SCHEDULE 1 Regulation 2(1)

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS

Column 1 *Product-type*	*Column 2* *Description*
MAIN GROUP 1	
Disinfectants and general biocidal products These product-types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.	
1 Human hygiene biocidal products	Products used for human hygiene purposes.
2 Private area and public health area disinfectants and other biocidal products	Products (which are not used for direct food or feedingstuff contact) used for the disinfection of air, surfaces, materials, equipment and furniture in private, public and industrial areas, including hospitals, as well as products used as algaecides. Usage areas include swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil or other substrates (in playgrounds).
3 Veterinary hygiene biocidal products	Products used for veterinary hygiene purposes, including products used in areas in which animals are housed, kept or transported.
4 Food and feed area disinfectants	Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.
5 Drinking water disinfectants	Products used for the disinfection of drinking water (for both humans and animals).
MAIN GROUP 2	**Preservatives**
6 In-can preservatives	Products used for the preservation of manufactured products, other than food or feedingstuff, in containers by the control of microbial deterioration to ensure their shelf life.
7 Film preservatives	Products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or

Column 1 *Product-type*	*Column 2* *Description*
	objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.
8 Wood preservatives	Products (both preventive and curative) used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms.
9 Fibre, leather, rubber and polymerised materials preservatives	Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.
10 Masonry preservatives	Products used for the preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack.
11 Preservatives for liquid-cooling and processing systems	Products used for the preservation of water (other than drinking water) or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.
12 Slimicides	Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, such as on wood and paper pulp or porous sand strata in oil extraction.
13 Metalworking-fluid preservatives	Products used for the preservation of metalworking fluids by the control of microbial deterioriation.
MAIN GROUP 3	**Pest control**
14 Rodenticides	Products used for the control of mice, rats or other rodents.
15 Avicides	Products used for the control of birds.
16 Molluscicides	Products used for the control of molluscs.
17 Piscicides	Products used for the control of fish except products for the treatment of fish diseases.
18 Insecticides, acaricides and products to control other arthropods	Products used for the control of arthropods (including insects, arachnids and crustaceans).
19 Repellents and attractants	Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.

Column 1 *Product-type*	*Column 2* *Description*
MAIN GROUP 4	**Other Biocidal products**
20 Preservatives for food or feedstocks	Products used for the preservation of food or feedstocks by the control of harmful organisms.
21 Antifouling products	Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.
22 Embalming and taxidermist fluids	Products used for the disinfection and preservation of human or animal corpses, or parts thereof.
23 Control of other vertebrates	Products used for the control of vermin.

SCHEDULE 2

Regulation 3(1)

REGULATIONS RELATING TO BIOCIDAL PRODUCTS

The Regulations referred to in regulation 3(1)(a) are—

(a) the Materials and Articles in Contact with Food Regulations 1987(**1**);

(b) the Flavourings in Food Regulations 1992(**2**);

(c) the Food Additive Labelling Regulations 1992(**3**);

(d) the Active Implantable Medical Devices Regulations 1992(**4**);

(e) the Egg Products Regulations 1993(**5**);

(f) the Medicines (Homoeopathic Medicinal Products For Human Use) Regulations 1994(**6**);

(g) the Medical Devices Regulations 1994(**7**);

(h) the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**8**);

(i) the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**9**);

(j) the Plant Protection Products Regulations 1995(**10**);

(k) the Dairy Products (Hygiene) Regulations 1995(**11**);

(l) the Dairy Products (Hygiene) (Scotland) Regulations 1995(**12**);

(**1**) S.I.1987/1523, amended by S.I. 1990/2487, 1991/1476, 1994/979.
(**2**) S.I. 1992/1971, amended by S.I. 1994/1486, 1996/1499.
(**3**) S.I. 1992/1978, amended by S.I. 1995/3123, 1995/3124, 1995/3187, 1996/1499, 1999/1136, 2000/1799.
(**4**) S.I. 1992/3146, amended by S.I. 1995/1671.
(**5**) S.I. 1993/1520, amended by S.I. 1995/1763, 1996/1499, 2000/656 and SS.I. 2000/62.
(**6**) S.I. 1994/105, amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2000/592.
(**7**) S.I. 1994/3017, amended by S.I. 2000/1315.
(**8**) S.I. 1994/3142, amended by S.I. 1997/654, 1997/1729, 1997/2884, 1998/1048, 1999/1540, 1999/3142, 2000/776.
(**9**) S.I. 1994/3144, amended by S.I. 1996/1499, 1997/2884, 1998/3105, 1999/1540, 2000/292.
(**10**) S.I. 1995/887, as amended by S.I. 1997/7, 1997/2499, 1999/3430.
(**11**) S.I. 1995/1086, amended by S.I. 1995/1763, 1996/1499, 1996/1699, 1997/1729, 1998/2424, 2000/656.
(**12**) S.I. 1995/1372, amended by S.I. 1995/1763, 1996/1499, 1996/2465, 1997/1729, 1998/2424 and SS.I. 2000/62.

