SCOTTISH STATUTORY INSTRUMENTS

2009 No. 85

RIVER FISH FARMING

The Aquatic Animal Health (Scotland) Regulations 2009

Made - - - - 5th March 2009

Laid before the Scottish

Parliament - - - 5th March 2009

Coming into force in accordance with regulation 1

The Scottish Ministers make these Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A(1) of Schedule 2 to, the European Communities Act 1972(2).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Scottish Ministers that it is expedient for any references to the following Community instruments to be construed as a reference to those instruments as amended from time to time:

- (a) Commission Decision 2004/453/EC(3) on implementing Council Directive 91/67/EEC as regards measures against certain diseases in aquaculture animals;
- (b) Council Directive 2006/88/EC(4) on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals; and
- (c) Commission Regulation (EC) No. 1251/2008(5) on implementing Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species.

⁽¹⁾ Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c. 51).

^{(2) 1972} c. 68. Section 2(2) was amended by the Scotland Act 1998 (c. 46) Schedule 8, paragraph 15(3) and section 27 of the Legislative and Regulatory Reform Act 2006. The functions conferred upon the Minister of the Crown under section 2(2) of the 1972 Act, insofar as within devolved competence, were transferred to the Scotlish Ministers by virtue of section 53 of the Scotland Act 1998 (c. 46).

⁽³⁾ O.J. No. L 156, 30.4.2004, p.5, corrected by O.J. No. L 202, 7.6.2004, p.4 which substitutes new text for the whole of Commission Decision 2004/453/EC.

⁽⁴⁾ O.J. No. L 328, 24.11.2006, p.14.

⁽⁵⁾ O.J. No. L 337, 16.12.2008, p.41.

PART 1

GENERAL

Citation, commencement and extent

- 1.—(1) These Regulations, which implement Directive 2006/88/EC, may be cited as the Aquatic Animal Health (Scotland) Regulations 2009.
 - (2) These Regulations come into force-
 - (a) for the purposes of regulation 5(1), on 1st May 2009;
 - (b) for the purposes of regulation 12(1), on 1st August 2009; and
 - (c) for all other purposes, on 27th March 2009.
 - (3) These Regulations extend to Scotland only.

Application

- 2.— These Regulations do not apply to-
 - (a) any ornamental aquatic animal reared in a non-commercial aquarium;
 - (b) any wild aquatic animal harvested or caught for direct entry into the food chain other than one which is to be treated as an aquaculture animal under regulation 18(3);
 - (c) any aquatic animal caught for the purpose of production of fishmeal, fish feed, fish oil or any similar product.

Interpretation

3.—(1) In these Regulations—

"the competent authority" means the Scottish Ministers;

"Decision 2004/453/EC" means Commission Decision 2004/453/EC(6) on implementing Council Directive 91/67/EEC as regards measures against certain diseases in aquaculture animals, as amended from time to time;

"Decision 946/2008/EC" means Commission Decision 2008/946/EC(7) on implementing Council Directive 2006/88/EC as regards requirements for quarantine of aquaculture animals;

"Directive 2006/88/EC" means Council Directive 2006/88/EC(8) on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals, as amended from time to time;

"inspector" means any person authorised by the competent authority to be an inspector for the purposes of these Regulations;

"listed disease" means-

- (a) a disease listed in the second column of Part II of Annex IV of Directive 2006/88/EC; or
- (b) a disease listed in the first column of Schedule 1 to these Regulations;

"non-commercial installation" means any aquaculture production business in which aquatic animals are kept with no intention of placing them on the market;

⁽⁶⁾ O.J. No. L 156, 30.4.2004, p.5, corrected by O.J. No. L 202, 7.6.2004, p.4 which substitutes new text for the whole of Commission Decision 2004/453/EC.

⁽⁷⁾ O.J. No. L 337, 16.12.2008, p.94.

⁽⁸⁾ O.J. No. L 328, 24.11.2006, p.14.

"operator", in relation to an aquaculture production business, a specialist transport business, a processing establishment, a non-commercial installation or a put and take fishery, means any person who is responsible for the management of that business, establishment, installation or fishery;

"processing establishment" means any food business which is approved for processing aquaculture animals for food purposes in accordance with Article 4 of Regulation (EC) No. 853/2004(9) laying down specific hygiene rules for food of animal origin, and which processes aquaculture animals under Part 4 of these Regulations or any provision in any Regulations made in relation to England, Wales or Northern Ireland which has equivalent effect to that Part;

"Regulation (EC) No. 1251/2008" means Commission Regulation (EC) No. 1251/2008(10) on implementing Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species, as amended from time to time;

"Scotland" includes so much of the internal waters and territorial sea of the United Kingdom as are adjacent to Scotland; and

"specialist transport business" means a business or undertaking which wholly or mainly transports live aquaculture animals in means of transport specially designed or adapted for that purpose.

- (2) Any expression used in these Regulations which is also used in Directive 2006/88/EC (except for the definitions of "operator" and "processing establishment" in paragraph (1) and "wild aquatic animal" in regulation 18(5)) has the meaning it bears in that Directive.
 - (3) Schedule 1 (list of diseases) has effect.

PART 2

AUTHORISATION AND REGISTRATION REQUIREMENTS

Application of Part 2

- **4.** This Part does not apply where any ornamental aquatic animal is kept in any pet shop, garden centre, garden pond, commercial aquarium, or with any wholesaler—
 - (a) without any direct contact with natural waters; or
 - (b) which is equipped with an effluent treatment system which, in the opinion of the competent authority, reduces the risk of transmitting diseases to natural waters to an acceptable level.

Authorisation

- **5.**—(1) Subject to regulation 14, it is an offence to operate an aquaculture production business or a processing establishment unless the business or establishment is authorised by the competent authority.
- (2) The competent authority may grant an authorisation in relation to two or more aquaculture production businesses which are situated in one mollusc farming area, provided the businesses relate exclusively to molluscs.
- (3) But a dispatch centre, purification centre or similar business in a mollusc farming area must be separately authorised.

