STATUTORY RULES OF NORTHERN IRELAND

2001 No. 422

Biocidal Products Regulations (Northern Ireland) 2001

Part I

General

Citation and commencement

1. These Regulations may be cited as the Biocidal Products Regulations (Northern Ireland) 2001 and shall come into operation on 16th January 2002.

Interpretation

2.—(1) In these Regulations—

"the 1978 Order" means the Health and Safety at Work (Northern Ireland) Order 1978;

"the 1995 Regulations" means the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 1995(**1**);

"active substance" means a substance or micro-organism having a general or specific action on or against harmful organisms;

"approved supply list" has the same meaning as it has in the 1995 Regulations;

"biocidal product" means an active substance or a preparation containing one or more active substances, in the form in which it is supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism by chemical or biological means;

"classified" means classified in accordance with regulation 5 of the 1995 Regulations;

"the Commission" means the Commission of the European Communities;

"Commission decision" means a decision taken in accordance with the procedures set out in Article 28(2);

"competent authority" means the authority appointed in a member State for the purpose of carrying out the duties of a competent authority under the Directive;

"the Directive" means Directive 98/8/EC of the European Parliament and the Council of 16th February 1998 concerning the placing of biocidal products on the market(**2**);

"the Executive" means the Health and Safety Executive for Northern Ireland;

"existing active substance" means an active substance which was on the market in the European Community before 14th May 2000 for a purpose other than process-orientated research and development or scientific research and development;

"feedingstuff" means feedingstuff for animals, birds or fish;

(**1**) S.R. 1995 No. 60, amended by S.R. 1996 No. 376, S.R. 1997 No. 398, S.R. 1998 No. 459, S.R. 1999 No. 150, S.R. 1999 No. 303 and S.R. 2001 No.168

(**2**) O.J. No. L123, 24.4.98, p.1

"the Great Britain Executive" means the Health and Safety Executive established under section 10 of the Health and Safety at Work etc. Act 1974(**3**);

"the Great Britain Regulations" means the Biocidal Products Regulations 2001(**4**)

"harmful organism" means an organism which has an unwanted presence or a detrimental effect for humans, their activities or the products they use or produce, or for animals or for the environment;

"letter of access" means a document—

(a) permitting the use by the Executive of information, which is—

(i) subject to the provisions of regulation 23 or 24, and

(ii) specified in that document; and

(b) signed by the owner of that information;

"low-risk biocidal product" means a biocidal product—

(a) which does not contain any active substance other than an active substance included only in Annex IA;

(b) which does not contain a substance of concern; and

(c) which, under the conditions subject to which that biocidal product may be used, poses a low risk to humans, animals and the environment;

"member State" means a member State of the Communities, except the United Kingdom;

"micro-organism" includes a fungus and a virus;

"the Ministers" has the meaning assigned to it by regulation 2(2) of the Great Britain Regulations;

"new active substance" means an active substance which is not an existing active substance;

"placing on the market" means—

(a) any supply, whether in return for payment or not, within Northern Ireland, including importation into Northern Ireland; or

(b) any subsequent storage,

other than a supply for storage followed by consignment from the customs territory of the European Community or followed by disposal, and "on the market" shall be construed accordingly;

"preparation" means a mixture or solution of two or more substances;

"process-orientated research and development" means the further development of a substance or preparation in the course of which pilot plant or production trials are used to test the fields of application of that substance or preparation;

"product-type" means one of the product-types specified in column 1, and described in column 2, of Schedule 1;

"residue" means a substance present in a biocidal product which remains as a result of the use of that biocidal product, including the metabolites of, and products resulting from the degradation or reaction of, such a substance;

"scientific research and development" means scientific experimentation, analysis or chemical research carried out under controlled conditions including the determination of intrinsic properties, performance and efficacy as well as scientific investigation relating to product development;

(**3**) 1974 c. 37
(**4**) S.I. 2001/880

"substance" means a chemical element and its compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

"substance of concern" means a substance, other than an active substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present in or produced in a biocidal product in sufficient concentrations to create such an effect; and

"territorial waters" means United Kingdom territorial waters adjacent to Northern Ireland and "within territorial waters" includes on, over and under them.

(2) In these Regulations, any requirement to submit or provide information, including information comprising, or included in, a dossier, in support of an application for the authorisation or the registration of a biocidal product under these Regulations, may be satisfied in whole or in part by—

(a) the submission of a letter of access in respect of that information; or

(b) a reference to information which the Executive or a competent authority already holds and which, by virtue of regulation 23 or 24, the Executive or the competent authority is entitled to use for the benefit of persons other than the persons who submitted that information.