(m) the Miscellaneous Food Additives Regulations 1995(**13**);

(n) the Cosmetic Products (Safety) Regulations 1996(**14**);

(o) the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997(**15**);

(p) the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998(**16**);

(q) the Medicated Feedingstuffs Regulations 1998(**17**);

(r) the Feedingstuffs (Zootechnical Products) Regulations 1999(**18**);

(s) the Feeding Stuffs Regulations 2000(**19**);

(t) the Feeding Stuffs (Scotland) Regulations 2000(**20**);

(u) the Feeding Stuffs (Wales) Regulations 2001(**21**);

SCHEDULE 3

Regulations 9(2), (6) and (10), 10(2), (6) and (11), 11(4) and (7), 12(4) and (9), 13(2) and (7), 14(2) and (8), 19(2) and (6) and 20(3) and Schedules 6 and 7

DETERMINATIONS OF THE MINISTERS

1. Subject to paragraph 2, the Ministers have determined that the biocidal product satisfies the following requirements, namely—

(a) the biocidal product is sufficiently effective;

(b) the biocidal product has no unacceptable effects on the target organisms, such as unacceptable resistance, cross-resistance, or unnecessary suffering and pain for vertebrates;

(c) the biocidal product and its residues have no unacceptable effects on human or animal health, surface water or groundwater, whether directly or indirectly; and

(d) the biocidal product, and its residues, have no unacceptable effects on the environment, having particular regard to—

(i) its fate and distribution in the environment, including in particular contamination of surface water (including estuarian and sea water), ground water and drinking water, and

(ii) its impact on non-target organisms.

2. In making the determinations referred to in paragraph 1, the Ministers shall have regard to—

(a) current scientific and technical knowledge;

(b) the evaluation, according to the common principles for the evaluation of dossiers laid down in Annex VI, of the dossiers submitted with the application in question;

(c) all normal conditions under which the biocidal product may be used;

(d) the ways in which any material treated with the biocidal product may be used; and

(**13**) S.I. 1995/3187, amended by S.I. 1997/1413, 1999/1136, 2000/1799.
(**14**) S.I. 1996/2925, amended by S.I. 1997/2914, 1998/1727, 1999/1552, 2000/1679.
(**15**) S.I. 1997/322, amended by S.I. 1997/2884, 1999/3142.
(**16**) S.I. 1998/994, amended by S.I. 1999/399, 1999/1585, 2000/656 and SS.I. 2000/62.
(**17**) S.I. 1998/1046, amended by S.I. 2000/1686.
(**18**) S.I. 1999/1871, amended by S.I. 2000/1686.
(**19**) S.I. 2000/2481.
(**20**) SS.I. 2000/453.
(**21**) S.I. 2001/343.

(e) the consequences of use and disposal of the biocidal product.

3. The Ministers have determined, according to the relevant requirements in Annexes IIA, IIB, IIIA, IIIB, IVA and IVB—

(a) the nature and quantity of—

(i) the active substance, and

(ii) where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants,

contained in the biocidal product; and

(b) the nature and quantity of the residues of toxicological or environmental significance which would result from the uses of the biocidal product if such biocidal product were authorised or registered.

4. The Ministers have determined—

(a) the physical and chemical properties of the biocidal product; and

(b) that such properties are acceptable for the purposes of the intended use, storage and transport of the biocidal product.

SCHEDULE 4

Regulations 10(4) and 12(5) and (7)

INFORMATION TO BE CONTAINED IN A DOSSIER SUBMITTED IN SUPPORT OF AN APPLICATION FOR THE REGISTRATION OF A BIOCIDAL PRODUCT

1. The name and address of the applicant.

2. The name and address of the manufacturer of the biocidal product.

3. The name and address of the manufacturer of the active substance in the biocidal product, and the location of manufacture.

4. The trade name of the biocidal product.

5. The name of each substance in the biocidal product, including the name of its active substance, and the amount of each substance, as a percentage of the whole.

6. The physical and chemical properties of the biocidal product relating to use, storage and transport.

7. The product-type and field of use of the biocidal product.

8. The intended category of users.

9. The intended method of use.

10. Efficacy data.

11. Analytical methods.

12. The classification, packaging and labelling of the biocidal product, including a draft label.

13. Where the biocidal product is a substance or preparation dangerous for supply within the meaning of regulation 2(1) of the 1994 Regulations, a safety data sheet for that biocidal product prepared in accordance with regulation 6 of those Regulations.

SCHEDULE 5

Regulations 11(6) and 12(8)

MATTERS IN RESPECT OF WHICH ADDITIONAL CONDITIONS MAY BE IMPOSED ON THE MUTUAL RECOGNITION OF AN AUTHORISATION OR A REGISTRATION OF A BIOCIDAL PRODUCT

1. Directions for use of the biocidal product in question, including its dose rate expressed in metric units.

2. Particulars of any likely direct or indirect adverse side effects and any directions for first-aid.

3. Directions for safe disposal of the biocidal product in question and its packaging, including any prohibition on the re-use of packaging.