⁽⁹⁾ O.J. No. L 139, 30.4.2004, p.55.

⁽¹⁰⁾ O.J. No. L 337, 16.12.2008, p.41.

- (4) The requirement for a non-commercial installation or a put and take fishery to be authorised under paragraph (1) only applies where the competent authority—
 - (a) considers that authorisation is necessary to prevent or limit the spread of disease; and
 - (b) serves the operator with a written notice to that effect.
- (5) Where the operator is served with a notice under paragraph (4)(b), the operator must apply for authorisation under regulation 8(1) within 28 days of the service.
- (6) Where the operator so applies, the operator is to be treated as having, as from the date of the application, an interim authorisation to carry on the activity to which the application relates until the interim authorisation lapses on the earliest of the dates mentioned in regulation 14(3).

Authorisation conditions for aquaculture production businesses

- **6.**—(1) The competent authority may grant an authorisation to an aquaculture production business, subject to such conditions as it considers appropriate, where it is satisfied that the operation of the business will not lead to an unacceptable risk of spreading disease.
 - (2) It is a condition of an authorisation that the business must-
 - (a) keep a record, in such form and manner as the competent authority may specify, of—
 - (i) the movement of any aquaculture animal or any aquaculture animal product into or out of the area in respect of which the business operates;
 - (ii) the number of any aquaculture animals that have died in each epidemiological unit within that area;
 - (iii) the results of any surveillance carried out by the business; and
 - (iv) the results of any surveillance carried out by the competent authority which have been notified to the business;
 - (b) follow good biosecurity practice;
 - (c) comply with any surveillance requirement imposed by the competent authority; and
 - (d) have a system in place which enables the operator to demonstrate to the competent authority that the requirements of subparagraphs (a) to (c) are being met.

Authorisation conditions for processing establishments

- 7.—(1) The competent authority may grant an authorisation to a processing establishment, subject to such conditions as it considers appropriate, where it is satisfied that the operation of the establishment will not lead to an unacceptable risk of spreading of disease.
 - (2) It is a condition of an authorisation that the operator must-
 - (a) keep a record, in such form and manner as the competent authority may specify, of the movement of any aquaculture animal or any aquaculture animal product into or out of the premises of the establishment;
 - (b) follow good biosecurity practice; and
 - (c) have a system in place which will enable the operator to demonstrate to the competent authority that the requirements of subparagraphs (a) and (b) are being met.

Application for an authorisation

8.—(1) An application for an authorisation must be in such form and contain such information as the competent authority may reasonably require.

- (2) The competent authority must serve an applicant with a written notice of the result of the application within 90 days of receiving it.
 - (3) Where the competent authority grants the authorisation, it must notify—
 - (a) the duration of the authorisation;
 - (b) any condition to which it is subject; and
 - (c) an authorisation number.
- (4) Where the competent authority refuses to grant an authorisation, or grants an authorisation subject to any condition, it must—
 - (a) give reasons for the refusal or the imposition of the condition; and
 - (b) inform the applicant of the right of appeal under regulation 40.
- (5) It is an offence for a person to make a statement in an application that is false, and which that person knows or suspects is false.

Amendment of an authorisation

- **9.**—(1) The competent authority may amend any authorisation, including any condition to which it is subject.
 - (2) The amendment may be made–
 - (a) on the initiative of the competent authority; or
 - (b) on application by an operator.
- (3) An application under paragraph (2)(b) must be in such form and contain such information as the competent authority may reasonably require.
 - (4) The competent authority must give written notice to the operator which—
 - (a) specifies the amendment or any decision not to make the amendment;
 - (b) gives the reason for the amendment or any decision not to make it, and
 - (c) informs the applicant of the right of appeal under regulation 40.

Suspension of an authorisation

- 10.—(1) The competent authority may suspend an authorisation by serving an operator with a written notice where it considers that an aquaculture production business, processing establishment, non-commercial installation or put and take fishery, authorised under this Part has not complied with, is not complying with, or is not likely to comply with, a condition of its authorisation or a requirement under these Regulations.
 - (2) The notice must-
 - (a) give the date on which the suspension is to take effect and its duration;
 - (b) give the reason for the suspension; and
 - (c) inform the operator of the right of appeal under regulation 40.

Revocation of an authorisation

11.—(1) The competent authority may revoke an authorisation by serving an operator with a written notice where it considers that an aquaculture production business, processing establishment, non-commercial installation, or put and take fishery, authorised under this Part has not complied with, is not complying with, or is not likely to comply with, a condition of its authorisation or a requirement under these Regulations.

- (2) The notice must—
 - (a) give the date on which the revocation is to take effect;
 - (b) give the reason for the revocation; and
 - (c) inform the operator of the right of appeal under regulation 40.

Registration

- **12.**—(1) It is an offence to operate a non-commercial undertaking, a put and take fishery, or a specialist transport business unless it is registered by the competent authority.
- (2) An application for registration must be in such form and contain such information as the competent authority may reasonably require.
 - (3) On receipt of the information, the competent authority must-
 - (a) undertake the registration; and
 - (b) serve the operator with a written notice of a registration number.
- (4) An operator must notify the competent authority in writing of any change in the information provided under paragraph (2) within 30 days of the change.
 - (5) It is an offence to fail to comply with paragraph (4).
- (6) It is an offence for a person to provide information to the competent authority that is false, and which that person knows or suspects is false.
- (7) This regulation does not apply where a non-commercial undertaking or a put and take fishery is required to be authorised by virtue of regulation 5(1) and (4).