(3) In these Regulations, a reference to "frame-formulation" is a reference to specifications for a group of biocidal products which—

(a) have the same use;

(b) are used by the same type of user; and

(c) contain the same active substances of the same specification,

and whose composition, when compared, subject to paragraph (4), with the composition of a biocidal product which has been authorised or registered in accordance with these Regulations, is the same as the composition of that biocidal product.

(4) In carrying out the comparison referred to in paragraph (3), there shall be disregarded a variation which does not reduce the efficacy of, nor affect the level of risk associated with, the biocidal products in question.

(5) In paragraph (4), "variation" means one or more of the following, that is to say—

(a) a lower percentage of each active substance;

(b) a change in the percentage of each substance which is not an active substance;

(c) the replacement of pigments, dyes or perfumes by other pigments, dyes or perfumes having the same or a lower risk.

(6) In these Regulations, any reference to the name of an active substance is a reference to—

(a) the name of that active substance as listed in Part I of the approved supply list; or

(b) if the name is not listed in Part I of the approved supply list, the name of that substance as given in the European Inventory of Existing Chemical Substances(**5**); or

(c) if the name—

(i) is not listed in Part I of the approved supply list, nor

(ii) given in the European Inventory of Existing Chemical Substances,

the International Organisation for Standardisation common name of that active substance; or

(d) if the name—

(**5**) A copy of the European Inventory of Existing Chemical Substances may be obtained from the European Communities Information Office, 8 Storey's Gate, London SW1P 3AT

(i) is not listed in Part I of the approved supply list, nor

(ii) given in the European Inventory of Existing Chemical Substances,

and there is no International Organisation for Standardisation common name for that active substance, the chemical designation of that active substance according to International Union of Pure and Applied Chemistry rules.

(7) In paragraph (6),

(a) "International Organisation for Standardisation" means the institution of that name founded in 1947 and currently having its headquarters at 1 rue de Varembé, CP56, 1211 Geneva 20, Switzerland, and

(b) "International Union of Pure and Applied Chemistry" means the institution of that name founded in 1919 and currently having its headquarters at Bank Court Chambers, 2–3 Pound Way, Templars Square, Cowley, Oxford OX4 3YF.

(8) In these Regulations, a reference to a biocidal product which contains an active substance shall include a reference to a biocidal product which is an active substance.

(9) In these Regulations a reference to a numbered Article or Annex is a reference to the Article in or Annex to the Directive so numbered.

(10) The Interpretation Act (Northern Ireland) 1954(**6**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Application

3.—(1) These Regulations shall not apply to a biocidal product where and to the extent that the biocidal product is placed on the market or used for a purpose over which control is exercised under—

(a) any of the Regulations set out in Schedule 2;

(b) Council Regulation (EEC) No. 2309/93(**7**), laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products; or

(c) sections 32 to 39 or section 58B of the Medicines Act 1968(**8**).

(2) Subject to Schedule 12, these Regulations, except regulation 29, shall not apply to a biocidal product which contains an existing active substance.

(3) These Regulations shall not apply to a biocidal product which is a relevant plant protection product where and to the extent that that biocidal product is placed on the market or used for a purpose over which, but for the provisions of Schedule 3 to the PPP Regulations, control under the PPP Regulations would otherwise be exercisable.

(4) These Regulations shall not apply to a biocidal product which, by virtue of regulation 19(1) of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**9**), continues to have a product licence under section 7 of the Medicines Act 1968 so long as that licence remains in force.

(5) These Regulations shall not apply to the placing on the market of a biocidal product prepared extemporaneously in the circumstances described in regulation 5(1)(*c*) of the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994(**10**).

(**6**) 1954 c. 33 (N. I.)
(**7**) O.J. No. L214, 24.8.93, p. 1
(**8**) 1968 c. 67; section 58B was added by the Medicines Act 1968 (Amendment) (No. 2) Regulations 1992 (S.I. 1992/3271)
(**9**) S.I. 1994/3142, to which there are amendments not relevant to these Regulations
(**10**) S.I. 1994/2987, to which there are amendments not relevant to these Regulations

(6) Regulations 30 to 32 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

(7) In this regulation—

(a) "the PPP Regulations" means the Plant Protection Products Regulations (Northern Ireland) 1995(**11**); and

(b) "relevant plant protection product" shall have the meaning assigned to it in paragraph 8 of Schedule 3 to the PPP Regulations.

Part II

Active Substances

Placing on the market of active substances

4.—(1) Subject to paragraph (2), a person shall not place on the market for use in a biocidal product a new active substance unless—

(a) an application has been made to the Executive, the Ministers or to a competent authority for the inclusion of that new active substance in Annex I, IA or IB; and

(b) the Executive, the Ministers or that competent authority has agreed to the applicant forwarding a summary of the dossiers submitted in support of the application to the Commission and the member States.