4. The period of time needed for the biocidal effect.

5. The interval to be observed between—

(a) applications of the biocidal product;

(b) application and the next use of the article, material or substance treated by the biocidal product; or

(c) application and the next access by humans or animals to the area where the biocidal product has been used,

including particulars of decontamination means and measures and duration of necessary ventilation of treated areas.

6. Particulars for adequate cleaning of equipment.

7. Particulars concerning precautionary measures during use, storage and transport, such as personal protective equipment to be used, measures for protection against fire, covering of furniture, removal of food and feedingstuff and directions to prevent animal exposure to the biocidal product in question.

8. Information on any specific dangers to the environment, including protection of non-target organisms and avoidance of contamination of water.

SCHEDULE 6

Regulation 26(6)

NON-CONFIDENTIAL INFORMATION

1. The name and address of the applicant for the authorisation or registration of the biocidal product.

2. The name of the biocidal product.

3. The name and address of the manufacturer of the biocidal product.

4. The name and address of the manufacturer of the active substance in the biocidal product.

5. The name and content of the active substance in the biocidal product.

6. The name of any other substance in the biocidal product which—

(a) is listed in Part I of the approved supply list; or

(b) is classified as being in one or more of the categories of danger specified in column 1 of Schedule 1 to the 1994 Regulations,

except a substance of which no account would be taken in the classification of that biocidal product by virtue of paragraph 18(1) of Part I of Schedule 3 to those Regulations.

7. Physical and chemical data concerning the biocidal product and the active substance contained in that biocidal product.

8. Any ways of rendering harmless the biocidal product and the active substance contained in that biocidal product.

9. A summary of the results of the tests, referred to in the dossiers submitted in support of an application under these Regulations, to establish—

(a) the efficacy;

(b) the effects on humans, animals and the environment; and

(c) where applicable, any ability to promote resistance,

of the biocidal product and the active substance contained in that biocidal product.

10. Recommended methods and precautions to reduce dangers from handling, storage, transport, use, fire or other hazards.

11. Safety data sheets.

12. Methods of analysis necessary to enable the Ministers to make the determination referred to in paragraph 3 of Schedule 3.

13. Methods of disposal of the biocidal product and its packaging.

14. Procedures to be followed and measures to be taken in the case of spillage or leakage of the biocidal product and the active substance contained in that biocidal product.

15. First aid and medical advice to be given in the case of injury to persons.

SCHEDULE 7

Regulation 28(1)

INFORMATION RELATING TO BIOCIDAL PRODUCTS TO BE GIVEN TO THE COMMISSION AND TO THE COMPETENT AUTHORITIES

1. The name of the applicant for, or the person to whom, the authorisation or registration was granted.

2. The trade name of the biocidal product.

3. The name and amount of each active substance which the biocidal product contains.

4. The name and amount of each substance which the biocidal product contains which is a substance dangerous for supply within the meaning of regulation 2(1) of the 1994 Regulations and its classification.

5. The product-type for the biocidal product and the use for which it is authorised or registered, as the case may be.

6. The type of formulation of the biocidal product, namely whether it is in the form of a powder, granules, a solid, a liquid concentrate or some other form.

7. Any proposed limits on residues which have been determined by the Ministers in accordance with paragraph 3(b) of Schedule 3.

8. Any conditions subject to which the authorisation or registration was granted.

9. The reasons for the modification or cancellation of an authorisation or registration.

10. Whether the biocidal product is a low-risk biocidal product or within a frame-formulation.

SCHEDULE 8

Regulation 29(2) and (7)

INFORMATION TO BE NOTIFIED TO THE NATIONAL POISONS INFORMATION SERVICE

1. The name of the biocidal product.

2. If the biocidal product is authorised or registered under these Regulations—

(a) the use for which it is so authorised or registered; and

(b) the name, address and telephone number and any e-mail address and any fax number of the person to whom the authorisation or registration was granted.

3. The date on which the biocidal product was first placed on the market in Great Britain.

4. The name, address and telephone number and any e-mail address and any fax number of—

(a) the manufacturer of the biocidal product;

(b) any importer of the biocidal product; and

(c) the individual to be contacted in an emergency in the event of an individual being affected by the biocidal product.

5. A description of the packaging of the biocidal product, including its size and type.

6. The pH, physical state and colour of the biocidal product.

7. The identity of the ingredients of the biocidal product, and their concentration in metric units.

8. The effects on human health of contact with the biocidal product.

9. Particulars of the likely direct or indirect adverse side effects of the biocidal product and any directions for first aid.

10. Any other information relating to the health and safety of humans which is given on the label of the biocidal product.

SCHEDULE 9

Regulation 31(2) and (3)

INFORMATION TO BE INCLUDED ON LABELS

1. The identity of the active substance in the biocidal product and its concentration in metric units.

2. The authorisation or registration number allocated to the biocidal product by the Ministers.

3. The type of formulation of the biocidal product, namely whether it is in the form of a powder, granules, a solid, a liquid concentrate or some other form.

