SCHEDULE 1

Regulation 22

AMENDMENTS TO THE 1994 REGULATIONS

1. In regulation 2(1) of the 1994 Regulations (interpretation)—

(a) for the definition of "authorised representative" there shall be substituted the following definition—

> ""authorised representative" means a person established within the Community who, explicitly designated by the manufacturer, acts for the manufacturer and may be addressed by authorities and bodies in the Community instead of the manufacturer;";

(b) after the definition of "intended purpose" there shall be inserted the following definition—

> ""*in vitro* diagnostic medical device" has the same meaning as in the *In Vitro* Diagnostic Medical Regulations 2000;";

(c) for the definition of "putting into service" there shall be substituted the following definition—

> ""putting into service" means, in relation to a device, the first making available of the device in the Community to a final user;"; and

(d) the definition of "used for *in vitro* diagnosis" is omitted.

2. In regulation 3(2) of the 1994 Regulations (application of the Regulations), for sub-paragraph (a) there shall be substituted the following sub-paragraph—

"(a) *in vitro* diagnostic medical devices;".

3. After regulation 12 of the 1994 Regulations (general provisions relating to conformity assessment procedures) there shall be inserted the following regulation—

"**CE marking of a product which is not a device**

12A.—(1) No person shall—

(a) affix the CE marking for a device to a product which is not a device;

(b) place on the market a product which has affixed to it the CE marking for a device if that product is not a device.

(2) No person shall provide information comprising a CE marking for a relevant device on—

(a) a product;

(b) the instructions for use for a product; or

(c) the sales packaging for a product,

if the product is not a device.

(3) No person shall—

(a) supply, offer to supply, or agree to supply a product which has affixed to it a CE marking for a device if—

(i) that supply, offer to supply or agreement to supply a product is also a placing on the market of that product, and

(ii) that product is not a device;

(b) expose or possess for supply a product which has affixed to it a CE marking for a device if—

(i) that exposure for supply or possession for supply of a product is also a placing on the market of that product, and

(ii) that product is not a device.".

4. In regulation 14 of the 1994 Regulations (registration of persons placing devices on the market) —

(a) after sub-paragraph (b) of paragraph (1) there shall be inserted the following—

"; and

(c) supply the Secretary of State, if the device is a Class IIb or III device and if the Secretary of State so requests, with all data allowing for the identification of the device together with the label and the instructions for use for when the device is put into service within the United Kingdom."; and

(b) after sub-paragraph (b) of paragraph (3) there shall be added the following—

"; and

(c) in the case of an authorised representative of the manufacturer, the fact that he is the manufacturer's authorised representative, and he shall furnish the Secretary of State with sufficient evidence that he is an authorised representative of the manufacturer.".

5. In regulation 16 of the 1994 Regulations (clinical investigations)—

(a) in paragraph (1)(a), before the words "the statement required" there shall be inserted the words "subject to paragraph (1A),";

(b) after paragraph (1), there shall be inserted the following paragraph—

"(1A) The ethics committee opinion that forms part of the information required under Section 2.2 of Annex VIII need not be provided to the Secretary of State at least 60 days prior to the intended investigation, but if it is not provided at least 60 days prior to the intended investigation, it must be provided to the Secretary of State by the manufacturer or his authorised representative as soon as it becomes available."; and

(c) for paragraph (3) there shall be substituted the following paragraphs—

"(3) The Secretary of State may, in respect of notice in writing given by a manufacturer or his authorised representative under paragraph (1), give written notice to the manufacturer or his authorised representative that devices may be made available for the purposes of the intended investigation—

(a) at any time after the giving of notice under paragraph (1); or

(b) if the ethics committee opinion required under Section 2.2 of Annex VIII is not available, at any time after a favourable opinion in respect of the investigational plan for the intended investigation is delivered by the committee,

but that written notice may at any time be withdrawn by the Secretary of State.

(3A) Where a written notice under paragraph (3) has been withdrawn by the Secretary of State, devices may not be made available for the programme of clinical investigation to which that notice relates unless the Secretary of State issues a further written notice under that paragraph stating that devices may again be made available for the purposes of that investigation.".

6. In regulation 17 of the 1994 Regulations (notified bodies), after paragraph (7) there shall be inserted the following paragraphs—

"(8) Notified bodies shall inform all other notified bodies and the Secretary of State of—

(a) all certificates suspended or withdrawn; and

(b) on request, all certificates issued or refused,

and they shall also make available to them, on request, any or all additional relevant information.

(9) Where, as respects a device, a notified body finds—

(a) that applicable requirements of the Directive have not been met or are no longer met; or

(b) a certificate should not have been issued,

it may (having regard in particular to the principle of proportionality and the ability of the manufacturer to take appropriate corrective measures) suspend or withdraw the certificate issued in respect of that device or place restrictions on it, and in such cases, or in cases where the notified body is aware of circumstances in which the Secretary of State may need to take action pursuant to regulation 19 or 19A, the notified body shall inform the Secretary of State thereof.

(10) The Secretary of State may request that a notified body supply to him any or all relevant information and documents, including budgetary documents, necessary to enable him to verify that the body meets the criteria set out in Annex XI, and the body shall supply to him the relevant information and documents so requested.".