(2) Paragraph (1) shall not apply to a new active substance intended for use in a biocidal product where that new active substance is placed on the market for use in an experiment or test for the purposes of—

(a) scientific research and development; or

(b) process orientated research and development.

(3) A person shall not place on the market an active substance intended exclusively for use in a biocidal product for the purpose of any experiment or test in Northern Ireland which may involve or result in the release into the environment of that active substance unless that active substance has been authorised in accordance with regulation 17.

Applications concerning new active substances

5. A person who applies to the Executive for the inclusion of a new active substance in Annex I, IA or IB shall submit to the Executive—

(a) a dossier relating to the new active substance satisfying the requirements of—

(i) Annex IVA, where the new active substance in question is a micro-organism, or

(ii) Annexes IIA and IIIA, where the new active substance in question is not a micro-organism;

(b) a dossier satisfying the requirements of regulation 9(4) to (6) for at least one biocidal product containing the new active substance; and

(c) a declaration that the new active substance is intended for inclusion in a biocidal product.

(**11**) S.R. 1995 No. 371, as amended by S.R. 1996 No. 456, S.R. 1997 No. 471, S.R. 1997 No. 507, S.R. 1999 No. 57 and S.R. 1999 No. 282

Assessment of applications concerning new active substances

6.—(1) Where the Executive receives an application under regulation 5, it shall ensure that the dossiers submitted as part of that application satisfy the requirements of that regulation and, where those dossiers do so, the Executive shall—

(a) accept the dossiers; and

(b) agree to the applicant forwarding a summary of the dossiers to the Commission and the member States.

(2) Subject to paragraph (5) and subject to regulation 39(2), within the period of 12 months of the Executive accepting the dossiers in accordance with paragraph (1)(*a*), the Executive shall—

(a) evaluate the dossiers submitted in accordance with regulation 5;

(b) make a recommendation as to whether the new active substance in question should, or should not, be included in Annex I, IA or IB; and

(c) send a copy of its evaluation and recommendation to the Commission, the member States and the applicant.

(3) Where necessary for the purpose of carrying out an evaluation required by paragraph (2)(*a*), the Executive shall—

(a) request in writing the applicant to provide such additional information relating to the new active substance as it may specify; and

(b) at the same time inform the Commission and the member States of its request.

(4) Where the Executive requests additional information under paragraph (3), the period of time between the date when the Executive requests the information and the date when the applicant responds to its satisfaction shall not be taken into account in calculating the period of 12 months referred to in paragraph (2).

(5) After the Executive has accepted the dossiers in accordance with paragraph (1)(*a*), it may make a request to the Commission for the evaluation of the dossiers to be carried out by a competent authority, and, in such a case—

(a) the Executive shall not be under a duty to evaluate those dossiers, unless and until there is a Commission decision to refuse its request; and

(b) where there is such a Commission decision to refuse, the Executive shall evaluate the dossiers within the period of 12 months of the date of that Commission decision.

(6) Where there is a Commission decision that the Executive shall evaluate the dossiers submitted to a competent authority in support of an application for the inclusion of a new active substance in Annex I, IA or IB, subject to regulation 39(2), within the period of 12 months of receiving the dossiers, the Executive shall—

(a) evaluate the dossiers;

(b) make a recommendation as to whether the new active substance should, or should not, be included in Annex I, IA or IB; and

(c) send a copy of its evaluation and recommendation to the Commission, the member States and the applicant.

(7) Paragraphs (3) and (4) shall apply where the Executive evaluates dossiers under paragraph (6)(*a*) as if the dossiers had been submitted under regulation 5.

Applications for variation or renewal of the inclusion of active substances in Annex I, IA or IB

7.—(1) A person may apply to the Executive for a variation of the requirements subject to which an active substance was included in Annex I, IA or IB.

(2) Before the expiry of the initial period, or any renewed period, as the case may be, of the inclusion of an active substance in Annex I, IA or IB, a person may apply to the Executive, for the renewal of the inclusion of that active substance in Annex I, IA or IB for a period not exceeding 10 years.

(3) A person who applies to the Executive under paragraph (1) or (2) shall submit dossiers in accordance with regulation 5.

(4) Regulation 6(1) to (5) shall apply to an application made under paragraph (1) or (2) as it applies to an application made under regulation 5, save that—

(a) in the case of an application made under paragraph (1), the recommendation to be made under regulation 6(2)(*b*) shall be as to whether the variation should, or should not, be made; and

(b) in the case of an application made under paragraph (2), the recommendation to be made under regulation 6(2)(*b*) shall be as to whether the inclusion of the active substance in Annex I, IA or IB should, or should not, be renewed.