4. The use for which the biocidal product is authorised or registered.

5. Directions for use of the biocidal product, including its dose rate in metric units.

6. Particulars of likely direct or indirect adverse side effects and any directions for first aid.

7. Directions for safe disposal of the biocidal product and its packaging, including any prohibition on the re-use of packaging.

8. The number or other reference assigned by the manufacturer of the biocidal product to the batch of biocidal products with which that biocidal product was made and the expiry date relevant to normal conditions of storage.

9. The period of time needed for the biocidal effect.

10. The interval to be observed between—

(a) applications of the biocidal product;

(b) application and the next use of the article, material or substance treated by the biocidal product; or

(c) application and the next access by humans or animals to the area where the biocidal product has been used,

including particulars of decontamination means and measures and duration of necessary ventilation of treated areas.

11. Instructions for adequate cleaning of equipment for use with the biocidal product.

12. Instructions concerning precautionary measures during use, storage and transport, such as personal protective equipment to be used, measures for protection against fire, covering of furniture, removal of food and feedingstuff and directions to prevent animal exposure to the biocidal product.

13. Any restriction on the category of persons who may use the biocidal product.

14. Information on any specific dangers to the environment, including protection of non-target organisms and avoidance of contamination of water.

SCHEDULE 10

Regulation 36(4)

APPEALS

PART I

1. In this Schedule—

(a) "appeal" means an appeal under regulation 36;

"appellant" means a person who has brought an appeal;

"appointed person" means a person appointed in accordance with paragraph 2;

"appropriate person" has the same meaning as it has in regulation 36;

"hearing" means a hearing to which Part II of this Schedule applies;

"the parties" means the appellant and the Ministers;

(b) a reference to "government department" includes, in the case of an appeal relating to a decision of the Ministers in or as regards Scotland, a reference to the Scottish Administration or any part thereof; and

(c) a reference to a numbered sub-paragraph is a reference to the sub-paragraph so numbered in the paragraph in which that reference occurs.

2. The appropriate person shall direct that an appeal shall be determined by a person appointed by him for the purpose and the appropriate person shall notify the parties in writing of the name of the appointed person.

3. Before the determination of an appeal, the appointed person shall ask the parties whether they wish to appear and be heard on the appeal and—

(a) the appeal may be determined without a hearing if the parties express a wish not to be heard as aforesaid;

(b) the appointed person shall, if either of the parties expresses a wish to appear and be heard, afford both of them an opportunity of so doing, in which case the provisions of Part II of this Schedule shall apply.

4. An appointed person may give such directions as he thinks appropriate to give effect to his determination.

5. The appropriate person may pay to an appointed person such remuneration and allowances as the appropriate person may, with the approval of the Minister for the Civil Service, determine.

PART II

6. An appeal brought pursuant to regulation 36(1)(j) shall be heard in private.

7.—(1) Subject to the following sub-paragraphs of this paragraph, a date, time and place for the holding of the hearing shall be fixed, and may be varied, by the appointed person, who shall give not less than 42 days' notice in writing of such date, time and place to the parties.

(2) With the consent of the parties, the appointed person may give such lesser period of notice as shall be agreed with the parties and in that event he may specify a date for service of the statement referred to in paragraph 8(1) later than the date determined in accordance with that paragraph.

(3) Where it becomes necessary or advisable to vary the time or place fixed for the hearing, the appointed person shall give such notice of the variation as may appear to him to be reasonable in the circumstances.

(4) Without prejudice to the foregoing provisions of this paragraph, the appointed person may require the Ministers to take one or more of the following steps, namely—

(a) to serve such notice of the hearing, in such form and on such persons or classes of persons as he may direct;

(b) to give such other notice of the hearing and in such form as he may direct,

and the requirements as to the period of notice contained in sub-paragraph (1) shall not apply to any such notices.

8.—(1) Not later than 28 days before the date of the hearing, or such later date as the appointed person may specify in accordance with paragraph 7(2), the Ministers shall serve on the appellant a written statement of any submission which the Ministers propose to put forward at the hearing and shall supply a copy of the statement to the appointed person.

(2) Where a government department has expressed in writing to the Ministers a view in support of the decision of the Ministers and the Ministers propose to rely on such expression of view in their submission at the hearing, the Ministers shall include the expression of view in their statement and shall supply a copy of the statement to the government department concerned.

(3) Where the Ministers intend to refer to, or put in evidence at the hearing, documents (including photographs), the statement of the Ministers shall be accompanied by a list of such documents, together with a written notice stating the times and place at which the documents may be inspected

by the appellant; and the Ministers shall afford the appellant a reasonable opportunity to inspect and, where practicable, to take copies of the documents.

