equipment used for the purposes of the business.
 - (3) The appropriate prohibition is
 - (a) in a case falling within sub-paragraph (a) of paragraph (2), a prohibition on the use of the process or treatment for the purposes of the business;

- (b) in a case falling within sub-paragraph (b) of that paragraph, a prohibition on the use of the premises or equipment for the purposes of the business or any other food business of the same class or description; and
- (c) in a case falling within sub-paragraph (c) of that paragraph, a prohibition on the use of the premises or equipment for the purposes of any food business.
- (4) If—
 - (a) a food business operator is convicted of an offence under these Regulations; and
 - (b) the court by or before which the operator is so convicted thinks it proper to do so in all the circumstances of the case,

the court may, by an order, impose a prohibition on the food business operator participating in the management of any food business, or any food business of a class or description specified in the order.

- (5) As soon as practicable after the making of an order under paragraph (1) or (4) (in these Regulations referred to as a "hygiene prohibition order"), the enforcement authority must
 - (a) serve a copy of the order on the relevant food business operator; and
 - (b) in the case of an order made under paragraph (1), affix a copy of the order in a conspicuous position on such premises used for the purposes of the food business as they consider appropriate,

and any person who knowingly contravenes such an order will be guilty of an offence.

- (6) A hygiene prohibition order will cease to have effect
 - (a) in the case of an order made under paragraph (1), on the issue by the enforcement authority of a certificate to the effect that they are satisfied that the food business operator has taken sufficient measures to secure that the health risk condition is no longer fulfilled with respect to the food business; and
 - (b) in the case of an order made under paragraph (4), on the giving by the court of a direction to that effect.
- (7) The enforcement authority must issue a certificate under sub-paragraph (a) of paragraph (6) within three days of their being satisfied as mentioned in that sub-paragraph; and on an application by the food business operator for such a certificate, the authority must
 - (a) determine, as soon as is reasonably practicable and in any event within 14 days, whether or not they are so satisfied; and
 - (b) if they determine that they are not so satisfied, give notice to the food business operator of the reasons for that determination.
- (8) The court must give a direction under sub-paragraph (b) of paragraph (6) if, on an application by the food business operator, the court thinks it proper to do so having regard to all the circumstances of the case, including in particular the conduct of the food business operator since the making of the order; but no such application will be entertained if it is made
 - (a) within six months of the making of the hygiene prohibition order; or
 - (b) within three months of the making by the food business operator of a previous application for such a direction.
- (9) Where a magistrates' court makes an order under paragraph (2) of regulation 8 with respect to any food business, paragraph (1) will apply as if the food business operator had been convicted by the court of an offence under these Regulations.
- (10) Where the commission of an offence by a food business operator leads to the conviction of another person pursuant to regulation 10, paragraph (4) will apply in relation to that other person as

it applies in relation to the food business operator and any reference in paragraph (5) or (8) to the food business operator will be construed accordingly.

Hygiene emergency prohibition notices and orders

- **8.**—(1) If an authorised officer of an enforcement authority is satisfied that the health risk condition is fulfilled with respect to any food business the officer may by a notice served on the relevant food business operator (in these Regulations referred to as a "hygiene emergency prohibition notice") impose the appropriate prohibition.
- (2) If a magistrates' court is satisfied, on the application of such an officer, that the health risk condition is fulfilled with respect to any food business, the court must, by an order (in these Regulations referred to as a "hygiene emergency prohibition order"), impose the appropriate prohibition.
- (3) Such an officer may not apply for a hygiene emergency prohibition order unless, at least one day before the date of the application, the officer has served notice on the relevant food business operator of his or her intention to apply for the order.
- (4) Paragraphs (2) and (3) of regulation 7 will apply for the purposes of this regulation as they apply for the purposes of that regulation, but as if the reference in paragraph (2) to risk of injury to health were a reference to imminent risk of injury.
- (5) As soon as practicable after the service of a hygiene emergency prohibition notice, an authorised officer of an enforcement authority must affix a copy of the notice in a conspicuous position on such premises used for the purposes of the food business as he or she considers appropriate; and any person who knowingly contravenes such a notice will be guilty of an offence.
- (6) As soon as practicable after the making of a hygiene emergency prohibition order, an authorised officer of an enforcement authority must
 - (a) serve a copy of the order on the relevant food business operator; and
 - (b) affix a copy of the order in a conspicuous position on such premises used for the purposes of the food business as the officer considers appropriate,

and any person who knowingly contravenes such an order will be guilty of an offence.

- (7) A hygiene emergency prohibition notice will cease to have effect
 - (a) if no application for a hygiene emergency prohibition order is made within the period of three days beginning with the service of the notice, at the end of that period; or
 - (b) if such an application is so made, on the determination or abandonment of the application.
- (8) A hygiene emergency prohibition notice or a hygiene emergency prohibition order will cease to have effect on the issue by the enforcement authority of a certificate to the effect that they are satisfied that the food business operator has taken sufficient measures to secure that the health risk condition is no longer fulfilled with respect to the food business.
- (9) The enforcement authority must issue a certificate under paragraph (8) within three days of their being satisfied as mentioned in that paragraph; and on an application by the food business operator for such a certificate, the authority must
 - (a) determine as soon as is reasonably practicable and in any event within 14 days whether or not they are so satisfied; and
 - (b) if they determine that they are not so satisfied, give notice to the food business operator of the reasons for that determination.
- (10) Where a hygiene emergency prohibition notice is served on a food business operator, the enforcement authority must compensate the officer in respect of any loss suffered by reason of the officer's complying with the notice unless —

- (a) an application for a hygiene emergency prohibition order is made within the period of three days beginning with the service of the notice; and
- (b) the court declares itself satisfied, on the hearing of the application, that the health risk condition was fulfilled with respect to the food business at the time when the notice was served.

and any disputed question as to the right to or the amount of any compensation payable under this paragraph is determinable by arbitration.

Remedial action notices and detention notices

- **9.**—(1) Where it appears to an authorised officer of an enforcement authority that in respect of an establishment subject to approval under Article 4(2) of Regulation 853/2004—
 - (a) any of the requirements of the Hygiene Regulations is being breached; or
 - (b) inspection under the Hygiene Regulations is being hampered,

the officer may, by a notice served on the relevant food business operator or the operator's duly authorised representative (in these Regulations referred to as a "remedial action notice")—

- (c) prohibit the use of any equipment or any part of the establishment specified in the notice;
- (d) impose conditions upon or prohibit the carrying out of any process;
- (e) require the rate of operation to be reduced to such extent as is specified in the notice, or to be stopped completely.
- (2) A remedial action notice must be served as soon as practicable stating why it is being served.
- (3) If it is served under paragraph (1)(a), it must specify the breach and the action needed to remedy it.
- (4) An authorised officer of the enforcement authority whose authorised officer served the original remedial action notice must, as soon as he or she is satisfied that such action has been taken, withdraw the notice by a further notice in writing served on the food business operator or his or her duly authorised representative.
- (5) An authorised officer of an enforcement authority may, at an establishment subject to approval under Article 4(2) of Regulation 853/2004, by a notice served on the relevant food business operator or his or her duly authorised representative (in this regulation referred to as a "detention notice") require the detention of any animal or food for the purposes of examination (including the taking of samples).
- (6) An authorised officer of the enforcement authority whose officer served the original detention notice must, as soon as he or she is satisfied that the animal or food need no longer be detained, withdraw the notice by a further notice in writing served on the food business operator or his or her duly authorised representative.
- (7) Any person who fails to comply with a remedial action notice or a detention notice will be guilty of an offence.