Public record of aquaculture production businesses and processing establishments

- 13.—(1) The competent authority must establish and maintain a record of—
 - (a) any aquaculture production business authorised under regulation 6; and
 - (b) any processing establishment authorised under regulation 7.
- (2) The record must contain the information set out in Part I of Annex II to Directive 2006/88/EC for a business authorised under regulation 6.
- (3) The record must contain the information set out in Part II of that Annex for an establishment authorised under regulation 7.
- (4) The record must be publicly available for inspection free of charge at all reasonable times and at such place as determined by the competent authority.
- (5) The competent authority must make arrangements for the provision of a copy of an entry in the record to any person on request.
- (6) These arrangements may include payment of a reasonable fee by the person making the request.

Transitional provision

- 14.—(1) This regulation applies where-
 - (a) a person operates an aquaculture production business or a processing establishment on 27th March 2009; and
 - (b) makes an application for an authorisation under regulation 8 before 1st May 2009.

- (2) The operator is to be treated as having, as from 1st May 2009, an interim authorisation to carry on the activity to which the application relates until the interim authorisation lapses in accordance with paragraph (3).
 - (3) The interim authorisation lapses on the earliest of the following dates—
 - (a) when the application is withdrawn;
 - (b) when the competent authority grants an authorisation under regulation 6 or 7;
 - (c) where the competent authority refuses to grant an authorisation under regulation 6 or 7 and the applicant does not appeal, on the date on which the right of appeal lapses under regulation 40;
 - (d) where the competent authority refuses to grant an authorisation under regulation 6 or 7 and the applicant does appeal, on the date on which the appeal is finally decided.

PART 3

PLACING ON THE MARKET

Application of Part 3

- 15.—(1) This Part does not apply in respect of any person who-
 - (a) places on the market for scientific purposes any aquaculture animal or aquaculture animal product; and
 - (b) has obtained the prior written consent of the competent authority.
- (2) The competent authority may, where it is satisfied that to do so will not lead to an unacceptable risk of spreading disease, grant consent for the purposes of paragraph (1)(b) subject to such conditions as it considers appropriate.

General health requirements

- **16.**—(1) It is an offence to place on the market any aquaculture animal for farming or to release any such animal into the wild or into a put and take fishery, unless the animal—
 - (a) is clinically healthy; and
 - (b) comes from a farm or mollusc farming area where there is no unexplained increased mortality.
 - (2) Paragraph (1)(b) does not apply where-
 - (a) the animal comes from a part of the farm or mollusc farming area, which, in the opinion of the competent authority, is independent of the epidemiological unit in which the increased mortality has occurred; and
 - (b) the placing on the market of the animal has the prior written consent of the competent authority.
- (3) It is an offence to release any ornamental aquatic animal kept in a closed ornamental facility into an open ornamental facility, farm, mollusc farming area, relaying area, put and take fishery, or into the wild, without the prior written consent of the competent authority.
- (4) It is an offence to contravene any of the following provisions of Regulation (EC) No. 1251/2008–
 - (a) Article 9 (introduction of aquaculture animals after inspection);

- (b) Article 15(1), (2) or (3) (requirements for the release of aquaculture animals and products thereof and for transport water).
- (5) In paragraph (3) "closed ornamental facility" and "open ornamental facility" have the same meaning as in Article 2(a) and (b) of Regulation (EC) No. 1251/2008.

Certification requirements

- 17.—(1) It is an offence to introduce any aquaculture animal or any aquaculture animal product into Scotland where the animal or product is required to be accompanied by an animal health certificate under Article 5 of Decision 2004/453/EC(11) or Chapter III or IV of Regulation (EC) No. 1251/2008 unless it is accompanied by such a certificate completed in accordance with the relevant model specified in that Article or Chapter.
- (2) A person is guilty of an offence if, for the purpose of procuring the issue of an animal health certificate under Article 5 of Decision 2004/453/EC or Chapter III of Regulation (EC) No. 1251/2008, that person—
 - (a) makes a statement which is false and which that person knows or suspects is false; or
 - (b) intentionally fails to disclose any material particular.
- (3) In paragraph (1) the reference to the introduction of any aquaculture animal or any aquaculture animal product into Scotland includes the introduction of any aquaculture animal or product into any zone or compartment within Scotland from any other zone or compartment within Scotland.

Additional certification provisions

- **18.**—(1) Where any aquaculture animal, which is susceptible to a disease listed in the second column of Part II of Annex IV to Directive 2006/88/EC or is a vector for that disease, is introduced into Scotland with the intention of being released into the wild or into a put and take fishery, the place of introduction is, for the purpose of regulation 17(1), to be treated as though it has, in relation to that disease, a Category I disease-free health status under Part A of Annex III to that Directive.
- (2) Where any wild aquatic animal, which is susceptible to a listed disease or is a vector for that disease, is introduced into Scotland with the intention of being released into the wild or into a put and take fishery, the animal is, for the purposes of regulations 17(1) and 18(1), to be treated as though it is an aquaculture animal introduced with the intention of being released into the wild or into a put and take fishery.
- (3) Where any wild aquatic animal, which is susceptible to a listed disease or is a vector for that disease, is introduced into Scotland for further processing before human consumption, the animal is, for the purpose of regulation 17(1), to be treated as though it is an aquaculture animal introduced for further processing before human consumption.
 - (4) In paragraph (1)-
 - (a) an animal is susceptible to a disease listed in the second column of Part II of Annex IV to Directive 2006/88/EC if it appears in the third column of that Part opposite the reference to the disease in the second column of that Part;
 - (b) an animal is a vector for a disease if it appears in Column 2 of the table in Annex I to Regulation (EC) No. 1251/2008 opposite the reference to the disease in Column 1 and it fulfils the conditions set out in Columns 3 and 4 of that table.
 - (5) In paragraphs (2) and (3)–

⁽¹¹⁾ O.J. No. L 156, 30.4.2004, p.5, corrected by O.J. No. L 202, 7.6.2004, p.4 which substitutes new text for the whole of Commission Decision 2004/453/EC.