(5) Where there is a Commission decision that the Executive shall evaluate the dossiers submitted to a competent authority in support of an application for—

(a) a variation of the requirements subject to which an active substance was included in Annex I, IA or IB; or

(b) the renewal of the inclusion of an active substance in Annex I, IA or IB,

subject to regulation 39(2), within the period of 12 months of receiving the dossiers, the Executive shall comply with the requirements specified in paragraph (6).

(6) The requirements referred to in paragraph (5) are that the Executive shall—

(a) evaluate the dossiers;

(b) make a recommendation as to whether—

(i) the variation should, or should not, be made, or

(ii) the new active substance should, or should not, continue to be included in Annex I, IA or IB,

as the case may be; and

(c) send a copy of its evaluation and recommendation to the Commission, the member State and the applicant.

(7) Regulation 6(3) and (4) shall apply where the Executive evaluates dossiers under paragraph (6)(*a*) as if the dossiers had been submitted under regulation 5.

Part III

Biocidal Products

Prohibitions

8.—(1) Subject to paragraphs (3) and (4), a person shall not place on the market a biocidal product unless that biocidal product—

(a) has been authorised or registered in accordance with these Regulations or the Great Britain Regulations; and

(b) is placed on the market in accordance with any condition or restriction which is specified in that authorisation or registration.

(2) Subject to paragraphs (3) and (4), a person shall not use a biocidal product which has been placed on the market unless that biocidal product—

(a) has been authorised or registered in accordance with these Regulations or the Great Britain Regulations; and

(b) is properly used.

(3) Paragraphs (1) and (2)(*a*) shall not apply to a biocidal product which is placed on the market for use in an experiment or test for the purposes of—

(a) scientific research and development; or

(b) process orientated research and development,

pursuant to regulation 16.

(4) Paragraphs (1) and (2) shall not apply to a biocidal product which does not contain any active substance other than an active substance included only in Annex IB.

(5) A person shall not use a biocidal product containing an active substance which is included in Annex IB unless that biocidal product is used in a manner which involves the rational application of a combination of physical, biological, chemical or other measures as appropriate to limit the use of biocidal products to the minimum necessary for the effective control of target organisms.

(6) In this regulation, "properly used" means used both—

(a) in accordance with the conditions of use specified in the label of the biocidal product in question; and

(b) in a manner which involves the rational application of a combination of physical, biological, chemical or other measures as appropriate to limit the use of biocidal products to the minimum necessary for the effective control of target organisms.

Authorisation of a biocidal product

9.—(1) Subject to the following paragraphs, the Executive may authorise a biocidal product for placing on the market and use for a period of time which ends on a date not later than the earliest date on which the entry in Annex I of any active substance in that biocidal product expires.

(2) The Executive shall not authorise a biocidal product under paragraph (1) unless—

(a) the following conditions are satisfied, namely—

(i) at least one active substance in the biocidal product is included in Annex I at the time the authorisation is granted;

(ii) any other active substances in the biocidal product are included in Annex I or Annex IA at the time the authorisation is granted, and

(iii) any requirements set out in Annex I or Annex IA relating to the active substances in the biocidal product have been fulfilled; and

(b) the Executive has made the determinations referred to in Schedule 3.

(3) The Executive shall not authorise a biocidal product under paragraph (1) for use by the public, or for placing on the market for use by the public, where that biocidal product is classified as—

(a) toxic;

(b) very toxic;

(c) carcinogenic category 1;

(d) carcinogenic category 2;

(e) mutagenic category 1;

(f) mutagenic category 2;

(g) toxic for reproduction category 1; or

(h) toxic for reproduction category 2.

(4) An applicant for the authorisation of a biocidal product under paragraph (1) shall submit his application to the Executive and with that application shall include—

(a) a dossier for that biocidal product satisfying, in the light of current scientific and technical knowledge—

(i) the requirements set out in Annex IVB where that biocidal product is a micro-organism, or

(ii) the requirements set out in Annexes IIB and IIIB where that biocidal product is not a micro-organism; and

(b) a dossier for each active substance in that biocidal product satisfying, in the light of current scientific and technical knowledge, the requirements of—

(i) Annex IVA, where the active substance in question is a micro-organism, and

(ii) Annexes IIA and IIIA, where the active substance in question is not a micro-organism.

(5) A dossier submitted in accordance with paragraph (4) shall include—

(a) a detailed and full description of any studies referred to in that dossier; and

(b) either—

(i) a detailed and full description of the methods used in carrying out such studies, or

(ii) a bibliographical reference to such methods.