(4) If so required by the appointed person, the appellant shall—

(a) serve on the Ministers and on the appointed person, within such time before the hearing as the appointed person may specify, a written statement of the submissions which he proposes to put forward at the hearing; and such statement shall be accompanied by a list of any documents (including photographs) which the appellant intends to refer to or put in evidence at the hearing; and

(b) afford the Ministers a reasonable opportunity to inspect and, where practicable, to take copies of such documents as are referred to in the foregoing provision.

9.—(1) The parties shall be entitled to appear at the hearing.

(2) Any other person may appear at the discretion of the appointed person provided that he has, not later than 7 days before the date of the hearing, served on the Ministers a statement of his proposed submissions.

(3) The Ministers shall send a copy of every statement served on them in accordance with sub-paragraph (2) to the appointed person and to the appellant.

(4) A body corporate may appear by its clerk or secretary or by any other officer appointed for the purpose by that body, or by counsel or a solicitor.

(5) A person may appear on his own behalf or be represented by counsel, a solicitor or any other person.

(6) Where there are two or more persons having a similar interest in the subject matter of the hearing, the appointed person may allow one or more persons to appear for the benefit of some or all persons so interested.

10.—(1) Where a government department has expressed in writing to the Ministers a view in support of the decision of the Ministers and the Ministers have included this view in the statement referred to in paragraph 8(1), the appellant may apply in writing to the appointed person, not later than 14 days before the date of the hearing, for a representative of the government department concerned to be made available at the hearing.

(2) The appointed person shall send an application made to him under sub-paragraph (1) to the government department concerned who shall make a representative of the department available to attend the hearing.

(3) A representative of a government department who, in pursuance of this paragraph, attends a hearing shall be called as a witness by the Ministers and shall state the reasons for the view expressed by his department and included in the statement of the Ministers under paragraph 8(1) and shall give evidence and be subject to cross-examination to the same extent as any other witness.

(4) Nothing in the last foregoing paragraph shall require a representative of a government department to answer any question which in the opinion of the appointed person is directed to the merits of government policy or to matters which affect the safety of the State and the appointed person shall disallow any such question.

11.—(1) Except as otherwise provided in this Part of this Schedule, the procedure at the hearing shall be such as the appointed person shall in his discretion determine and the appointed person shall state at the commencement of the hearing the procedure which, subject to consideration of any submission by the parties, he proposes to adopt.

(2) Unless in any particular case the appointed person with the consent of the appellant otherwise determines—

(a) in the case of an appeal to the Secretary of State, the appellant shall be heard first and shall have the right of final reply; and

(b) in the case of an appeal to the Secretary of State and the Scottish Ministers, acting jointly—

(i) the appellant shall be heard first,

(ii) the other persons entitled or permitted to appear shall be heard in such order as the appointed person may determine, and

(iii) any closing statements shall be made in the same order, unless the appointed person otherwise determines.

(3) The parties shall be entitled to make an opening statement, to call evidence and to cross-examine persons giving evidence, but any other person appearing at the hearing may do so only to the extent permitted by the appointed person.

(4) Subject to sub-paragraph (5), any evidence may be admitted at the discretion of the appointed person, who may direct that documents tendered in evidence may be inspected by any person entitled or permitted to appear at the hearing and that facilities be afforded him to take or obtain copies thereof.

(5) The appointed person shall not require or permit the giving or production of any evidence, whether written or oral, which would be contrary to the public interest.

(6) The appointed person may allow the Ministers or the appellant, or the parties, to alter or add to the submissions contained in any statement served under paragraph 8(1) or (4), or to any list of documents which accompanied such statement, so far as may be necessary for the purpose of determining the questions in controversy between the parties, but shall (if necessary by adjourning the hearing) give the appellant or the Ministers, as the case may be, an adequate opportunity of considering any such fresh submission or document.

(7) If any person entitled to appear at the hearing fails to appear, the appointed person may proceed with the hearing at his discretion.

(8) The appointed person shall be entitled (subject to disclosure thereof at the hearing) to take into account any written representations or statements received by him before the hearing from any person.

(9) The appointed person may from time to time adjourn the hearing, and where he does so, shall give reasonable notice to every person entitled or permitted to appear at the hearing of the date, time and place of the adjourned hearing.

12.—(1) Where, after the close of the hearing, the appointed person proposes to take into consideration—

(a) any new evidence, including expert opinion on a matter of fact; or

(b) any new issue of fact, not being a matter of government policy or a matter affecting the safety of the State,

which was not raised at the hearing and which he considers to be material to his decision, he shall not come to a decision without first notifying the parties of the substance of the new evidence or of the new issue of fact and affording them an opportunity of making representations thereon in writing within 21 days or of asking within that time for the re-opening of the hearing.

(2) If he thinks fit, the appointed person may cause the hearing to be re-opened and shall cause it to be re-opened if asked to do so in accordance with sub-paragraph (1).

(3) Where the hearing is re-opened, paragraphs 7(1) and 7(4) shall apply as they applied to the original hearing with the substitution in paragraph 7(1) of "28" for "42".