- (a) "wild aquatic animal" means any live aquatic animal which can survive in the natural aquatic environment in Scotland and is not an aquaculture animal;
- (b) an animal is susceptible to a listed disease if it appears—
 - (i) in the third column of Part II of Annex IV to Directive 2006/88/EC opposite the reference to the disease in the second column of that Part; or
 - (ii) in the second column of Schedule 1 to these Regulations opposite the reference to the disease in the first column of that Schedule:
- (c) an animal is a vector for a listed disease if it appears in Column 2 of the table in Annex I to Regulation (EC) 1251/2008 opposite the reference to the disease in Column 1 and it fulfils the conditions set out in Columns 3 and 4 of that table.
- (6) In paragraphs (1) to (3) any reference to the introduction of any animal into Scotland includes the introduction of the animal into any zone or compartment within Scotland from any other zone or compartment within Scotland.

Disease prevention requirements in respect of transport

- **19.**—(1) It is an offence to transport any aquaculture animal in a manner which does not fulfil any of the requirements in paragraph (2).
 - (2) The requirements are-
 - (a) the duration of the transport must be as short as reasonably possible;
 - (b) the means of transport must be cleaned and disinfected before dispatch;
 - (c) if the animal is transported overland in water-
 - (i) it must be transported in such a way that the water cannot escape from the means of transport; and
 - (ii) any water exchange is carried out only at a water station which the competent authority has approved; and
 - (d) the conditions of transport must minimise the risk of spreading disease to-
 - (i) the animal being transported;
 - (ii) any aquatic animal at any place of transit;
 - (iii) any aquatic animal at the place of destination.
- (3) Where a person imports from a third country any aquaculture animal which is intended for quarantine the animal must be transported directly from the border inspection post to a quarantine facility.
- (4) The operator of a quarantine facility must not release an aquaculture animal from a quarantine facility without the prior written consent of the competent authority.
 - (5) In paragraphs (3) and (4)–
 - (a) "border inspection post" means, in relation to a species of animal, a place for the time being specified in relation to that species in Schedule 2 to the Animals and Animal Products (Import and Export) (Scotland) Regulations 2007(12);
 - (b) "quarantine facility" has the meaning given in Article 2(1) of Commission Decision 2008/946/EC(13) on implementing Council Directive 2006/88/EC as regards requirements for quarantine of aquaculture animals.
 - (6) It is an offence not to comply with paragraph (3) or (4).

⁽¹²⁾ S.S.I. 2007/194, as amended by S.S.I. 2007/375 and 2008/155.

⁽¹³⁾ O.J. No. L 337, 16.12.2008, p.94.

Recording of information in respect of transport

- **20.**—(1) It is an offence for a person who transports any aquaculture animal to fail to keep a record of any of the information referred to in paragraph (2).
 - (2) The information is-
 - (a) the number of animals that die in the course of transport;
 - (b) all facilities operating under an authorisation or registration granted under Part 2 and which are visited in the course of the transport;
 - (c) any water exchange in the course of the transport;
 - (d) the source of any water introduced into the means of transport;
 - (e) the location at which any water from the means of transport is discharged.
- (3) The competent authority may specify the form and manner in which the information referred to in paragraph (2) must be recorded.
- (4) It is a defence for a person charged with an offence in relation to paragraph (2)(a) to show that it was not practicable to keep such a record.

Exemption for transport in small containers

- **21.** Regulations 19(1) and (2) and 20 do not apply where the transport is by means of a container which—
 - (a) is watertight and airtight;
 - (b) is no larger than one cubic metre; and
 - (c) is accompanied by a label or document which documents its contents, place of origin, any place of transit and its place of destination.

PART 4

NOTIFICATION AND CONTROL OF DISEASE OUTBREAKS

Interpretation of Part 4

- 22. In this Part-
 - "confirmed designation" means a designation made by the competent authority under regulation 28;
 - "confirmed designation area" means the area in respect of which a confirmed designation has been made;
 - "initial designation" means a designation made by the competent authority under regulation 24;
 - "initial designation area" means the area in respect of which an initial designation has been made.

Obligation to notify in case of suspicion of a listed disease or increased mortality

- 23.—(1) A relevant person is guilty of an offence if that person—
 - (a) knows or suspects that a listed disease is present in aquatic animals; and
 - (b) fails immediately to notify the competent authority of that knowledge or suspicion.
- (2) A relevant person is guilty of an offence if that person-

- (a) knows or suspects that increased mortality has occurred or is occurring in aquaculture animals; and
- (b) fails immediately to notify the competent authority or a veterinarian of that knowledge or suspicion.
- (3) In this regulation "relevant person" means-
 - (a) the owner of, or any person attending, those aquatic animals;
 - (b) any person accompanying those aquaculture animals during transport;
 - (c) any veterinarian, or other professional, involved in providing aquatic animal health services to those aquatic animals;
 - (d) any other person with an occupational relationship to those aquatic animals of susceptible species or to products of such animals.

Initial designation

- **24.**—(1) Where the competent authority suspects that a listed disease or an emerging disease is present, or may become present, in aquatic animals in Scotland, it must designate such area as it considers appropriate to prevent or limit the spread of that disease.
 - (2) Where the competent authority has made an initial designation, it must—
 - (a) take samples of any aquatic animal or water which it suspects is infected;
 - (b) examine the samples in a laboratory designated by the authority under Article 57 of Directive 2006/88/EC;
 - (c) undertake an epizootic investigation in accordance with Article 29 of Directive 2006/88.
- (3) A person commits an offence if, without the prior written consent of the competent authority, that person—
 - (a) moves any aquatic animal into, out of or within an initial designation area; or
 - (b) disposes of any dead aquatic animal which comes from that area.