(6) The information in dossiers submitted to the Executive in accordance with paragraph (4) shall be sufficient to enable the Executive to make the determination referred to in Schedule 3.

(7) The Executive—

(a) shall evaluate dossiers submitted in accordance with paragraph (4) in accordance with the common principles set out in Annex VI; and

(b) subject to regulations 18(3) and 39(2), shall decide without undue delay whether or not to authorise the biocidal product in question.

(8) If the evaluation of a dossier shows that additional information, which may include data and results from further testing, is necessary for the purpose of evaluating the risks of the biocidal product in question, the Executive shall request in writing the applicant to provide such additional information as it may specify.

(9) Where the Executive requests additional information under paragraph (8), the period of time within which the Executive shall decide whether or not to authorise the biocidal product in question shall not commence until the dossier is complete.

(10) In an authorisation granted under paragraph (1), the Executive shall specify—

(a) the conditions and requirements relating to the placing on the market and use of the biocidal product referred to in the authorisation necessary to ensure—

(i) compliance with any requirements set out in Annex I or Annex IA relating to the active substance in that biocidal product; and

(ii) that the requirements referred to in paragraphs 1(a)–(d) and 4(b) of Schedule 3 remain satisfied; and

(b) any other conditions or restrictions subject to which the authorisation is granted.

(11) The Executive may renew an authorisation granted under this regulation for a period of time which ends on a date not later than the earliest date on which the entry in Annex I of any active substance in the biocidal product the subject of the authorisation expires.

(12) Paragraphs (2) to (10) shall apply in the case of an application for the renewal of an authorisation under paragraph (11) as they apply in the case of an application for an authorisation under paragraph (1).

(13) Where an application for the renewal of an authorisation of a biocidal product granted under this regulation has been made, the Executive may, where necessary, renew that authorisation for such further period as is required to enable the Executive—

(a) to verify that the conditions specified in paragraph 2(*a*) continue to be satisfied; and

(b) to confirm, or otherwise, the determinations referred to in paragraph 2(*b*).

Registration of a low-risk biocidal product

10.—(1) Subject to the following paragraphs, the Executive may register a low-risk biocidal product for placing on the market and use for a period of time which ends on a date not later than the earliest date on which the entry in Annex IA of any active substance in that low-risk biocidal product expires.

(2) The Executive shall not register a low-risk biocidal product under paragraph (1) unless—

(a) any requirements set out in Annex IA relating to the active substance in that low-risk biocidal product have been fulfilled; and

(b) the Executive has made the determinations referred to in Schedule 3.

(3) The Executive shall not register a low-risk biocidal product under paragraph (1) for use by the public, or for placing on the market for use by the public, where that low-risk biocidal product is classified as toxic or very toxic.

(4) Subject to paragraph (7), an applicant for the registration of a low-risk biocidal product under paragraph (1) shall submit his application to the Executive and with that application shall include—

(a) a dossier containing the information set out in Schedule 4; and

(b) a dossier for each active substance in that low-risk biocidal product satisfying, in the light of current scientific and technical knowledge, the requirements of—

(i) Annex IVA, where the active substance in question is a micro-organism, and

(ii) Annexes IIA and IIIA, where the active substance in question is not a micro-organism.

(5) A dossier submitted in accordance with paragraph (4) shall include—

(a) a detailed and full description of any studies referred to in that dossier; and

(b) either—

(i) a detailed and full description of the methods used in carrying out such studies, or

(ii) a bibliographical reference to such methods.

(6) The information in dossiers submitted to the Executive in accordance with paragraph (4) shall be sufficient to enable the Executive to make the determinations referred to in Schedule 3.

(7) Where the applicant justifies the omission to the satisfaction of the Executive, the applicant may omit from a dossier submitted in accordance with paragraph (4)(*a*) information which—

(a) is not necessary owing to the nature of—

(i) the low-risk biocidal product, or

(ii) its proposed uses;

(b) it is not scientifically necessary or technically possible to supply.

(8) The Executive—

(a) shall evaluate dossiers submitted in accordance with paragraph (4) in accordance with the common principles set out in Annex VI; and

(b) subject to regulation 39(2), shall decide within 60 days of its receiving an application whether or not to register the low-risk biocidal product in question.

(9) If the evaluation of a dossier shows that additional information, which may include data and results from further testing, is necessary for the purpose of evaluating the risks of the low-risk biocidal product in question, the Executive shall request in writing the applicant to provide such additional information as it may specify.

(10) Where the Executive requests additional information under paragraph (9), the period of time referred to in paragraph (8)(*b*) shall not commence until the dossier is complete.