13. The appointed person shall notify the determination on the appeal, and the reasons therefor, in writing to the parties and to any person who, having appeared at the hearing, has asked to be notified of the decision.

SCHEDULE 11

Regulation 38

ENFORCEMENT, OFFENCES AND CIVIL LIABILITY

Interpretation

1. In this Schedule—

(a) "the 1998 Regulations" means the Health and Safety (Enforcing Authority) Regulations 1998(**22**);

"domestic premises" means premises occupied as a private dwelling (including any garden, yard, garage, outhouse or other appurtenance of such premises which is not used in common by the occupants of more than one such dwelling);

"inspector" means an inspector appointed under section 19 of the 1974 Act;

"justice" means—

(i) in relation to England and Wales, a justice of the peace;

(ii) in relation to Scotland, a sheriff, stipendiary magistrate or justice of the peace:

"local authority" means—

(i) in relation to England, a county council so far as they are the council for an area for which there are no district councils, a district council, a London borough council, the Common Council of the City of London, the Sub-Treasurer of the Inner Temple, the Under-Treasurer of the Middle Temple or the Council of the Isles of Scilly;

(ii) in relation to Scotland, the council for a local government area; and

(iii) in relation to Wales, a county council or a county borough council;

"work" shall be construed in accordance with section 52 of the 1974 Act; and

(b) a reference to a numbered sub-paragraph is a reference to the sub-paragraph so numbered in the paragraph in which that reference occurs.

Application of the 1974 Act

2.—(1) Sections—

(a) 16 to 26 (approval of codes of practice and enforcement);

(b) 33 to 42 (provisions as to offences); and

(c) 47(2) (civil liability),

of the 1974 Act shall, subject to the following provisions of this Schedule, and to the extent that they would not otherwise do so, apply to these Regulations as if they were health and safety regulations for the purposes of that Act.

(2) Any function of the Health and Safety Commission under any other provision of the 1974 Act which is exercisable in relation to any function of the Health and Safety Executive under or in respect of health and safety regulations (including their enforcement) shall be exercisable as if these

(**22**) S.I. 1998/494, amended by S.I. 1999/2024, 1999/3232.

Regulations were, to the extent they would not otherwise be so, health and safety regulations for the purposes of that Act.

(3) The sections of the 1974 Act which are applied to these Regulations by sub-paragraph (1) shall so apply as if any reference to—

(a) danger, or danger to health and safety, were a reference to danger to the health or safety of humans or animals or to danger to the environment; and

(b) harm were a reference to harm to humans, animals or the environment.

(4) Sections 22 and 25 of the 1974 Act, as applied to these Regulations by sub-paragraph (1), shall apply as if the reference in those sections to serious personal injury were a reference to—

(a) serious personal injury to humans;

(b) a breach of the Regulations and serious injury to animals; or

(c) a breach of the Regulations and serious harm to the environment.

Offences

3. A failure to discharge a duty—

(a) placed on the Ministers by these Regulations; or

(b) placed on any person by regulation 5, 7(3), 9(4) to (6), 9(8), 10(4) to (6), 10(9), 11(5), 12(5), 17(4), 26(2), 34(1) to (4) and 37,

shall not be an offence under section 33(1)(c) of the 1974 Act.

Limitation on entry to domestic premises in certain circumstances

4.—(1) An inspector may not enter domestic premises in the exercise of his powers under the 1974 Act, as applied to these Regulations by virtue of paragraph 2, in respect of an activity which is not, or is not related to, an activity involving work, unless a justice has issued a warrant authorising him to enter and exercise his powers in those domestic premises.

(2) A justice may not issue such a warrant, unless on an application made by the inspector, he is satisfied—

(a) that the inspector has reasonable grounds for believing that there is present in the domestic premises anything to which those powers relate; and

(b) that—

(i) it is not practicable to communicate with any person entitled to grant entry to the domestic premises,

(ii) a person entitled to grant entry to the domestic premises has unreasonably refused an inspector entry,

(iii) entry to the domestic premises is unlikely to be granted unless a warrant is produced, or

(iv) the purpose of entry may be frustrated or seriously prejudiced unless an inspector arriving at the domestic premises can secure immediate entry to them.

Allocation of enforcement responsibility

5.—(1) Notwithstanding the 1998 Regulations, and subject to sub-paragraphs (2) to (7), the enforcing authority for these Regulations shall be the Health and Safety Executive.

(2) Where an active substance is placed on the market—

(a) in or from any shop, mobile vehicle, market stall or other retail outlet; or

(b) otherwise to members of the public, including by way of free sample, prize or mail order,

the enforcing authority for regulation 4 shall be the local weights and measures authority.

(3) Where a biocidal product is placed on the market—

(a) in or from any shop, mobile vehicle, market stall or other retail outlet; or

(b) otherwise to members of the public, including by way of free sample, prize or mail order,

the enforcing authority for regulations 8(1), 30 and 31 shall be the local weights and measures authority.