Offences due to fault of another person

10. Where the commission by any person of an offence under these Regulations is due to the act or default of some other person, that other person will be guilty of the offence; and a person may be convicted of the offence by virtue of this regulation whether or not proceedings are taken against the first-mentioned person.

Defence of due diligence

- 11.—(1) In any proceedings for an offence under these Regulations, it is, subject to paragraph (2), a defence for the accused to prove that he or she took all reasonable precautions and exercised all due diligence to avoid the commission of the offence whether by the accused or a person under the accused's control.
- (2) If in any case the defence provided by paragraph (1) involves the allegation that the commission of the offence was due to an act or default of another person, or to reliance on information supplied by another person, the accused will not, without leave of the court, be entitled to rely on that defence unless
 - (a) at least seven clear days before the hearing; and
 - (b) where the accused has previously appeared before a court in connection with the alleged offence, within one month of the accused's first such appearance,

the accused has served on the prosecutor a notice in writing giving such information identifying or assisting in the identification of that other person as was then in his or her possession.

PART III

ADMINISTRATION AND ENFORCEMENT

Procurement of samples

- 12. An authorised officer of an enforcement authority may
 - (a) purchase a sample of any food, or any substance capable of being used in the preparation of food;
 - (b) take a sample of any food, or any such substance, which
 - (i) appears to the officer to be intended for placing on the market or to have been placed on the market, for human consumption, or
 - (ii) is found by the officer on or in any premises which the officer is authorised to enter by or under regulation 14;
 - (c) take a sample from any food source, or a sample of any contact material, which is found by the officer on or in any such premises; and
 - (d) take a sample of any article or substance which is found by the officer on or in any such premises and which the officer has reason to believe may be required as evidence in proceedings under any of the provisions of these Regulations.

Analysis etc. of samples

- **13.**—(1) An authorised officer of an enforcement authority who has procured a sample under regulation 12 must
 - (a) if he or she considers that the sample should be analysed, submit it to be analysed
 - (i) by the public analyst for the area in which the sample was procured, or
 - (ii) by the public analyst for the area which consists of or includes the area of the authority;
 - (b) if he or she considers that the sample should be examined, submit it to be examined by a food examiner.
- (2) A person, other than such an officer, who has purchased any food, or any substance capable of being used in the preparation of food, may submit a sample of it —

- (a) to be analysed by the public analyst for the area in which the purchase was made; or
- (b) to be examined by a food examiner.
- (3) If, in any case where a sample is proposed to be submitted for analysis under this regulation, the office of public analyst for the area in question is vacant, the sample must be submitted to the public analyst for some other area.
- (4) If, in any case where a sample is proposed to be or is submitted for analysis or examination under this regulation, the food analyst or examiner determines that he or she is for any reason unable to perform the analysis or examination, the sample must be submitted or, as the case may be, sent by him or her to such other food analyst or examiner as he or she may determine.
- (5) A food analyst or examiner must analyse or examine as soon as practicable any sample submitted or sent to him or her under this regulation, but may, except where
 - (a) he or she is the public analyst for the area in question; and
 - (b) the sample is submitted to him or her for analysis by an authorised officer of an enforcement authority,

demand in advance the payment of such reasonable fee as he or she may require.

- (6) Any food analyst or examiner who has analysed or examined a sample must give to the person by whom it was submitted a certificate specifying the result of the analysis or examination.
- (7) Any certificate given by a food analyst or examiner under paragraph (6) must be signed by him or her, but the analysis or examination may be made by any person acting under his or her direction.
 - (8) In any proceedings under these Regulations, the production by one of the parties
 - (a) of a document purporting to be a certificate given by a food analyst or examiner under paragraph (6); or
- (b) of a document supplied to him or her by the other party as being a copy of such a certificate, will be sufficient evidence of the facts stated in it unless, in a case falling within sub-paragraph (a), the other party requires that the food analyst or examiner to be called as a witness.
- (9) In this regulation where two or more public analysts are appointed for any area, any reference in these Regulations to the public analyst for that area will be construed as a reference to either or any of them.

Powers of entry

- **14.**—(1) An authorised officer of an enforcement authority other than the Agency will, on producing, if so required, some duly authenticated document showing his or her authority, have a right at all reasonable hours
 - (a) to enter any premises within the authority's area or as the case may be district for the purpose of ascertaining whether there is or has been on the premises any contravention of the provisions of the Hygiene Regulations;
 - (b) to enter any premises, whether within or outside the authority's area or as the case may be district, for the purpose of ascertaining whether there is on the premises any evidence of any such contravention within that area or district; and
 - (c) to enter any premises for the purpose of the performance by the authority of their functions under the Hygiene Regulations,

but admission to any premises used only as a private dwelling-house may not be demanded as of right unless 24 hours' notice of the intended entry has been given to the occupier.

(2) An authorised officer of the Agency must, on producing if so required some duly authenticated document showing his or her authority, have a right at all reasonable hours to enter any premises for the purpose of —

- (a) ascertaining whether there is or has been on the premises any contravention of the provisions of the Hygiene Regulations;
- (b) ascertaining whether there is on the premises any evidence of any such contravention; and
- (c) the performance by the Agency of its functions under the Hygiene Regulations,

but admission to any premises used only as a private dwelling-house cannot be demanded as of right unless 24 hours' notice of the intended entry has been given to the occupier.

- (3) If a justice of the peace, on sworn information in writing, is satisfied that there is reasonable ground for entry onto any premises for any such purpose as is mentioned in paragraph (1) or (2) and either
 - (a) that admission to the premises has been refused, or a refusal is apprehended, and that notice of the intention to apply for a warrant has been given to the occupier; or
 - (b) that an application for admission, or the giving of such a notice, would defeat the object of the entry, or that the case is one of urgency, or that the premises are unoccupied or the occupier is temporarily absent,

the justice may by warrant signed by him or her authorise the authorised officer to enter the premises, if need be by reasonable force.

- (4) Every warrant granted under this regulation will continue in force for a period of one month.
- (5) An authorised officer entering any premises by virtue of this regulation, or of a warrant issued under it, may take with him or her such other persons as he or she considers necessary, and on leaving any unoccupied premises which the officer has entered by virtue of such a warrant must leave them as effectively secured against unauthorised entry as that in which they were found.
- (6) An authorised officer entering premises by virtue of this regulation, or of a warrant issued under it, may inspect any records (in whatever form they are held) relating to a food business and, where any such records are stored in any electronic form
 - (a) may have access to, and inspect and check the operation of, any computer and any associated apparatus or material which is or has been in use in connection with the records; and
 - (b) may require any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material to afford the officer such assistance as he or she may reasonably require.
 - (7) Any officer exercising any power conferred by paragraph (6) may
 - (a) seize and detain any records which the officer has reason to believe may be required as evidence in proceedings under any of the provisions of these Regulations; and
 - (b) where the records are stored in any electronic form, require the records to be produced in a form in which they may be taken away.
- (8) If any person who enters any premises by virtue of this regulation, or of a warrant issued under it, discloses to any person any information obtained by him or her on the premises with regard to any trade secret, he or she will, unless the disclosure was made in the performance of his or her duty, be guilty of an offence.
- (9) Nothing in this regulation authorises any person, except with the permission of the local authority under the Animal Health Act 1981(8), to enter any premises
 - (a) on which an animal or bird affected with any disease to which that Act applies is kept; and
 - (b) which is situated in a place declared under that Act to be infected with such a disease.