(11) In a registration granted under paragraph (1), the Executive shall specify—

(a) the conditions and restrictions relating to the placing on the market and use of the low-risk biocidal product referred to in the registration necessary to ensure—

(i) compliance with any requirements set out in Annex IA relating to the active substance in that low-risk biocidal product, and

(ii) that the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3 remain satisfied; and

(b) any other conditions or restrictions subject to which the registration is granted.

(12) The Executive may renew a registration granted under this regulation for a period of time which ends on a date not later than the earliest date on which the entry in Annex IA of any active substance in the low-risk biocidal product the subject of the registration expires.

(13) Paragraphs (2) to (11) shall apply in the case of an application for the renewal of a registration under paragraph (12) as they apply in the case of an application for a registration under paragraph (1).

(14) Where an application for the renewal of a registration of a low-risk biocidal product granted under this regulation has been made, the Executive may, where necessary, renew that registration for such further period as is required to enable the Executive—

(a) to verify that the requirements referred to in paragraph (2)(*a*) continue to be fulfilled; and

(b) to confirm, or otherwise, the determinations referred to in paragraph (2)(*b*).

Mutual recognition of authorisations

11.—(1) Where a biocidal product has been authorised for placing on the market and use under the Directive in a member State, a person may apply to the Executive for authorisation of that biocidal product for placing on the market and use under this regulation.

(2) Subject to the following paragraphs and to regulations 18(3) and 39(2), within 120 days of the Executive receiving an application in accordance with this regulation, it shall authorise the biocidal product in question subject to the conditions and restrictions imposed on authorisation of that biocidal product in the member State where authorisation was first granted.

(3) Subject to paragraphs (8) and (9), the Executive shall not authorise a biocidal product under this regulation unless the following conditions are satisfied, namely—

(a) at least one of the active substances in the biocidal product is included in Annex I;

(b) any other active substances in the biocidal product are included in Annex I or Annex IA; and

(c) any requirements set out in Annex I or Annex IA relating to the active substance in the biocidal product have been fulfilled.

(4) Subject to paragraphs (8) and (9), the Executive shall not authorise a biocidal product under this regulation if it considers that—

(a) the biocidal product does not satisfy the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3; or

(b) the nature and quantity of—

(i) the active substance in,

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

(iii) the residues of toxicological or environmental significance which result from authorised uses of,

the biocidal product cannot be determined according to the relevant requirements in Annexes IIA, IIB, IIIA, IIIB, IVA and IVB.

(5) An applicant for authorisation of a biocidal product under this regulation shall submit with his application—

(a) a summary of the dossier submitted in support of the application for authorisation of that biocidal product in the member State in which the authorisation was first granted; and

(b) a certified copy of that authorisation.

(6) Where the Executive is satisfied that—

(a) the target species is not present in harmful quantities;

(b) there is unacceptable tolerance or resistance of the target organism to the biocidal product; or

(c) the relevant circumstances of use differ significantly from those in the member State where the biocidal product was first authorised, such that an authorisation without additional conditions may present unacceptable risks to humans, animals or the environment,

it may propose conditions and restrictions relating to the matters referred to in Schedule 5 concerning the placing on the market and the use of the biocidal product in addition to those conditions and restrictions imposed in the member State in which the biocidal product was first authorised.

(7) The additional conditions and restrictions proposed pursuant to paragraph (6) shall be such as to ensure—

(a) compliance with any requirements set out in Annex I or Annex IA relating to the active substance in the biocidal product in question; and

(b) that the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3 remain satisfied.

(8) Where, under this regulation, the Executive proposes to refuse to authorise a biocidal product or to impose conditions or restrictions in addition to those imposed in the member State in which the biocidal product was first authorised, it shall—

(a) notify the Commission, member States and the applicant; and

(b) provide the Commission, member States and the applicant with an explanatory document setting out—

(i) the name and specification of the biocidal product, and

(ii) the grounds on which it proposes to refuse authorisation, or to impose additional conditions or restrictions on authorisation.

(9) Where a Commission decision—

(a) confirms a proposed refusal, the Executive shall refuse to authorise the biocidal product in question;

(b) confirms any of the proposed additional conditions and restrictions, the Executive shall authorise the biocidal product in question subject to—

(i) the conditions and restrictions confirmed by the Commission decision, and

(ii) any conditions and restrictions imposed in the member State in which the biocidal product was first authorised;

(c) confirms that an authorisation, which the Executive proposes should be refused, should be granted, the Executive shall authorise the biocidal product in question subject to any conditions and restrictions imposed in the member State in which the biocidal product was first authorised;

(d) confirms that none of the additional conditions and restrictions proposed by the Executive should be imposed, the Executive shall authorise the biocidal product in question subject to any conditions and restrictions imposed in the member State in which the biocidal product was first authorised but without imposing the additional conditions and restrictions which it proposed.