(4) Where a biocidal product is sold—

(a) in or from any shop, mobile vehicle, market stall or other retail outlet; or

(b) otherwise to members of the public, including by way of free sample, prize or mail order,

the enforcing authority for regulation 22(3) shall be the local weights and measures authority.

(5) The enforcing authority for regulation 33 shall be the local weights and measures authority.

(6) The 1998 Regulations shall apply to the enforcement of regulations 8(2), 8(5) and 22(4).

(7) The enforcing authority for regulations 8(2), 8(5) and 22(4)—

(a) in respect of any use not related to an activity involving work; or

(b) in respect of any use by a domestic servant in a private household,

shall be the local authority for the area in which the use occurs.

SCHEDULE 12

Regulation 39(1), (2) and (3)

FEES

1. On the making of an application to the Ministers under regulation 5 for the inclusion of an active substance in Annex I, IA or IB, there shall be payable by the applicant to the Ministers—

(a) for ensuring that the dossiers submitted as part of that application satisfy the requirements of regulation 5 in accordance with regulation 6(1); and

(b) for determining the application in accordance with regulation 6(2),

a fee or fees to be determined in accordance with paragraphs 7 and 9 to 12.

2. There shall be payable by the applicant to the Ministers in connection with the determination of an application to the Ministers specified in paragraph 3, a fee or fees to be determined in accordance with paragraphs 7 and 9 to 12.

3. The applications to the Ministers referred to in paragraph 2 are—

(a) an application under regulation 7(1) for a variation of the requirements subject to which an active substance is included in Annex I, IA or IB;

(b) an application under regulation 7(2) for the renewal of the inclusion of an active substance in Annex I, IA or IB;

(c) an application under regulation 9 for the authorisation of, or the renewal of an authorisation of, a biocidal product;

(d) an application under regulation 10 for the registration of, or the renewal of the registration of, a biocidal product;

(e) an application under regulation 11(5) for the authorisation of a biocidal product;

(f) an application under regulation 12(5) for the registration of a biocidal product;

(g) an application under regulation 13 for the provisional authorisation of, or the renewal of the provisional authorisation of, a biocidal product;

(h) an application under regulation 14 for the provisional registration of, or the renewal of a provisional authorisation of, a biocidal product;

(i) an application for an authorisation under regulation 17.

4. There shall be payable by the applicant to the Ministers in connection with the evaluation of dossiers following a decision referred to in regulation 6(6) or regulation 7(5), a fee or fees to be determined in accordance with paragraphs 7 and 9 to 12.

5. There shall be payable by a person who provides information under regulation 16(5) or 20(5)(b) a fee or fees to be determined in accordance with paragraphs 7 and 9 to 12.

6. There shall be payable by a person who requests a modification under regulation 20(2) a fee or fees to be determined in accordance with paragraphs 7 and 9 to 12.

7. On receipt of—

(a) an application referred to in paragraph 1;

(b) an application specified in paragraph 3;

(c) dossiers referred to in paragraph 4;

(d) information referred to in paragraph 5; or

(e) a request referred to in paragraph 6,

the Ministers shall prepare and send to the applicant, the person providing the information or the person making the request, as the case may be, an estimate of the cost of the work necessary for the determination of the application, the evaluation of dossiers, or the consideration of the information or the request.

8. The amount estimated in accordance with paragraph 7 shall be paid forthwith by the person to whom the estimate is sent.

9. On the determination of the application, completion of the evaluation of dossiers or consideration of the information or request, the Ministers shall prepare a detailed statement of the work carried out in relation to that determination, evaluation or consideration, as the case may be, and of the cost reasonably incurred by the Ministers or any person acting on their behalf in carrying out that work.

10. If the cost referred to in paragraph 9 is greater than the amount estimated in accordance with paragraph 7, the amount of the difference shall be—

(a) notified by the Ministers to the applicant or the person providing the information or making the request, as the case may be;

(b) the amount of the final fee payable; and

(c) paid by the applicant or that person forthwith.

11. If the cost referred to in paragraph 9 is less than the amount estimated in accordance with paragraph 7, the fee shall be adjusted accordingly and the amount of the difference shall be paid forthwith by the Ministers to the applicant or the person providing the information or making the request, as the case may be.

12. In estimating or stating the cost of carrying out any work, the Ministers may take into account the cost to them, or to any person acting on their behalf, of employing an officer for any period to perform the work concerned and shall determine that cost by reference to the average cost of employing an officer of the grade appropriate for that work for that period.

SCHEDULE 13

Regulations 3(2), 36(2) and 40

TRANSITIONAL PROVISIONS

1. In this Schedule—

"COPR 1986" means the Control of Pesticides Regulations 1986(**23**);

"COPR approval" means an approval granted under COPR 1986;

"COPR biocidal product" means a biocidal product to which COPR 1986 applies; and

"unlisted active substance" means an existing active substance which is not included in Annex I, IA or IB.