Contents and publication of an initial designation

- 25.—(1) An initial designation must-
 - (a) be in the form of a written notice;
 - (b) describe the area which is the subject of the designation;
 - (c) describe the circumstances in which a person commits an offence under regulation 24(3);
 - (d) make reference to any consent given by the competent authority under regulation 24(3).
- (2) An initial designation may require that-
 - (a) any equipment, material or substance liable to transmit disease must not be moved into, out of or within the initial designation area or any part of that area;
 - (b) any means of transport liable to transmit disease must not be moved into, out of or within that area or any part of that area.
- (3) The competent authority must serve a copy of an initial designation on any person it considers likely to be materially affected by the making of the designation.
 - (4) It is an offence not to comply with any requirement imposed under paragraph (2).

Actions by an inspector in respect of an initial designation

26.—(1) This regulation applies where the competent authority has made an initial designation.

- (2) An inspector may-
 - (a) take samples of any aquatic animal or water in the initial designation area;
 - (b) dispose of any such animal.
- (3) An inspector may by written notice direct a person to-
 - (a) take steps to secure the disposal of any dead aquatic animal in the initial designation area;
 - (b) operate a disinfection facility at the entrance to, and exit from, any farm or mollusc farming area in the initial designation area;
 - (c) disinfect any means of transport in that area;
 - (d) take any other steps which the inspector considers necessary to eradicate the disease or to prevent or limit the spread of the disease to other aquatic animals.
- (4) An inspector may by written notice prohibit any person from entering any farm or mollusc farming area within the initial designation area.
- (5) Where an inspector considers that a requirement under paragraph (3) has not been complied with, the inspector may—
 - (a) enter any place within the initial designation area;
 - (b) take or cause to be taken such steps as the inspector considers necessary to-
 - (i) ensure compliance with the requirement; or
 - (ii) remedy the consequences of the failure to carry it out;
 - (c) recover any expenses reasonably incurred in so doing from any person who has failed to comply with the requirement
 - (6) It is an offence not to comply with a requirement imposed under paragraph (3) or (4).

Withdrawal of an initial designation

- 27. The competent authority must withdraw an initial designation when-
 - (a) it is satisfied that the suspected disease is not present, or is not likely to become present, in the initial designation area; or
 - (b) it has designated the area under the following regulation.

Confirmed designation

- **28.**—(1) Where the competent authority has confirmed that a listed disease or an emerging disease is present in aquatic animals in Scotland it must designate such area as it considers appropriate to prevent or limit the spread of that disease.
- (2) A person commits an offence if, without the prior written consent of the competent authority, that person—
 - (a) moves any aquatic animal into, out of or within a confirmed designation area; or
 - (b) disposes of any dead aquatic animal which comes from that area.

Contents and publication of a confirmed designation

- **29.**—(1) A confirmed designation must—
 - (a) be in the form of a written notice;
 - (b) describe the area which is the subject of the designation;
 - (c) describe the circumstances in which a person commits an offence under regulation 28(2);

- (d) make reference to any consent given by the competent authority under regulation 28(2).
- (2) A confirmed designation may require that-
 - (a) any equipment, material or substance liable to transmit disease must not be moved into, out of or within the confirmed designation area or any part of that area;
 - (b) any means of transport liable to transmit disease must not be moved into, out of or within that area or any part of that area.
- (3) The competent authority must-
 - (a) publish a confirmed designation in such manner as it considers appropriate;
 - (b) serve a copy of a confirmed designation on any person it considers likely to be materially affected by the making of the designation.
- (4) It is an offence not to comply with any requirement imposed under paragraph (2).

Actions by an inspector in respect of a confirmed designation

- **30.**—(1) This regulation applies where the competent authority has made a confirmed designation.
 - (2) An inspector may-
 - (a) take samples of any aquatic animal or water in the confirmed designation area;
 - (b) slaughter or kill and destroy or dispose of any such animal.
 - (3) An inspector may by written notice direct any person to-
 - (a) take steps to secure the slaughter or killing and destruction or disposal of any aquatic animal in the confirmed designation area;
 - (b) operate a disinfection facility at the entrance to, and exit from, any farm or mollusc farming area in that area;
 - (c) disinfect any means of transport in that area;
 - (d) take any other steps which the inspector considers necessary to eradicate the disease or to prevent or limit the spread of the disease to other aquatic animals.
- (4) An inspector may by written notice prohibit any person from entering any farm or mollusc farming area within the confirmed designation area.
- (5) Where an inspector considers that a requirement under paragraph (3) has not been complied with, the inspector may—
 - (a) enter any place within the confirmed designation area;
 - (b) take or cause to be taken such steps as the inspector considers necessary to-
 - (i) ensure compliance with the requirement; or
 - (ii) remedy the consequences of the failure to carry it out;
 - (c) recover any expenses reasonably incurred in so doing from any person who has failed to comply with the requirement.
 - (6) It is an offence not to comply with a requirement imposed under paragraph (3) or (4).

Withdrawal of a confirmed designation

31. The competent authority must withdraw a confirmed designation when it is satisfied that the listed disease or the emerging disease is not present in the confirmed designation area.

PART 5

ADDITIONAL PROVISION IN RELATION TO GYRODACTYLUS SALARIS

Additional powers in relation to Gyrodactylus salaries

- **32.**—(1) Where the competent authority has made an initial designation under regulation 24(1) or a confirmed designation under regulation 28(1) in relation to *Gyrodactylus salaris*, it may exercise the powers in paragraphs (2) and (3).
 - (2) The competent authority may, where it considers it appropriate to do so, arrange for-
 - (a) the creation and maintenance of barriers to the movement of any aquatic animal in any inland waters in Scotland—
 - (i) to prevent the spread of Gyrodactylus salaris; and
 - (ii) to facilitate treatment with chemical agents with a view to eradicating *Gyrodactylus* salaris from the waters concerned;
 - (b) the treatment with chemical agents of any waters in the initial designation area or the confirmed designation area, as the case may be, with a view to eradicating *Gyrodactylus salaris* from the waters concerned; and
 - (c) the dismantling and removal of barriers created under subparagraph (a).
- (3) For the purpose of facilitating the exercise of their power under paragraph (2)(a), the competent authority may purchase land in Scotland compulsorily.