Obstruction etc. of officers

- **15.**—(1) Any person who
 - (a) intentionally obstructs any person acting in the execution of the Hygiene Regulations; or
- (b) without reasonable cause, fails to give to any person acting in the execution of the Hygiene Regulations any assistance or information which that person may reasonably require of him or her for the performance of that person's functions under the Hygiene Regulations, will be guilty of an offence.
- (2) Any person who, in purported compliance with any such requirement as is mentioned in sub-paragraph (b) of paragraph (1)—
 - (a) furnishes information which he or she knows to be false or misleading in a material particular; or
- (b) recklessly furnishes information which is false or misleading in a material particular, will be guilty of an offence.
- (3) Nothing in sub-paragraph (b) of paragraph (1) is to be construed as requiring any person to answer any question or give any information if to do so might incriminate him or her.

Time limit for prosecutions

- **16.** No prosecution for an offence under these Regulations which is punishable under subparagraph (2) of regulation 17 may be begun after the expiry of
 - (a) three years from the commission of the offence; or
 - (b) one year from its discovery by the prosecutor,

whichever is the earlier.

Offences and penalties

- 17.—(1) Subject to paragraph (4), any person who contravenes or fails to comply with any of the specified Community provisions will be guilty of an offence.
 - (2) Subject to paragraph (3), a person guilty of an offence under these Regulations will be liable
 - (a) on summary conviction to a fine not exceeding the statutory maximum; or
 - (b) on conviction on indictment to imprisonment for a term not exceeding two years, to a fine or to both.
- (3) A person guilty of an offence under regulation 15 will be liable on summary conviction to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or to both.
- (4) A person will not be considered to have contravened or failed to comply with Article 4(2) of Regulation 852/2004 as read with paragraph 4 of Chapter IV of Annex II to that Regulation (bulk foodstuffs in liquid, granulate or powder form to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs) provided the requirements of Schedule 3 are met.

Offences by bodies corporate

- **18.**—(1) Where an offence under these Regulations which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of
 - (a) any director, manager, secretary or other similar officer of the body corporate; or
 - (b) any person who was purporting to act in any such capacity,

he or she as well as the body corporate will be deemed to be guilty of that offence and will be liable to be proceeded against and punished accordingly.

(2) In sub-paragraph (a) of paragraph (1) "director", in relation to any body corporate established by or under any enactment for the purpose of carrying on under national ownership any industry or part of an industry or undertaking, being a body corporate whose affairs are managed by its members, means a member of that body corporate.

Offences by Scottish partnerships

19. Where an offence under these Regulations which has been committed by a Scottish partnership is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner, that partner, as well as the partnership will be deemed to be guilty of that offence and liable to be proceeded against and punished accordingly.

Right of appeal

- **20.**—(1) Any person who is aggrieved by
 - (a) a decision of an authorised officer of an enforcement authority to serve a hygiene improvement notice;
 - (b) a decision of an enforcement authority to refuse to issue a certificate under paragraph (6) of regulation 7 or paragraph (8) of regulation 8; or
 - (c) a decision of an authorised officer of an enforcement authority to serve a remedial action notice,

may appeal to a magistrates' court.

- (2) The procedure on an appeal to a magistrates' court under paragraph (1) is by way of complaint for an order, and the Magistrates' Courts Act 1980(9) will apply to the proceedings.
 - (3) The period within which an appeal under paragraph (1) may be brought is
 - (a) one month from the date on which notice of the decision was served on the person desiring to appeal; or
 - (b) in the case of an appeal against a decision to issue a hygiene improvement notice, the period specified in sub-paragraph (a) or, if it is shorter, the period specified in the notice pursuant to sub-paragraph (d) of paragraph (1) of regulation 6,

and the making of a complaint for an order will be deemed for the purposes of this paragraph to be the bringing of the appeal.

Appeals to Crown Court

- **21.** A person who is aggrieved by
 - (a) the dismissal by a magistrates' court of an appeal to it under paragraph (1) of regulation 20; or
 - (b) any decision of such a court to make a hygiene prohibition order or a hygiene emergency prohibition order,

may appeal to the Crown Court.

Appeals against hygiene improvement notices and remedial action notices

- **22.**—(1) On an appeal against a hygiene improvement notice or a remedial action notice, the court may cancel or affirm the notice and, if it affirms it, may do so either in its original form or with such modifications as the court may in the circumstances think fit.
- (2) Where any period specified in a hygiene improvement notice pursuant to sub-paragraph (d) of paragraph (1) of regulation 6 would otherwise include any day on which an appeal against that notice is pending, that day will be excluded from that period.
- (3) Any appeal will be regarded as pending for the purposes of paragraph (2) until it is finally disposed of, is withdrawn or is struck out for want of prosecution.

Application of section 9 of the Food Safety Act 1990

23. Section 9 of the Act (inspection and seizure of suspected food)(10) applies for the purposes of these Regulations with the modification that it applies in relation to an authorised officer of an enforcement authority as it applies in relation to an authorised officer of a food authority.

PART IV

MISCELLANEOUS AND SUPPLEMENTARY PROVISIONS

Power to issue codes of recommended practice

- **24.**—(1) For the guidance of food authorities, the National Assembly for Wales may issue codes of recommended practice as regards the execution and enforcement of the Hygiene Regulations.
- (2) The Agency may, after consulting the National Assembly for Wales, give a food authority a direction requiring them to take any specified steps in order to comply with a code issued under this regulation.
- (3) In exercise of the functions conferred on them by or under the Hygiene Regulations, every food authority
 - (a) must have regard to any relevant provision of any such code; and
 - (b) must comply with any direction which is given under this regulation and requires them to take any specified steps in order to comply with such a code.
- (4) Any direction under paragraph (2) will, on the application of the Agency, be enforceable by mandatory order.
- (5) The Agency must consult the National Assembly for Wales before making an application under paragraph (4).
- (6) Before issuing any code under this regulation, the National Assembly for Wales will have regard to any relevant advice given by the Agency.

Protection of officers acting in good faith

- **25.**—(1) An officer of an enforcement authority is not personally liable in respect of any act done by him or her—
 - (a) in the execution or purported execution of the Hygiene Regulations; and
 - (b) within the scope of his or her employment,

if the officer did that act in the honest belief that his or her duty under the Hygiene Regulations required or entitled him or her to do it.

- (2) Nothing in paragraph (1) is to be construed as relieving any enforcement authority of any liability in respect of the acts of their officers.
- (3) Where an action has been brought against an officer of an enforcement authority in respect of an act done by him or her—
 - (a) in the execution or purported execution of the Hygiene Regulations; but
 - (b) outside the scope of his or her employment,

the authority may indemnify the officer against the whole or a part of any damages which the officer has been ordered to pay or any costs which the officer may have incurred if they are satisfied that the officer honestly believed that the act complained of was within the scope of his or her employment.

(4) A public analyst appointed by a food authority will be treated for the purposes of this regulation as being an officer of the authority, whether or not the officer's appointment is a whole-time one.

Revocation and suspension of designations and appointments

- **26.**—(1) Subject to paragraphs (2) and (3), the Agency may at any time revoke or suspend
 - (a) the appointment of an official veterinarian;
 - (b) the designation of an approved veterinarian; or
 - (c) the appointment of an official auxiliary,

if it appears to the Agency that the person in question is unfit to perform any of the functions of that post under the Hygiene Regulations.