Mutual recognition of registrations

12.—(1) Where a biocidal product has been registered for placing on the market and use under the Directive in a member State, a person may apply to the Executive for registration of that biocidal product for placing on the market and use under this regulation.

(2) Subject to the following paragraphs and to regulation 39(2), within 60 days of the Executive receiving an application in accordance with this regulation, it shall register the biocidal product in question subject to the conditions and restrictions imposed on registration of that biocidal product in the member State where registration was first granted.

(3) Subject to paragraphs (10) to (13), the Executive shall not register a biocidal product under this regulation unless—

(a) the biocidal product is a low-risk biocidal product; and

(b) any requirements set out in Annex IA relating to the active substance in the biocidal product have been fulfilled.

(4) Subject to paragraphs (12) and (13), the Executive shall not register a biocidal product under this regulation if it considers that—

(a) the biocidal product does not satisfy the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3; or

(b) the nature and quantity of—

(i) the active substance in,

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

(iii) the residues of toxicological or environmental significance which result from authorised uses of,

the biocidal product cannot be determined according to the relevant requirements in Annexes IIA, IIB, IIIB, IVA and IVB.

(5) Subject to paragraphs (6) and (7), an applicant for registration of a biocidal product under this regulation shall submit with his application—

(a) a dossier containing the information set out in Schedule 4; and

(b) a certified copy of the registration of that biocidal product in the member State in which registration was first granted.

(6) Where the applicant justifies the omission to the satisfaction of the Executive, the applicant may omit from a dossier submitted in accordance with paragraph (5)(*a*) information which—

(a) is not necessary owing to the nature of—

(i) the low-risk biocidal product, or

(ii) its proposed uses;

(b) it is not scientifically necessary or technically possible to supply.

(7) The data referred to in paragraph 10 of Schedule 4 may be provided in summary form.

(8) Where the Executive is satisfied that—

(a) the target species is not present in harmful quantities;

(b) there is unacceptable tolerance or resistance of the target organism to the biocidal product; or

(c) the relevant circumstances of use differ significantly from those in the member State where the biocidal product was first registered, such that registration without additional requirements or conditions may present unacceptable risks to humans, animals or the environment,

it may propose conditions and restrictions relating to the matters referred to in Schedule 5 concerning the placing on the market and the use of the biocidal product in addition to those conditions and restrictions imposed in the member State in which the first registration was granted.

(9) The additional conditions and restrictions proposed pursuant to paragraph (8) shall be such as to ensure—

(a) compliance with any requirements set out in Annex IA relating to the active substance in the biocidal product in question; and

(b) that the requirements referred to in paragraph 1(a)–(d) and 4(b) of Schedule 3 remain satisfied.

(10) If the Executive is satisfied that the biocidal product, in respect of which an application has been made under paragraph (1), is not a low-risk biocidal product, it—

(a) may provisionally refuse to register the biocidal product; and

(b) shall immediately communicate its concerns to the competent authority which verified the dossier submitted in support of the application for first registration.

(11) If, within 90 days of the Executive communicating its concerns in accordance with paragraph 10(b), the Executive and the competent authority which verified the dossier submitted in support of the application for first registration cannot reach an agreement as to whether a biocidal product is a low-risk biocidal product, the Executive shall notify the Commission of the lack of agreement.

(12) Notwithstanding paragraphs (10) and (11), where, under this regulation the Executive proposes to refuse to register a biocidal product, or to impose conditions or restrictions in addition to those imposed in the member State in which the low-risk biocidal product was first registered, it shall—

(a) notify the Commission, member States and the applicant; and

(b) provide the Commission, member States and the applicant with an explanatory document setting out—

(i) the name and specification of the biocidal product, and

(ii) the grounds on which it proposes to refuse registration, or to impose additional conditions or restrictions on, registration.

(13) Where a Commission decision—

(a) confirms a proposed or provisional refusal, the Executive shall refuse to register the biocidal product in question;

(b) confirms any of the proposed additional conditions or restrictions, the Executive shall register the biocidal product in question subject to—

(i) the conditions and restrictions confirmed by the Commission decision, and

(ii) any conditions and restrictions imposed in the member State in which the biocidal product was first registered;

(c) confirms that a registration, which the Executive proposes should be refused or has provisionally refused, should be granted, the Executive shall register the biocidal product in question subject to any conditions and restrictions imposed in the member State in which the biocidal product was first registered;

(d) confirms that none of the additional conditions and restrictions proposed by the Executive should be imposed, the Executive shall register the biocidal product in question subject to any conditions and restrictions imposed in the member State in which the biocidal product was first registered but without imposing the additional conditions and restrictions which it proposed.