Clearance of certain fish farms – Gyrodactylus salaries

- **33.**—(1) This regulation applies where the competent authority has made an initial designation under regulation 24(1) or a confirmed designation under regulation 28(1) in relation to infection with *Gyrodactylus salaris*.
 - (2) An inspector may by written notice direct a person to-
 - (a) withdraw all aquatic animals from the waters of the farm;
 - (b) drain, clean and disinfect all pools and cages in the farm;
 - (c) destroy all-
 - (i) dead aquatic animals;
 - (ii) live aquatic animals withdrawn from the farm which show clinical signs of the disease known as gyrodactylosis caused by *Gyrodactylus salaris*;
 - (iii) live aquatic animals withdrawn from the farm which show signs of the presence of *Gyrodactylus salaris*;
 - (d) clean and disinfect or destroy equipment, material or substances liable to be contaminated with *Gyrodactylus salaris*;
 - (e) obtain the prior written consent of the competent authority before repopulating the farm.
 - (3) It is an offence not to comply with a requirement imposed under paragraph (2).

Power to take other measures – Gyrodactylus salaris

34. The competent authority may take such other measures (including regulating entry to and exit from an initial designation area or a confirmed designation area) as it considers appropriate for the purpose of eradicating, or preventing, or limiting the spread of *Gyrodactylus salaris*.

PART 6

ENFORCEMENT, APPEALS AND PENALTIES

Entry and inspection of land and premises

- **35.**—(1) An inspector may, on producing some duly authenticated document showing the inspector's authority if required, enter and inspect any land or premises at any reasonable time for the purposes of administering and enforcing these Regulations.
 - (2) An inspector may be accompanied by-
 - (a) such persons, equipment and vehicles as the inspector considers necessary;
 - (b) a representative of the European Commission acting for the purposes of Directive 2006/88/EC.
- (3) An inspector may not enter any premises which are a dwelling unless a justice of the peace has issued a warrant authorising the inspector to do so.
- (4) A justice of the peace may only issue such a warrant if satisfied that there is good reason to believe that the inspector will not be able to administer or enforce these Regulations without the warrant.
 - (5) A warrant issued under paragraph (3) remains in force-
 - (a) for one month; or
 - (b) until the purpose for which it is issued has been fulfilled,

whichever is the sooner.

Search and examination of land and premises

- **36.** Where an inspector exercises the power conferred by regulation 35, the inspector may—
 - (a) search the land or premises for any item, including any aquatic animal or water;
 - (b) examine anything that is-
 - (i) on the land or premises;
 - (ii) attached to or otherwise forms part of the land or premises.

Production of documents

- **37.** For the purposes of administering or enforcing these Regulations, an inspector may require any person—
 - (a) to produce any document or record that is in that person's possession or control;
 - (b) to render any such document or record on a computer system into a visible and legible form, including requiring it to be produced in a form in which it may be taken away.

Seizure of items

- **38.**—(1) This regulation applies where an inspector exercises the powers conferred by regulation 36 or 37.
 - (2) An inspector may–
 - (a) seize, detain or remove any item which is on the land or premises;
 - (b) take copies of or extracts from any document or record found on the land or premises.

- (3) The power conferred in paragraph (2)(a) shall be construed as including power to take and examine samples of any aquatic animal or water.
- (4) An inspector to whom any document or record has been produced in accordance with a requirement imposed under regulation 37 may—
 - (a) seize, detain or remove that document or record;
 - (b) take copies of or extracts from that document or record.
- (5) If, in the opinion of the inspector, it is not for the time being practicable for the inspector to seize and remove any item, the inspector may require any person on the land or premises to secure that the item is not removed or otherwise interfered with until such time as the inspector may seize and remove it.
 - (6) The powers conferred by this regulation may only be exercised—
 - (a) for the purposes of determining whether an offence under these Regulations has been committed; or
 - (b) in relation to an item which an inspector reasonably believes to be evidence of the commission of an offence under these Regulations.
 - (7) Any item seized by an inspector may be disposed of as the competent authority thinks fit.
 - (8) It is an offence not to comply with a requirement imposed by an inspector under paragraph (5).

Enforcement notices

- **39.**—(1) Where the competent authority considers that any person has not complied with, is not complying with, or is not likely to comply with, the conditions of an authorisation under Part 2 or a requirement under these Regulations, it may serve that person with an enforcement notice.
 - (2) An enforcement notice must state-
 - (a) the steps which the relevant person must take or is prohibited from taking;
 - (b) the date by which the steps must be taken;
 - (c) the reasons for the service of the notice and for the requirements in it;
 - (d) that there is a right of appeal under regulation 40.
- (3) Where an inspector considers that a requirement in an enforcement notice has not been complied with, the inspector may—
 - (a) take such steps as the inspector considers necessary—
 - (i) to ensure compliance with the requirements of the notice; or
 - (ii) to remedy the consequences of the failure to carry them out;
 - (b) recover any expenses reasonably incurred in so doing from any person who has failed to comply with the notice.
 - (4) It is an offence not to comply with an enforcement notice.

Appeals

- **40.**—(1) A person may appeal to the competent authority against any of the following–
 - (a) refusal to grant an authorisation under regulation 8;
 - (b) any condition to which an authorisation is subject;
 - (c) any amendment made to an authorisation under regulation 9 or any decision not to grant an amendment under that regulation;
 - (d) suspension or revocation of an authorisation under regulation 10 or 11;

- (e) service of an enforcement notice under regulation 39.
- (2) An appellant may within 21 days beginning with the date on which the relevant event occurs, serve the competent authority with a written notice that the appellant wishes to—
 - (a) appear before and be heard by an independent person appointed by the competent authority; or
 - (b) provide written representations to the competent authority.
 - (3) Where an appellant gives notice under paragraph (2)(a)–
 - (a) the competent authority must appoint an independent person to hear representations and specify a time limit within which representations to that person must be made;
 - (b) if the appellant so requests, the hearing must be in public;
 - (c) the person appointed must report to the competent authority; and
 - (d) if the appellant so requests, the competent authority must provide a copy of the appointed person's report to the appellant.
 - (4) Where an appellant provides written representations under paragraph (2)(b)–
 - (a) the competent authority must appoint an independent person to consider the representations; and
 - (b) the requirements in paragraph (3)(c) and (d) apply.
- (5) The competent authority must give the appellant written notice of its final decision and the reasons for it.