- (2) Where the Agency revokes or suspends a designation or appointment under paragraph (1), the Agency must, as soon as practicable, give to the person whose designation or appointment has been revoked or suspended a notice in writing of the reasons for the revocation or suspension and afford that person an opportunity of
 - (a) making representations in writing to the Agency with regard to the revocation or suspension; or
 - (b) being heard by a person nominated by the Agency for the purpose pursuant to sub-paragraph (a) of paragraph (5).
 - (3) A notice given under paragraph (2) must inform the person to whom it is given
 - (a) of his or her right to make representations in writing;
 - (b) of the manner in which and the time (not being less than 21 days from the giving of the notice) within which such representations may be made;
 - (c) of his or her right to be heard; and
 - (d) of the manner in which and the time (not being less than 21 days from the giving of the notice) within which he or she may apply for an opportunity to be heard.
- (4) In the event of the person whose designation or appointment has been revoked or suspended making any representations (whether orally or in writing) under paragraph (3) the Agency must reconsider whether that person is unfit to perform any of the functions of the post he or she holds under the Hygiene Regulations and must, as soon as practicable, reconsider its decision to revoke or suspend the designation or appointment under paragraph (1) in the light of those representations.
- (5) Where a person requests the opportunity to be heard pursuant to sub-paragraph (b) of paragraph (2)—

- (a) the Agency must nominate a person to determine the matter from the list established under paragraph (6);
- (b) the person so nominated must serve a notice on the person requesting the opportunity to be heard and the Agency informing them of the time (not being less than 21 days from the giving of the notice) of the hearing; and
- (c) the person so nominated must, within 21 days of the hearing, notify the person requesting the opportunity to be heard and the Agency of his or her decision.
- (6) The Agency must establish and maintain a list of people who may be nominated for the purposes of this regulation and must consult those organisations appearing to it to represent official veterinarians, approved veterinarians and official auxiliaries before including any person on the list.

Food which has not been produced, processed or distributed in accordance with the Hygiene Regulations

- 27.—(1) On an inspection of any food, an authorised officer of an enforcement authority may certify that it has not been produced, processed or distributed in compliance with the Hygiene Regulations.
- (2) Where any food is certified as mentioned in paragraph (1) it will be treated for the purposes of section 9 of the Act as failing to comply with food safety requirements.
- (3) Where any food certified as mentioned in paragraph (1) is part of a batch, lot or consignment of food of the same class or description, all the food in the batch, lot or consignment must, until it is proved that it has been produced, processed or distributed in compliance with the Hygiene Regulations, be treated for the purposes of paragraph (2) as having been so certified.

Service of documents

- **28.**—(1) Any document which is required or authorised under these Regulations to be served on a food business operator may be served
 - (a) by delivering it to that person;
 - (b) in the case of an incorporated company or body, by delivering it to their secretary at their registered or principal office, or by sending it in a prepaid letter addressed to the secretary at that office; or
 - (c) in the case of any other food business operator, by leaving it or sending it in a prepaid letter addressed to the operator at the operator's usual or last known residence.
- (2) Where a document is to be served on a food business operator under these Regulations and it is not reasonably practicable to ascertain the name and address of the person on whom it should be served, or the premises of the food business operator are unoccupied, the document may be served by addressing it to the food business operator concerned in the capacity of occupier of those premises (naming them), and
 - (a) by delivering it to some other person at the premises; and
 - (b) if there is no other person at the premises to whom it can be delivered, by affixing it or a copy of it to some conspicuous part of the premises.

Bulk transport in sea-going vessels of liquid oils or fats and the bulk transport by sea of raw sugar

29. Schedule 3 (bulk transport in sea-going vessels of liquid oils or fats and the bulk transport by sea of raw sugar) has effect.

Temperature control requirements

30. Schedule 4 (temperature control requirements) has effect.

Direct supply by the producer of small quantities of meat from poultry and lagomorphs slaughtered on the farm

31. Schedule 5 (direct supply by the producer of small quantities of meat from poultry and lagomorphs slaughtered on the farm) has effect.

Restrictions on the sale of raw milk intended for direct human consumption and amendments to the Food Labelling Regulations 1996

- **32.**—(1) Schedule 6 (restrictions on the sale of raw milk intended for direct human consumption) has effect.
- (2) In paragraph (1) of regulation 31 of the Food Labelling Regulations 1996(11) delete the words "Subject to paragraph (3) of this regulation, and except" and replace with the word "Except".
- (3) In paragraph (2) of regulation 31 of the Food Labelling Regulations 1996 delete the words "Subject to paragraph (3) of this regulation, in" and replace with the word "In".
- (4) In paragraphs (1) and (2) of regulation 31 of the Food Labelling Regulations 1996 immediately after the words "harmful to health." insert the words "The Food Standards Agency strongly advises that it should not be consumed by children, pregnant women, older people or those who are unwell or have chronic illness.".
 - (5) Delete paragraph (3) of regulation 31.

Revocations

33. The instruments specified in Column 1 of Schedule 7 are revoked to the extent specified in Column 3 of that Schedule.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(12).

29 November 2005

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

⁽¹¹⁾ S.I. 1996/1499

^{(12) 1998} c. 38.

SCHEDULES

SCHEDULE 1

Regulation 2(1)

DEFINITIONS OF COMMUNITY LEGISLATION

"Regulation 178/2002" ("Rheoliad 178/2002") means Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(13) as last amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council amending Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(14);

"Regulation 852/2004" ("*Rheoliad 852/2004*") means Regulation (EC) No. 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs(**15**);

"Regulation 853/2004" ("*Rheoliad853/2004*") means Regulation (EC) No. 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin(**16**) as read with Directive 2004/41; and

"Regulation 854/2004" ("Rheoliad 854/2004") means Regulation (EC) No. 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption(17) as amended by Regulation 882/2004 of the European Parliament and of the Council on official controls performed to ensure that verification of compliance with feed and food law, animal health and animal welfare rules(18) and as read with Directive 2004/41; and

"Directive 2004/41" ("*Cyfarwyddeb 2004/41*") means Directive 2004/41 of the European Parliament and of the Council repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended of human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC(19).

⁽¹³⁾ OJ No. L31, 1.2.2002, p.1.

⁽¹⁴⁾ OJ No. L245, 29.9.2003, p.4.

⁽¹⁵⁾ OJ No. L139, 30.4.2004, p.1. The revised text of Regulation 852/2004 is now set out in a Corrigendum (OJ No. L226, 25.6.2004, p.3).

⁽¹⁶⁾ OJ No. L139, 30.4.2004, p.55. The revised text of Regulation 853/2004 is now set out in a Corrigendum (OJ No. L226, 25.6.2004, p.22).

⁽¹⁷⁾ OJ No. L155, 30.4.2004, p.206. The revised text of Regulation 854/2004 is now set out in a Corrigendum (OJ No. L226, 25.6.2004, p.83).

⁽¹⁸⁾ OJ No. L165, 30.4.2004, p.1. The revised text of Regulation 882/2004 is now set out in a Corrigendum (OJ No. L191, 28 5 2004 p.1.)

⁽¹⁹⁾ OJ No. L157, 30.4.2004, p.33. The revised text of Directive 2004/41 is now set out in a Corrigendum (OJ No. L195, 2.6.2004, p.12).