2. Subject to paragraphs 3 and 4, where a decision is made under Article 16(2) that—

(a) an unlisted active substance shall be included in Annex I, IA or IB; or

(b) an unlisted active substance shall not be included in either Annex I, IA or IB,

these Regulations shall apply to every biocidal product which contains the unlisted active substance to which the decision in question relates when that decision takes effect.

3. These Regulations shall not apply to a biocidal product—

(a) when a decision referred to in paragraph 2(a) relating to an unlisted active substance in that biocidal product takes effect, if that biocidal product is not within a product-type in which the unlisted active substance may be used in accordance with any requirement to which the inclusion of the unlisted active substance in Annex I, IA or IB, as the case may be, is subject;

(b) when a decision referred to in paragraph 2(b) relating to an unlisted active substance in that biocidal product takes effect, if the biocidal product is not within a product-type in which, in accordance with that decision, the unlisted active substance may not be used.

4. Where there is more than one unlisted active substance in a biocidal product, these Regulations shall not apply to that biocidal product until a decision referred to in paragraph 2 is made in relation to the last of those unlisted active substances to be considered for inclusion in Annex I, IA or IB, provided that such a decision has been made to include all the other active substances in that biocidal product in either Annex I, IA or IB.

5. Where—

(a) there is made a decision referred to in paragraph 2(a); and

(b) by virtue of that paragraph, these Regulations apply to a biocidal product containing the unlisted active substance in question,

the person responsible for first placing the biocidal product on the market in Great Britain may make an application under regulation 9 or regulation 10, as the case may be, in respect of that biocidal product not later than 3 months after that decision takes effect, or such longer period as the Ministers may determine.

6. Where—

(a) there is made a decision referred to in paragraph 2(a); and

(b) by virtue of that paragraph, these Regulations apply to a biocidal product containing the unlisted active substance in question,

the Ministers may grant a certificate of exemption in accordance with paragraph 15 where a person informs the Minister in writing that he intends to make an application to the Ministers under

(**23**) S.I. 1986/1510, as amended by S.I. 1997/188.

regulation 11 or regulation 12 after a competent authority in another member State has authorised or registered that biocidal product for placing on the market and use under the Directive.

7. During—

(a) the period of time in which an application may be made in accordance with paragraph 5; and

(b) the period of time between such application being made and the Ministers deciding whether or not to authorise or register the biocidal product in question,

the Ministers may grant a certificate of exemption in accordance with paragraph 15.

8. Where—

(a) there is made a decision referred to in paragraph 2(a);

(b) by virtue of that paragraph these Regulations apply to a biocidal product containing the unlisted active substance in question; and

(c) the competent authority of a member State has authorised or registered that biocidal product for placing on the market and use,

the person responsible for first placing the biocidal product on the market in Great Britain may make an application under regulation 11 or 12, as the case may be, in respect of that biocidal product not later than 3 months after that authorisation or registration was granted, or such longer period as the Ministers may determine.

9. During—

(a) the period of time in which an application may be made in accordance with paragraph 8; and

(b) the period of time between such application being made and the Ministers deciding whether or not to authorise or register the biocidal product in question,

the Ministers may grant a certificate of exemption in accordance with paragraph 15.

10. Where—

(a) no application is made in accordance with paragraph 5 or 8; or

(b) such an application is made but the Ministers refuse to authorise or register the biocidal product in question,

the Ministers may grant a certificate of exemption in accordance with paragraph 15.

11. Where—

(a) an application is made in accordance with paragraph 8;

(b) the Ministers refuse to authorise or register the biocidal product, as the case may be; and

(c) such refusal is upheld by a Commission decision,

the Ministers may grant a certificate of exemption in accordance with paragraph 15.

12. Where—

(a) there is made a decision referred to in paragraph 2(b); and

(b) by virtue of that paragraph these Regulations apply to a biocidal product containing the unlisted active substance in question,

the Ministers may grant a certificate of exemption in accordance with paragraph 15.

13. Where—

(a) there is made a decision referred to in paragraph 2; and

(b) by virtue of that paragraph these Regulations apply to a COPR biocidal product containing the unlisted active substance in question,

COPR 1986 shall cease to apply to that COPR biocidal product when that decision takes effect.

14. The Ministers shall—

(a) notify in writing the holder of a COPR approval in respect of a COPR biocidal product to which paragraph 10 applies that COPR 1986 no longer applies to that biocidal product; and

(b) at the same time, revoke that COPR approval.

15. A certificate of exemption granted pursuant to paragraph 6, 7, 9, 10, 11 or 12 shall be in writing and may exempt any person or class of persons or any biocidal product or class of biocidal products from all or any of the requirements or prohibitions imposed by these Regulations, other than regulation 29, relating to—

(a) placing on the market;

(b) use;

(c) advertisements;

(d) packaging and labelling; or

(e) storage (including storage for disposal).

16. An exemption certificate granted in accordance with paragraph 15—

(a) may be granted subject to conditions;

(b) may be revoked by a certificate in writing at any time; and

(c) shall be granted for a period not exceeding three years.