7. For paragraph (1) of regulation 18 of the 1994 Regulations (prohibition on supply etc.) there shall be substituted the following paragraph—

"(1) Subject to paragraph (6), the supply, offer to supply, agreement to supply, exposure for supply or possession for supply of a device—

(a) which constitutes a placing on the market or putting into service of the device; or

(b) in circumstances where that device has been placed on the market or put into service,

if the device does not comply with the relevant essential requirements, is prohibited.".

8.—(1) In paragraph (3) of regulation 19 of the 1994 Regulations (enforcement etc.), after the words "and accordingly" there shall be added the words " but subject to paragraph (3A),".

(2) After paragraph (3) of regulation 19 of the 1994 Regulations there shall be inserted the following paragraph—

"(3A) The powers of an enforcement authority to serve restriction notices under regulation 19A are only exercisable by the Secretary of State.".

(3) For paragraphs (6) and (7) of regulation 19 of the 1994 Regulations there shall be substituted the following paragraphs—

"(6) In paragraph (5), "non-conforming devices" means devices which, whether or not the Secretary of State considers them unsafe, are devices with or which require a CE marking which he considers to be devices—

(a) which do not conform as respects a relevant essential requirement; or

(b) to which a CE marking has or should have been applied following the EC declaration of conformity assessment procedure set out in the Directive, and—

(i) the manufacturer or his authorised representative has failed to comply with his obligations under that procedure, or

(ii) they do not conform to the design or type described in any relevant EC design-examination or EC type-examination certificate.

(7) Except in the case of a device which in the opinion of an enforcement authority is likely to compromise the health or safety of any person, where an enforcement authority

has reasonable grounds for suspecting that a device is a device in respect of which there is a failure to comply with these Regulations, that authority may serve upon the manufacturer or his authorised representative a notice—

(a) specifying the description of the device to which the notice relates;

(b) stating that the enforcement authority suspects the device is a device in respect of which there is failure to comply with these Regulations and the reasons for that suspicion;

(c) specifying the relevant provision of these Regulations;

(d) requiring the person on whom the notice is served—

(i) to secure that any device to which the notice relates conforms as regards the specified provision within such period as may be specified in the notice, or

(ii) to provide evidence within that period to the satisfaction of the enforcement authority that all the provisions of these Regulations have been complied with so far as they relate to that device; and

(e) warning the person on whom the notice is served that unless the requirements of sub-paragraph (d) are met, further action may be taken under these Regulations or the 1987 Act in respect of that device or any device of the same type supplied by that person.".

9. After regulation 19 of the 1994 Regulations there shall be inserted the following regulation—

"**Restriction notices**

19A.—(1) Where an enforcement authority is of the opinion that it is necessary to restrict the availability of a particular device, or of devices of a particular class or description, in order to protect the health or safety of any individual or of individuals of any class or description, they may serve on any person a notice ("a restriction notice") including such directions restricting the availability of that device or those devices as appear to them to be necessary in order to protect the health or safety of that individual or individuals of that class or description.

(2) The enforcement authority responsible for serving a restriction notice may, in appropriate circumstances, withdraw the notice.

(3) A direction in a restriction notice that has not been withdrawn by an enforcement authority or set aside by an order of a court or a sheriff is a safety provision for the purposes of sections 14 to 17 of the 1987 Act.

(4) Where, in the course of or as a result of enforcement action in relation to a suspected contravention of a direction in a restriction notice, an application has been made to a magistrates' court or a sheriff—

(a) under section 15 of the 1987 Act (appeals against suspension notices), the court or the sheriff may make an order setting aside the restriction notice and any suspension notice served in respect of the suspected contravention of the direction;

(b) under section 16 or 17 of the 1987 Act (which relate to forfeiture of goods), the court or the sheriff may make an order setting aside the restriction notice,

if the court or the sheriff is satisfied that the restriction notice should not have been served or should be withdrawn.

(5) In England, Wales or Northern Ireland, for the purposes of the rights of appeal under section 15(5) and 16(5) of the 1987 Act, an order or decision not to make an order—

(a) under paragraph 4(a) is an order or decision not to make an order under section 15 of the 1987 Act;

(b) under paragraph 4(b) is an order or decision not to make an order under section 16 of the 1987 Act,

and a decision, in Scotland, not to make an order under paragraph 4(b) may, within 21 days of the decision, be appealed to the High Court by Bill of Suspension on the ground of an alleged miscarriage of justice, and the appeal shall be treated in the same way as an appeal under section 17(8) of the 1987 Act.".

10. In paragraph (1) of regulation 22 of the 1994 Regulations (transitional provisions), after sub-paragraph (b) there shall be added the following—

"; or

(c) shall prohibit the putting into service before 30th June 2001 of a device which—

(i) was placed on the market on or before 31st December 1994, and

(ii) satisfies the requirements of the laws of that part of the United Kingdom in which it is put into service as in force on 31st December 1994.".