SCHEDULE 2

Regulations 2(1) and 17

SPECIFIED COMMUNITY PROVISIONS

1. Provision of Community Regulations	2. Subject matter
Article 3 of Regulation 852/2004	Requirement that food business operators ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in Regulation 852/2004.
Article 4(1) of Regulation 852/2004	Requirement that food business operators carrying out primary production and specified associated operations comply with the general hygiene provisions laid down in Part A of Annex I to Regulation 852/2004 and any specific requirements provided for in Regulation 853/2004.
Article 4(2) of Regulation 852/2004	Requirement that food business operators carrying out any stage of production, processing and distribution of food after those stages to which Article 4(1) applies comply with the general hygiene requirements laid down in Annex II to Regulation 852/2004 and any specific requirements provided for in Regulation 853/2004.
Article 4(3) of Regulation 852/2004	Requirement that food business operators, as appropriate, adopt certain specific hygiene measures.
Article 5(1) of Regulation 852/2004	Requirement that food business operators put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.
Article 5(2) of Regulation 852/2004	Requirement that when any modification is made in the product, process, or any step, food business operators review the procedure referred to in Article 5(1) and make the necessary changes to it.
Article 5(4)(a) of Regulation 852/2004	Requirement that food business operators provide the competent authority with evidence of their compliance with Article 5(1).
Article 5(4)(b) of Regulation 852/2004	Requirement that food business operators ensure that any documents describing the procedures developed in accordance with Article 5 are up to date.
Article 5(4)(c) of Regulation 852/2004	Requirement that food business operators retain documents and records for an appropriate period.

1. Provision of Community Regulations	2. Subject matter
Article 6(1) of Regulation 852/2004	Requirement that food business operators co-operate with the competent authorities in accordance with other applicable Community legislation or national law.
Article 6(2), first paragraph Regulation 852/2004	Requirement that a food business operator notify the competent of authority of each establishment under its control that carries out any of the stages of production, processing and distribution of food.
Article 6(2), second paragraph Regulation 852/2004	Requirement that food business operators ensure that the competent of authority has up to date information on establishments.
Article 6(3) of Regulation 852/2004	Requirement that food business operators ensure that establishments are approved by the competent authority when approval is required.
Article 3(1) of Regulation 853/2004	Requirement that food business operators comply with the relevant provisions of Annexes II and III to Regulation 853/2004.
Article 3(2) of Regulation 853/2004	Requirement that food business operators do not use any substance other than potable water or, when Regulation 852/2004 or Regulation 853/2004 permits its use, clean water, to remove surface contamination from products of animal origin, unless use of the substance has been approved.
Article 4(1) of Regulation 853/2004	Requirement that food business operators place products of animal origin manufactured in the Community on the market only if they have been prepared and handled exclusively in establishments — (a) that meet the relevant requirements of Regulation 852/2004, those of Annexes II and III of Regulation 853/2004 and other relevant requirements of food law; and (b) that the competent authority has registered or, where required in accordance with Article 4(2), approved.
Article 4(2) of Regulation 853/2004	Requirement that establishments handling those products of animal origin for which Annex III to Regulation 853/2004 lays down requirements do not operate unless the competent authority has approved them in accordance with Article 4(3).
Article 4(3) of Regulation 853/2004	Requirement that establishments subject to approval in accordance with Article 4(2) do not operate unless the competent authority has, in accordance with Regulation 854/2004 —

1. Provision of Community Regulations	2. Subject matter
	 (c) granted the establishment approval to operate following an on-site visit; or (d) provided the establishment with conditional approval.
Article 4(4) of Regulation 853/2004	Requirement that food business operators co-operate with the competent authorities in accordance with Regulation 854/2004 including ensuring that an establishment ceases to operate if it is no longer approved.
Article 5(1) of Regulation 853/2004	Requirement that food business operators do not place on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) unless it has — (a) a health mark applied in accordance with Regulation 854/2004; or (b) when Regulation 854/2004 does not provide for the application of a health mark, an identification mark applied in accordance with Section 1 of Annex II to Regulation 853/2004.
Article 5(2) of Regulation 853/2004	Requirement that food business operators apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with Regulation 853/2004 in establishments meeting the requirements of Article 4.
Article 5(3) of Regulation 853/2004	Requirement that food business operators do not remove a health mark applied in accordance with Regulation 854/2004 from meat unless they cut or process it or work upon it in another manner.
Article 6(1) and (2) of Regulation 853/2004	Requirement that food business operators ensure that importation of products of animal origin only takes place where certain conditions are met.
Article 6(3) of Regulation 853/2004	Requirement that food business operators importing products of animal origin must ensure that — (a) products are made available for control upon importation in accordance with Council Directive 97/78/EC(20); (b) importation complies with the requirements of Council Directive 2002/99/EC(21); and

⁽²⁰⁾ OJ No. L24, 30.1.1998, p.9. (21) OJ No. L18, 23.1.2003, p.11.

1. Provision of Community Regulations	2. Subject matter
	(c) operations under their control that take place after importation are carried out in accordance with the requirements of Annex III to Regulation 853/2004.
Article 6(4) of Regulation 853/2004	Requirement that food business operators importing food containing both products of plant origin and processed products of animal origin ensure that the processed products of animal origin satisfy the requirements of paragraphs (1) to (3) of Article 6.
Article 7 of Regulation 853/2004	Requirement that food business operators ensure that certificates or other documents accompany consignments of products of animal origin when required in accordance with Annex II or III to Regulation 853/2004.
Article 8 of Regulation 853/2004	Requirement that food business operators intending to place specified foods of animal origin on the market in Sweden or Finland comply with the rules set out in Article 8(2).

SCHEDULE 3

Regulation 29

BULK TRANSPORT IN SEA-GOING VESSELS OF LIQUID OILS OR FATS AND THE BULK TRANSPORT BY SEA OF RAW SUGAR

Offence

1. A person who contravenes or fails to comply with any of the requirements of this Schedule will be guilty of an offence.

Liquid oils or fats

- **2.**—(1) The bulk transport in sea-going vessels of liquid oils or fats which are to be processed, and which are intended for or likely to be used for human consumption, is permitted in tanks that are not exclusively reserved for the transport of foodstuffs, subject to the following conditions
 - (a) where the oil or fat is transported in a stainless steel tank, or tank lined with epoxy resin or technical equivalent, the immediately previous cargo transported in the tank must have been a foodstuff or a cargo from the list of acceptable previous cargoes for liquid oils or fats; and
 - (b) where the oil or fat is transported in a tank of materials other than those specified in sub-paragraph (a), the three previous cargoes transported in the tanks must have been foodstuffs or from the list of acceptable previous cargoes for liquid oils or fats.
- (2) For the purposes of this paragraph, "list of acceptable previous cargoes for liquid oils or fats" means the list set out in the Annex to Commission Directive 96/3/EC.
- **3.** The bulk transport in sea-going vessels of liquid oils or fats which are not to be further processed, and which are intended for or are likely to be used for human consumption, is permitted

in tanks that are not exclusively reserved for the transport of foodstuffs, subject to the following conditions —

- (a) the tank must be of stainless steel or lined with epoxy resin or technical equivalent; and
- (b) the three previous cargoes transported in the tank must have been foodstuffs.
- **4.** The captain of a sea-going vessel transporting, in tanks, bulk liquid oils or fats intended for or likely to be used for human consumption must keep accurate documentary evidence relating to the three previous cargoes carried in the tanks concerned, and the effectiveness of the cleaning process applied between those cargoes.
- **5.** Where the cargo has been trans-shipped, in addition to the documentary evidence required by virtue of paragraph 4, the captain of the receiving vessel must keep accurate documentary evidence that the transport of the bulk liquid oil or fat complied with the provisions of paragraph 2 or 3 during previous shipment and of the effectiveness of the cleaning process used between those cargoes on the vessel from which they were trans-shipped.
- **6.** Upon request, the captain of the vessel must provide the enforcement authority with the documentary evidence described in paragraphs 4 and 5.