Obstruction

- 41. It is an offence-
 - (a) to intentionally obstruct any person acting in the execution of these Regulations;
 - (b) to fail without reasonable cause to give to such person any assistance or information which that person may reasonably require for the purposes of that person's functions under these Regulations; or
 - (c) to knowingly or recklessly give false or misleading information to such person.

Offences by bodies corporate

- 42.—(1) Where an offence under these Regulations committed-
 - (a) by a body corporate, is shown to have been committed with the consent or connivance of, or is attributable to any neglect on the part of a person who—
 - (i) is a director, manager, secretary or other similar person of the body corporate; or
 - (ii) was purporting to act in any such capacity,
 - (b) by a Scottish partnership, is committed with the consent or connivance of, or is attributable to any neglect on the part of a person who—
 - (i) is a partner, or
 - (ii) was purporting to act in that capacity; or
 - (c) by an unincorporated association other than a Scottish partnership, is committed with the consent or connivance of, or is attributable to any neglect on the part of, a person who—
 - (i) is concerned in the management or control of the association, or
 - (ii) was purporting to act in the capacity of a person so concerned,

the individual (as well as the body corporate, Scottish partnership or, as the case may be, unincorporated association) is guilty of the offence, and is liable to be proceeded against and punished accordingly.

(2) For the purposes of this regulation, "director", in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

Penalties

- **43.** A person who is guilty of an offence under these Regulations is liable–
 - (a) on summary conviction, to a fine not exceeding the statutory maximum;
 - (b) on conviction on indictment, to a fine.

PART 7

MISCELLANEOUS

Vaccination

44. It is an offence to vaccinate an aquatic animal against a listed disease without the prior written consent of the competent authority.

Public register of disease-free zones and compartments

- **45.**—(1) The competent authority must establish and maintain a register of declarations made in relation to Scotland under Article 50 of Directive 2006/88/EC.
- (2) The register must be publicly available for inspection free of charge at all reasonable times and at such place as determined by the competent authority.

Disclosure of information

- **46.**—(1) The competent authority, any local authority, the Scottish Environmental Protection Agency and the Food Standards Agency may disclose information to each other for the purposes of these Regulations or Directive 2006/88/EC.
- (2) The competent authority may disclose information to the equivalent authority in England, Wales or Northern Ireland for the purposes of these Regulations or the equivalent Regulations in England, Wales or Northern Ireland, or for the purposes of Directive 2006/88/EC.

Service of notices

- 47.—(1) Any notice served under these Regulations may be served on a person by-
 - (a) delivering it to that person;
 - (b) sending it by post;
 - (c) transmitting it electronically.
- (2) Where the person on whom a notice to be served is a body corporate, the notice is duly served if it is served on the secretary or clerk of that body.

- (3) For the purposes of this regulation and section 7 of the Interpretation Act 1978(14) (references to service by post) in its application to this regulation, the proper address of any person to whom a notice is given is—
 - (a) if the person has given an address for service, that address;
 - (b) if no address has been given-
 - (i) in the case of the secretary or clerk of a body corporate, the registered or principal office of that body;
 - (ii) in any other case, the person's last known address at the time of service.
 - (4) If the notice is transmitted electronically, it is to be treated as duly served if-
 - (a) the person upon whom the notice is required or authorised to be served ("the recipient") has indicated to the person serving the notice the recipient's willingness to receive notices transmitted by electronic means and has provided an address suitable for that purpose; and
 - (b) the notice is sent to the address provided.

Repeals, amendments and revocations

48. Schedule 2 (repeals, amendments and revocations) has effect.

St Andrew's House, Edinburgh 5th March 2009

R CUNNINGHAM Authorised to sign by the Scottish Ministers

SCHEDULE 1

Regulation 3(3)

List of diseases

Disease	Susceptible species
Infection with Gyrodactylus salaris	Atlantic salmon (Salmo salar), rainbow trout (Oncorhynchus mykiss), Arctic char (Salvelinus alpinus), North American brook trout (S. fontinalis), grayling (Thymallus thymallus), North American lake trout (Salvelinus namaycush), and brown trout (Salmo trutta). Other species of fish on sites where any of the above species are present shall also be considered as susceptible species
Bacterial kidney disease	Fish belonging to the family Salmonidae
Spring viraemia of carp	Bighead carp (Aristichthys nobilis), goldfish (Carassius auratus), crucian carp (C. carassius), grass carp (Ctenopharyngodon idellus), common carp and koi carp (Cyprinus carpio), silver carp (Hypophthalmichthys molitrix), sheatfish (Silurus glanis) and tench (Tinca tinca)

SCHEDULE 2

Regulation 48

Repeals, amendments and revocations

- 1. The Diseases of Fish Act 1937(15) is repealed.
- 2. In Schedule 8 to the Water Act 1973(16), omit paragraph 43.
- **3.** In section 41(1) of the Salmon and Freshwater Fisheries Act 1975(17), for the definition of "fish farm", substitute—

""fish farm"-

- (a) means a pond, stew, hatchery or other place used for keeping, with a view to their sale or to their transfer to other waters (including another fish farm), live fish, live eggs of fish, or foodstuff of fish, and
- (b) includes any buildings used in connection with a place mentioned in paragraph (a) and the banks and margins of any water in such a place;".
- **4.** In section 1(1) of the Import of Live Fish (Scotland) Act 1978(18), omit "Without prejudice to section 1(1) of the Diseases of Fish Act 1937 and".
- **5.** In Part 1 of paragraph 12 of Schedule 4 to the Customs and Excise Management Act 1979(**19**), omit the entry relating to the Diseases of Fish Act 1937.