11. In paragraph (1) of regulation 23 of the 1994 Regulations (notification of decisions etc.)—

(a) after the words "in the refusal" there shall be inserted the words " or withdrawal of approval"; and

(b) after sub-paragraph (b) there shall be inserted the following—

"; and

(c) a statement, if the applicant was not entitled under the 1987 Act to make representations in respect of the decision, that the decision maker will, on request, review the decision and in the course of so doing will give him or his authorised representative an opportunity to make representations in respect of the decision.".

SCHEDULE 2

Regulation 23

AMENDMENTS TO THE 1995 REGULATIONS

1. In regulation 2 of the 1995 Regulations (interpretation)—

(a) after the definition of "the 1994 Regulations" there shall be inserted the following definitions—

""the 1998 Directive" means Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices;

"the 2000 Regulations" means the *In Vitro* Diagnostic Medical Devices Regulations 2000;"; and

(b) after the definition of "half day" there shall be inserted the following definition—

""*in vitro* diagnostic medical device" has the same meaning as in the 2000 Regulations;".

2. After regulation 6 of the 1995 Regulations (withdrawals) there shall be inserted the following regulations—

"**Fees in connection with the registration of devices and changes to registration details**

7. Any person required to supply the Secretary of State with any information under regulation 14 of the 1994 Regulations shall, in respect of the processing of that information with regard to the possible registration of devices by the Secretary of State or possible changes to registration details, pay to the Secretary of State a fee of £70, and that fee—

(a) shall be payable when the information is supplied by that person to the Secretary of State; and

(b) shall accompany that information when it is supplied.

(2) Any person required to supply the Secretary of State with any information under regulation 14 of the 2000 Regulations shall, in respect of the processing of that information with regard to the possible registration of *in vitro* diagnostic medical devices by the Secretary of State or possible changes to registration details, pay to the Secretary of State a fee of £70, and that fee—

(a) shall be payable when the information is supplied by that person to the Secretary of State; and

(b) shall accompany that information when it is supplied.

Fees payable in connection with the designation of UK notified bodies under regulation 15 of the 2000 Regulations

8.—(1) A corporate or other body that applies to the Secretary of State for designation under regulation 15(1) of the 2000 Regulations shall, in connection with that application for designation, pay to the Secretary of State—

(a) if it is the second or subsequent such application and the application is being made only to address the grounds for rejection of a previous application, a fee of £650;

(b) in all other cases, a fee of £2,600.

(2) A corporate or other body that applies to the Secretary of State for a variation under regulation 15(4) of the 2000 Regulations of the tasks that the body may carry out shall, in connection with that application for a variation, pay to the Secretary of State a fee of £1,300.

(3) Where, pursuant to regulation 15(7) of the 2000 Regulations the Secretary of State inspects premises for the purposes of deciding whether or not a body is one in respect of which the criteria set out in Annex IX of the 1998 Directive are met, the body shall pay to the Secretary of State—

(a) in respect of an initial inspection pursuant to regulation 15(7)(a) of those Regulations, a fee of £3,200, plus—

(i) an amount for time spent by a member of staff out of the office while undertaking a site visit (to include time spent travelling) at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate of £51.39 per hour for time spent travelling,

(ii) the actual costs of travel, accommodation and subsistence, and

(iii) out of pocket expenses;

(b) in respect of any other inspection pursuant to regulation 15(7)(a) of those Regulations, a fee of £2,600, plus—

(i) an amount for time spent by a member of staff out of the office while undertaking a site visit (to include time spent travelling) at a rate, for the

time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate of £51.39 per hour for time spent travelling,

(ii) the actual costs of travel, accommodation and subsistence, and

(iii) out of pocket expenses; and

(c) in respect of an inspection pursuant to regulation 15(7)(b) of those Regulations, a fee of £2,600, plus—

(i) an amount for time spent by a member of staff out of the office while undertaking a site visit (to include time spent travelling) at a rate, for the time spent on site, of £185 per half day (periods of less than a half day counting as a half day) up to a maximum of two half days on any one date, and at a rate of £51.39 per hour for time spent travelling,

(ii) the actual costs of travel, accommodation and subsistence, and

(iii) out of pocket expenses.

(4) A fee under this regulation—

(a) in connection with an application—

(i) shall be payable when the application to the Secretary of State is made, and

(ii) shall accompany the application when it is made;

(b) in connection with an inspection, shall be payable within one month of receipt by the body of a written notice from the Secretary of State requiring payment of the fee.

Unpaid fees

9. All unpaid sums due by way of, or on account of, any fees payable under these Regulations are recoverable as debts due to the Crown.

Waiver, reductions and refunds

10. The Secretary of State may—

(a) waive payment of any fee or reduce any fee or part of a fee otherwise payable under these Regulations;

(b) refund the whole or part of any fee paid pursuant to these Regulations.".

3. In the Table set out in the Schedule to the 1995 Regulations(**1**), in the entries in Column 3—

(a) for the words "the rate of", at each place where they occur, there shall be substituted the words "a rate, for the time spent on site, of"; and

(b) after the words "any one date," at each place where they occur, there shall be added the words "and at a rate of £51.39 per hour for time spent travelling,".

(**1**) Amended by regulation 2 of S.I.1997/694.