Raw sugar

- 7. The bulk transport by sea of raw sugar which is not intended for use as food or as a food ingredient without a full and effective refining process is permitted in receptacles, containers or tankers that are not exclusively used for the transport of foodstuffs.
- **8.** The receptacles, containers or tankers referred to in paragraph 7 will be subject to the following conditions—
 - (a) prior to loading the raw sugar, the receptacle, container or tanker must be effectively cleaned to remove residues of the previous cargo and other soiling and inspected to establish that such residues have been removed effectively; and
 - (b) the immediate previous cargo prior to the raw sugar must not have been a bulk liquid.
- **9.** A food business operator who is responsible for the transport of raw sugar by sea under paragraph 7 must keep documentary evidence, accurately describing in detail the immediate previous cargo carried in the receptacle, container or tanker concerned, and the type and effectiveness of the cleaning process applied prior to the transport of the raw sugar.
- **10.** The documentary evidence must accompany the consignment of raw sugar during all stages of transport to the refinery and a copy must be retained by the refinery. The documentary evidence must be marked as follows in a clearly visible and indelible fashion, in one or more Community languages: "This product must be refined before being used for human consumption".
- 11. On request, a food business operator responsible for the transport of the raw sugar or the refining process must provide the enforcement authority with the documentary evidence referred to in paragraphs 9 and 10.
- 12. Raw sugar which has been transported by sea in receptacles, containers or tankers which are not exclusively reserved for the transport of foodstuffs will be subjected to a full and effective refining process before being considered suitable for use as food or as a food ingredient.
- 13. In fulfilling the obligations under Article 5(1) of Regulation 852/2004 (hazard analysis and critical control points) in relation to the bulk transport of raw sugar by sea under paragraph 7, a food business operator who is responsible for the transport or refining of raw sugar must
 - (a) consider the cleaning process undertaken prior to the loading of the sugar for transport by sea to be a critical control point as referred to in Article 5(2)(b) of Regulation 852/2004; and

(b) take into account the nature of the previous cargo which has been transported in any receptacle, container or tanker used for the transport of the sugar.

Interpretation

- **14.**—(1) For the purposes of this Schedule any words or expressions used both in this Schedule and in Commission Directive 96/3/EC or Commission Directive 98/28/EC granting a derogation from certain provisions of Directive 93/43/EEC on the hygiene of foodstuffs as regards the transport by sea of bulk raw sugar(**22**) bear the same meanings as they respectively have in those Directives.
- (2) In this Schedule, "Commission Directive 96/3/EC" means Commission Directive 96/3/EC granting a derogation from certain provisions of Council Directive 93/43/EEC on the hygiene of foodstuffs as regards the transport of bulk liquid oils and fats by sea(23) as amended by Commission Directive 2004/4/EC amending Directive 96/3/EC granting a derogation from certain provisions of Council Directive 93/43/EEC on the hygiene of foodstuffs as regards the transport of bulk liquid oils and fats by sea(24).

SCHEDULE 4

Regulation 30

TEMPERATURE CONTROL REQUIREMENTS

Scope

- 1. This Schedule does not apply in relation to
 - (a) any food business operation to which Regulation 853/2004 applies; or
 - (b) any food business operation carried out on a ship or aircraft.

Chill holding requirements

- 2.—(1) Subject to sub-paragraph (2) and paragraph 3, any person who keeps any food
 - (a) which is likely to support the growth of pathogenic micro-organisms or the formation of toxins; and
- (b) with respect to which any commercial operation is being carried out, at or in food premises at a temperature above 8°C will be guilty of an offence.
- (2) Sub-paragraph (1) does not apply in relation to any food which, as part of a mail order transaction, is being conveyed to the final consumer.
 - (3) Subject to paragraph 3, no person must supply by mail order any food which
 - (a) is likely to support the growth of pathogenic micro-organisms or the formation of toxins; and
 - (b) is being or has been conveyed by post or by a private or common carrier to the final consumer,

at a temperature which has given rise to or is likely to give rise to a risk to health.

⁽²²⁾ OJ No. L140, 12.5.98, p.10.

⁽²³⁾ OJ No. L21, 27.1.96, p.42.

⁽²⁴⁾ OJ No. L15, 22.1.2004, p.25.

General exemptions from the chill holding requirements

- 3. Sub-paragraphs (1) and (3) of paragraph 2 do not apply in relation to
 - (a) food which
 - (i) has been cooked or reheated,
 - (ii) is for service or on display for sale, and
 - (iii) needs to be kept at or above 63°C in order to control the growth of pathogenic microorganisms or the formation of toxins;
 - (b) food which, for the duration of its shelf life may be kept at ambient temperatures with no risk to health;
 - (c) food which is being or has been subjected to a process such as dehydration or canning intended to prevent the growth of pathogenic micro-organisms at ambient temperatures, but not where
 - (i) after or by virtue of that process the food was contained in a hermetically sealed container, and
 - (ii) that container has been opened;
 - (d) food which must be ripened or matured at ambient temperatures, but not when the process of ripening or maturation is completed;
 - (e) raw food intended for further processing (including cooking) before human consumption, but only if that processing, if undertaken correctly, will render that food fit for human consumption;
 - (f) food to which Council Regulation 1906/90 applies; and
 - (g) food to which Council Regulation 1907/90 applies.

Upward variation of the 8°C temperature by manufacturers etc.

- **4.**—(1) In any proceedings for an offence consisting of a contravention of sub-paragraph (1) of paragraph 2, it is a defence for the accused to prove that
 - (a) a food business responsible for manufacturing, preparing or processing the food, including, where relevant, the accused, has recommended that it is kept
 - (i) at or below a specified temperature between 8°C and ambient temperatures, and
 - (ii) for a period not exceeding a specified shelf life;
 - (b) that recommendation has, unless the accused is that food business, been communicated to the accused either by means of a label on the packaging of the food or by means of some other appropriate form of written instruction;
 - (c) the food was not kept by the accused at a temperature above the specified temperature; and
 - (d) at the time of the commission of the alleged offence, the specified shelf life had not been exceeded.
- (2) A food business responsible for manufacturing, preparing or processing food must not recommend that any food is kept
 - (a) at or below a specified temperature between 8°C and ambient temperatures; and
 - (b) for a period not exceeding a specified shelf life,

unless that recommendation is supported by a well-founded scientific assessment of the safety of the food at the specified temperature.

Chill holding tolerance periods

- **5.**—(1) In any proceedings for an offence consisting of a contravention of sub-paragraph (1) of paragraph 2, it is a defence for the accused to prove that the food
 - (a) was for service or on display for sale;
 - (b) had not previously been kept for service or on display for sale at a temperature above 8°C or, where a recommendation has been made pursuant to sub-paragraph (1) of paragraph 4, the recommended temperature; and
 - (c) had been kept for service or on display for sale for a period of less than four hours.
- (2) In any proceedings for an offence consisting of a contravention of sub-paragraph (1) of paragraph 2, it is a defence for the accused to prove that the food—
 - (a) was being transferred
 - (i) from premises at which the food was going to be kept at or below 8°C or in appropriate circumstances the recommended temperature to a vehicle used for the purposes of a food business, or
 - (ii) to such premises from such a vehicle; or
 - (b) was kept at a temperature above 8°C or, in appropriate circumstances, the recommended temperature for an unavoidable reason, such as—
 - (i) to accommodate the practicalities of handling during and after processing or preparation,
 - (ii) the defrosting of equipment, or
 - (iii) temporary breakdown of equipment,

and was kept at a temperature above 8°C or, in appropriate circumstances, the recommended temperature for a limited period only and that period was consistent with food safety.