^{(15) 1937} c. 33 (1 Edw. 8 & 1 Geo. 6).

^{(16) 1973} c. 37.

^{(17) 1975} c. 51; section 41(1) was amended by the Environment Act 1995 (c. 25), Schedule 15, paragraph 20(a).

^{(18) 1978} c. 35.

^{(19) 1979} c. 2.

- **6.** The Diseases of Fish Act 1983(20) is repealed.
- 7. In the Salmon Act 1986(21)-
 - (a) in section 24(2)(b), omit "within the meaning of the Diseases of Fish Act 1937"; and
 - (b) omit paragraph 6 of Schedule 4.
- **8.** In the Water Act 1989(22)—
 - (a) in section 141(4)(b), for ", the Salmon and Freshwater Fisheries Act 1975 and the Diseases of Fish Act 1937" substitute "and the Salmon and Freshwater Fisheries Act 1975";
 - (b) omit paragraphs 3 and 8 of Schedule 17; and
 - (c) in Part 1 of Schedule 27, omit the entries relating to the Diseases of Fish Act 1937 and the Diseases of Fish Act 1983.
- 9. In the Environment Act 1995(23)—
 - (a) in section 2(1)(a)(v), omit "the Diseases of Fish Act 1937,";
 - (b) omit section 6(7)(b)(i); and
 - (c) in Schedule 15-
 - (i) in paragraph 2(4)(c)(ii) omit "or under the Diseases of Fish Act 1937,"; and
 - (ii) omit paragraphs 4 and 23.
- 10. In the Salmon and Freshwater Fisheries (Consolidation) (Scotland) Act 2003(24)-
 - (a) in section 8(1), omit "Without prejudice to section 3 of the Diseases of Fish Act 1937 (c. 33) (powers and duties of fishery boards),"; and
 - (b) in section 69, in the definition of "fish farm" for "section 10(1) of the Diseases of Fish Act 1937" substitute "section 41(1) of the Salmon and Freshwater Fisheries Act 1975 (c. 51)".
- 11. In section 3(5)(b)(ii) of the Gangmasters (Licensing) Act 2004(25), for "the Diseases of Fish Act 1937 (c. 33)", substitute "Salmon and Freshwater Fisheries Act 1975 (c. 51)".
 - 12. The Diseases of Fish (Control) Regulations 1994(26) are revoked.
 - 13. The Fish Health Regulations 1997(27) are revoked.
 - 14. The Diseases of Fish (Control) Amendment (Scotland) Regulations 2000(28) are revoked.
 - **15.** The Fish Health Amendment (Scotland) Regulations 2001(**29**) are revoked.
- **16.** In Schedule 1 to the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002(**30**) omit paragraph 21.

^{(20) 1983} c. 30.

^{(21) 1986} c. 62.

^{(22) 1989} c. 15.

^{(23) 1995} c. 25.

^{(24) 2003} asp 15.

⁽**25**) 2004 c. 11.

⁽²⁶⁾ S.I.1994/1447.

⁽²⁷⁾ S.I. 1997/1881. (28) S.S.I. 2000/330.

⁽²⁸⁾ S.S.I. 2000/330. (29) S.S.I. 2001/409.

⁽**30**) S.I. 2002/794.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Council Directive 2006/88/EC (O.J. No. L 238, 24.11.2006, p.14) on animal health requirements for aquaculture animals and products thereof and on the prevention and control of certain diseases in aquatic animals.

Part 2 of these Regulations requires aquaculture production businesses, certain processing establishments and the import of ornamental aquatic animals to be authorised by the competent authority (regulation 5). Some undertakings, including put and take fisheries and specialist transport businesses, are required to be registered (regulation 12). Although these Regulations generally come into force on 27th March 2009, regulation 5(1), which makes it an offence to operate an aquaculture production business or certain types of processing establishment without authorisation, comes into force on 1st May 2009. Regulation 12(1), which makes it an offence to operate certain undertakings unless registered, comes into force on 1st August 2009.

Part 3 imposes health requirements in relation to the placing on the market of aquaculture and other aquatic animals. One of the principal mechanisms for ensuring that health standards are met is the requirement for any necessary animal health certificates to be properly completed and to accompany the introduction of aquaculture animals into Scotland (regulation 17(1)). This Part also introduces disease prevention requirements in respect of the transport of such animals (regulations 19 to 21).

Part 4 establishes a system for the notification and control of disease outbreaks in aquatic animals. The competent authority is required to designate an area where a listed or emerging disease is suspected (regulation 24) and to make a confirmed designation (regulation 28) where such a disease is confirmed. Inspectors are given powers to require others to take steps necessary to eradicate or prevent the spread of disease to other aquatic animals (regulations 26 and 30).

Part 5 makes provision as regards measures which may be taken in relation to *Gyrodactylus salaris* (Gs). The measures which may be taken include the creation of barriers to movements of fish and the treatment of waters with chemical agents (regulation 32), the clearance of fish farms (regulation 33) and such other measures as the competent authority considers appropriate (regulation 34).

Part 6 gives enforcement powers to inspectors, and allows the service of an enforcement notice (regulation 39). Appeals may be made against such a notice or in relation to an authorisation under Part 2. A person found guilty of an offence under these Regulations is liable on summary conviction to a fine not exceeding the statutory maximum or on conviction on indictment to an unlimited fine (regulation 43).

Part 7 makes provision prohibiting vaccination without the prior permission of the competent authority (regulation 44), and as to the keeping of a public register of disease-free zones and compartments (regulation 45).

Regulatory Impact Assessment relating to these Regulations has been placed in the Scottish Parliament Information Centre, and a copy is available from Scottish Government Marine Directorate, Pentland House, 47 Robb's Loan, Edinburgh, EH14 1TY.