Hot holding requirements

- **6.** Any person who in the course of the activities of a food business keeps at or in food premises at a temperature below 63°C any food which
 - (a) has been cooked or reheated;
 - (b) is for service or on display for sale; and
 - (c) needs to be kept at or above 63°C in order to control the growth of pathogenic microorganisms or the formation of toxins,

will be guilty of an offence.

Hot holding defences

- 7.—(1) In any proceedings for an offence consisting of a contravention of paragraph 6, it is a defence for the accused to prove that
 - (a) a well-founded scientific assessment of the safety of the food at temperatures below 63°C has concluded that there is no risk to health if, after cooking or re-heating, the food is held for service or on display for sale
 - (i) at a holding temperature which is below 63°C, and
 - (ii) for a period not exceeding any period of time specified in that scientific assessment;

- (b) at the time of the commission of the alleged offence, the food was held in a manner which was justified in the light of that scientific assessment.
- (2) In any proceedings for an offence consisting of a contravention of paragraph 6, it is a defence for the accused to prove that the food
 - (a) had been kept for service or on display for sale for a period of less than two hours; and
 - (b) had not previously been kept for service or on display for sale by that person.

Interpretation

8. In this Schedule —

"Council Regulation 1906/90" ("Rheoliad y Cyngor 1906/90") means Council Regulation (EEC) No. 1906/90 on certain marketing standards for poultry(25) as last amended by Council Regulation (EC) No. 1101/98 amending Regulation (EEC) No. 1906/90 on certain marketing standards for poultrymeat(26);

"Council Regulation 1907/90" ("Rheoliad y Cyngor 1907/90") means Council Regulation (EEC) No. 1907/90 on certain marketing standards for eggs(27) as last amended by Council Regulation (EC) No. 2052/2003 amending Regulation (EEC) No. 1907/90 on certain marketing standards for eggs(28);

"recommended temperature" ("tymheredd a argymhellwyd") means a specified temperature which has been recommended in accordance with sub-paragraph (1)(a)(i) of paragraph 4; and "shelf life" ("oes silff") means —

- (a) in relation to food with respect to which an indication of minimum durability is required in accordance with regulation 20 of the Food Labelling Regulations 1996(29) (form of indication of minimum durability), the period up to and including the date required to be included in that indication;
- (b) in relation to food with respect to which a "use by" date is assigned in the form required in accordance with regulation 21 of the Food Labelling Regulations 1996 (form of indication of "use by" date), the period up to and including that date; and
- (c) in relation to food which is not required to bear an indication of minimum durability or a "use by" date, the period for which the food can be expected to remain fit for sale if it is kept in a manner which is consistent with food safety.

SCHEDULE 5

Regulation 31

DIRECT SUPPLY BY THE PRODUCER OF SMALL QUANTITIES OF MEAT FROM POULTRY AND LAGOMORPHS SLAUGHTERED ON THE FARM

Scope

1. The requirements of this Schedule apply in relation to the direct supply by the producer of small quantities of meat from poultry or lagomorphs that have been slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat.

⁽²⁵⁾ OJ No. L173, 6.7.90, p.1.

⁽²⁶⁾ OJ No. L157, 30.5.98, p.12.

⁽²⁷⁾ OJ No. L173, 6.7.90, p.5.

⁽²⁸⁾ OJ No. L305, 22.11.2003, p.1.

⁽²⁹⁾ S.I. 1996/1499, to which there are amendments not relevant to these Regulations.

Offence

2. A person who contravenes or fails to comply with any of the requirements of this Schedule will be guilty of an offence.

Requirements

- **3.** No person may sell meat from poultry or lagomorphs unless it bears a label or other marking clearly indicating the name and address of the farm where it was slaughtered.
 - **4.** The producer must
 - (a) keep a record in adequate form to show the number of birds and the number of lagomorphs received into, and the amounts of fresh meat despatched from, his or her premises during each week:
 - (b) retain the record for a period of one year; and
 - (c) make the record available to an authorised officer on request.

SCHEDULE 6

Regulation 32

RESTRICTIONS ON THE SALE OF RAW MILK INTENDED FOR DIRECT HUMAN CONSUMPTION

- **1.** Any person who sells raw milk intended for direct human consumption in contravention of paragraph 5 will be guilty of an offence.
- **2.**—(1) If any person other than the occupier of a production holding or a distributor sells raw cows' milk intended for direct human consumption that person will be guilty of an offence.
- (2) If the occupier of a production holding sells raw cows' milk intended for direct human consumption in contravention of paragraph 3 he or she will be guilty of an offence.
- (3) If a distributor sells raw cows' milk intended for direct human consumption in contravention of paragraph 4 he or she will be guilty of an offence.
- **3.** The occupier of a production holding may only sell raw cows' milk intended for direct human consumption—
 - (a) at or from the farm premises where the animals from which the milk has been obtained are maintained; and
 - (b) to
 - (i) the final consumer for consumption other than at those farm premises,
 - (ii) a temporary guest or visitor to those farm premises as or as part of a meal or refreshment, or
 - (iii) a distributor.
 - **4.** A distributor may only sell raw cows' milk intended for direct human consumption
 - (a) which he or she has bought pursuant to sub-paragraph (b)(iii) of paragraph 3;
 - (b) in the containers in which he or she receives the milk, with the fastenings of the containers unbroken;
 - (c) from a vehicle which is lawfully used as a shop premises; and
 - (d) direct to the ultimate consumer.

5. The raw milk must meet the following standards:

Plate count at 30°C (cfu per ml)	≤ 20,000
Coliforms (cfu per ml)	< 100

- **6.** In the case where farm premises are being used for the sale of raw cows' milk intended for direct human consumption pursuant to sub-paragraph (a) of paragraph 3, the Agency must carry out such sampling, analysis and examination of the milk as it considers necessary to ensure that it meets the standards specified in paragraph 5.
- 7. In any case where the Agency carries out sampling, analysis and examination of raw cows' milk in accordance with paragraph 6, there will be due to the Agency from the occupier of the production holding who is selling the milk a fee of £63, which is payable by the occupier to the Agency on demand.

8. In this Schedule —

"distributor" ("dosbarthwr") means a person who sells raw cows' milk that has been produced on a production holding of which he or she is not the occupier;

"farm premises" ("mangre fferm") means a farm occupied by the occupier of a production holding as a single farm and includes the production holding and any other building situated on that farm and occupied by the same occupier;

"occupier" ("meddiannydd") means any person carrying on the business of producing or handling raw cows' milk or the occupier's duly authorised representative;

"production holding" ("daliad cynhyrchu") means premises at which milk-producing cows are kept; and

"shop premises" ("mangre siop") means premises from which any food is sold to the final consumer.

SCHEDULE 7

Regulation 33

REVOCATIONS

1. Instruments	2. Reference	3. Extent of revocation
The Milk and Dairies (General) Regulations 1959	S.I.1959/277	The whole Regulations
The Ice-Cream (Heat Treatment, etc.) Regulations 1959	S.I. 1959/734	The whole Regulations
The Food Premises (Registration) Regulations 1991	S.I. 1991/2825	The whole Regulations
The Meat Hygiene Appeals Tribunal (Procedure) Regulations 1992	S.I. 1992/2921	The whole Regulations
The Egg Products Regulations 1993	S.I. 1993/1520	The whole Regulations

1. Instruments	2. Reference	3. Extent of revocation
The Meat Products (Hygiene) Regulations 1994	S.I. 1994/3082	The whole Regulations
The Fresh Meat (Hygiene and Inspection) Regulations 1995	S.I. 1995/539	The whole Regulations
The Poultry Meat, Farmed Game Bird Meat and Rabbit Meat (Hygiene and Inspection) Regulations 1995	S.I. 1995/540	The whole Regulations
The Dairy Products (Hygiene) Regulations 1995	S.I. 1995/1086	The whole Regulations
The Dairy Products (Hygiene) (Charges) Regulations 1995	S.I. 1995/1122	The whole Regulations
The Eggs (Marketing Standards) Regulations 1995	S.I. 1995/1544	In regulation 2(1), the definitions of "the Agency" and "Council Decision"; paragraph (b) of "Community provisions"; and in paragraph (a) of the definition of "food authority" the words "except in relation to regulation 3(2),". Regulation 3. In regulation 4, paragraphs (1) (b) and (2)(b). In regulation 6, the words "or the Agency"; the words "or (b)"; the words "or, as the case may be, the Agency," in both places where they occur; and the words "or, as the case may be, it,".
The Food Safety (General Food Hygiene) Regulations 1995	S.I. 1995/1763	The whole Regulations
The Wild Game Meat (Hygiene and Inspection) Regulations 1995	S.I. 1995/2148	The whole Regulations
The Food Safety (Temperature Control) Regulations 1995	S.I. 1995/2200	The whole Regulations
The Minced Meat and Meat Preparations (Hygiene) Regulations 1995	S.I. 1995/3205	The whole Regulations

1. Instruments	2. Reference	3. Extent of revocation
The Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998	S.I. 1998/994	The whole Regulations
The Gelatine (Intra- Community Trade) (Wales) Regulations 2001	S.I. 2001/2219 (W.159)	The whole Regulations
The Food Safety (Ships and Aircraft) (Wales) Order 2003	S.I. 2003/1774 (W.191)	In article 2(1), paragraph (a) of the definition of "the principal Hygiene and Temperature Control provisions" Paragraph 2(b) of the Schedule
The Collagen and Gelatine (Intra-Community Trade) (Wales) Regulations 2003	S.I. 2003/3229 (W.309)	The whole Regulations

EXPLANATORY NOTE

(This note is not part of the Regulations)

- 1. These Regulations which are made in relation to Wales provide for the execution and enforcement of
 - (a) Regulation (EC) No. 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs (OJ No. L139, 30.4.2004, p.1. The revised text of Regulation 852/2004 is now set out in a Corrigendum (OJ No. L226, 25.6.2004, p.3)) ("Regulation 852/2004");
 - (b) Regulation (EC) No. 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin (OJ No. L139, 30.4.2004, p.55. The revised text of Regulation 853/2004 is now set out in Corrigendum (OJ No. L226, 25.6.2004, p.22)) ("Regulation 853/2004"); and
 - (c) Regulation (EC) No. 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ No. L155, 30.4.2004, p.206. The revised text of Regulation 854/2004 is now set out in a Corrigendum (OJ No. L226, 25.6.2004, p.83)) ("Regulation 854/2004"). Regulation 852/2004, Regulation 853/2004 and Regulation 854/2004 are referred to as "the Community Regulations".

2. These Regulations —

- (a) create certain presumptions that, for the purposes thereof, specified food is intended for human consumption (regulation 3);
- (b) provide that the Food Standards Agency is the competent authority for the purposes of the Community Regulations except where it has delegated competencies (regulation 4);

- (c) make provision for the enforcement and execution of these Regulations and of the Community Regulations (regulation 5);
- (d) provide for the following enforcement measures to be available in respect of a food business operator
 - (i) hygiene improvement notices (regulation 6);
 - (ii) hygiene prohibition orders (regulation 7);
 - (iii) hygiene emergency prohibition notices and orders (regulation 8); and
 - (iv) remedial action notices and detention notices (regulation 9);
- (e) provide that where the commission of an offence thereunder is due to the act or default of some other person that other person is guilty of the offence (regulation 10);
- (f) provide that in proceedings for an offence thereunder it is a defence for the accused to prove that the accused took all reasonable precautions and exercised all due diligence to avoid the commission of the offence (regulation 11);
- (g) provide for the procurement and analysis of samples (regulations 12 and 13 respectively);
- (h) provide powers of entry for authorised officers of an enforcement authority (regulation 14);
- (i) provide for the offence of obstructing an officer (regulation 15);
- (j) provide a time limit for bringing prosecutions (regulation 16);
- (k) provide that a person who contravenes or fails to comply with specified provisions of Regulation 852/2004 or Regulation 853/2004 is guilty of an offence (regulation 17(1));
- (1) provide penalties for offences (regulation 17(2) and (3));
- (m) provide that a person is considered not to have contravened or failed to comply with a specified provision of Regulation (EC) No. 852/2004 (requirement for bulk foodstuffs in liquid, granulate or powder form to be transported in receptacles and / or containers / tankers reserved for the transport of foodstuffs) provided the requirements of Schedule 3 are complied with (regulation 17(4));
- (n) provide that where an offence thereunder which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, an officer of the body corporate or a person purporting to act as such that officer or person as well as the body corporate is deemed to be guilty of that offence and may be proceeded against and punished accordingly (regulation 18);
- (o) provide that where an offence thereunder which has been committed by a Scottish partnership is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner that partner as well as the partnership is deemed to be guilty of that offence and may be proceeded against and punished accordingly (regulation 19);
- (p) provide rights of appeal in respect of hygiene improvement notices, remedial action notices, hygiene prohibition orders and hygiene emergency prohibition orders (regulations 20 to 22);
- (q) provide for the application of section 9 of the Food Safety Act 1990 (1990 c. 16) (regulation 23);
- (r) provide for the issue of codes to food authorities by the National Assembly for Wales of recommended practice (regulation 24);
- (s) provide for the protection of officers acting in good faith (regulation 25);
- (t) provide for the revocation or suspension of the designation or, as the case may be, appointment of specified officials (regulation 26);

- (u) provide that when an authorised officer of an enforcement authority has certified that any food has not been produced, processed or distributed in compliance with the Hygiene Regulations, it must be treated for the purposes of section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements (regulation 27);
- (v) provide for the service of documents (regulation 28);
- (w) provide that the requirements set out in the following Schedules has effect
 - (i) Schedule 3 (bulk transport in sea-going vessels of liquid oils or fats and the bulk transport by sea of raw sugar) (regulation 29);
 - (ii) Schedule 4 (temperature control requirements) (regulation 30);
 - (iii) Schedule 5 (direct supply by the producer of small quantities of meat from poultry and lagomorphs slaughtered on the farm) (regulation 31); and
 - (iv) Schedule 6 (restrictions on the sale of raw milk intended for direct human consumption (regulation 32);
- (x) amend Regulation 31 of the Food Labelling Regulations 1996 (Raw Milk) (regulation 32); and
- (y) provide for the revocation of specified instruments to the extent specified (regulation 33).
- **3.** A full Regulatory Appraisal on the effect that these Regulations will have on the costs of business has been prepared and placed in the Library of the National Assembly for Wales. Copies may be obtained from the Food Standards Agency, Southgate House, Wood Street, Cardiff CF10 1EW.