Provisional authorisation

13.—(1) Subject to the following paragraphs, the Executive may authorise, for a period not exceeding three years, a biocidal product for placing on the market and use which contains a new active substance which is not included in Annex I or Annex IA but in respect of which an application has been made to the Executive under regulation 5.

(2) The Executive shall not authorise a biocidal product under paragraph (1) unless—

(a) in accordance with regulation 6(2), it has evaluated the new active substance contained in that biocidal product which is not included in Annex I or Annex IA and has recommended that that new active substance should be included in Annex I; and

(b) the Executive has made the determinations referred to in Schedule 3.

(3) The Executive shall not authorise a biocidal product under paragraph (1) where—

(a) a member State has made an objection in accordance with Article 18(2) to the completeness of the dossiers submitted in support of the application under regulation 5; and

(b) objection has been upheld by a Commission decision.

(4) The Executive shall not authorise a biocidal product under paragraph (1) where the evaluation required by paragraph (2)(*a*) shows that—

(a) under normal conditions under which the new active substance may be used in the biocidal product, there are risks to the health of humans or animals or to the environment which give rise to concern; and

(b) there is another active substance included in Annex I for the same product-type which, having regard to current scientific and technical knowledge, presents significantly less risk than the new active substances to the health of humans or animals or to the environment when used under normal conditions in biocidal products authorised in accordance with these Regulations, provided that—

(i) the chemical diversity of all the active substances included in Annex I is adequate to minimise the occurrence of resistance in organisms targeted by that biocidal product,

(ii) the Executive does not consider that it is necessary to acquire experience of using the new active substance in practice, and

(iii) the active substance included in Annex I can be used on the target organism with similar efficacy as the new active substance without significant economic and practical disadvantages for the user and without an increased risk to the health of humans or animals or to the environment.

(5) The Executive shall not authorise a biocidal product under paragraph (1) for use by the public, or for placing on the market for use by the public, where that biocidal product is classified as—

(a) toxic;

(b) very toxic;

(c) carcinogenic category 1;

(d) carcinogenic category 2;

(e) mutagenic category 1;

(f) mutagenic category 2;

(g) toxic for reproduction category 1; or

(h) toxic for reproduction category 2.

(6) Paragraphs (4) to (9) of regulation 9 shall apply in the case of an application for an authorisation under paragraph (1) as they apply in the case of an application for an authorisation under paragraph (1) of that regulation.

(7) In an authorisation granted under paragraph (1), the Executive shall specify—

(a) the conditions and restrictions relating to the placing on the market and use of the biocidal product referred to in the authorisation necessary to ensure—

(i) compliance with any requirements which it has recommended should attach to the inclusion in Annex I of the new active substance in that biocidal product, and

(ii) that the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3 remain satisfied; and

(b) any other conditions or restrictions subject to which the authorisation is granted.

(8) If, on the expiry of the period for which an authorisation has been granted under paragraph (1), a decision has not been taken concerning the inclusion in Annex I of the new active substance in the biocidal product referred to in that authorisation, the Executive may authorise that biocidal product for placing on the market and use for a further period of one year.

(9) Paragraphs (2) to (7) shall apply in the case of an application for an authorisation under paragraph (8) as they apply in the case of an application for an authorisation under paragraph (1).

(10) The Executive shall inform the Commission and the member States of every authorisation granted in accordance with paragraph (8).

Provisional registration

14.—(1) Subject to the following paragraphs of this regulation, the Executive may register, for a period not exceeding three years, a biocidal product for placing on the market and use which—

(a) contains a new active substance which is not included in Annex IA but in respect of which an application has been made to the Executive under regulation 5;

(b) does not contain a substance of concern;

(c) does not contain an active substance included in Annex I; and

(d) under the conditions under which that biocidal product may be used poses a low risk to humans, animals and the environment.

(2) The Executive shall not register a biocidal product under paragraph (1) unless—

(a) in accordance with regulation 6(2), it has evaluated the new active substance contained in that biocidal product which is not included in Annex IA and has recommended that the new active substance should be included in Annex IA; and

(b) the Executive has made the determinations referred to in Schedule 3.

(3) The Executive shall not register a biocidal product under paragraph (1) where—

(a) a member State has made an objection in accordance with Article 18(2) to the completeness of the dossiers submitted in support of the application under regulation 5; and

(b) that objection has been upheld by a Commission decision.

(4) The Executive shall not register a biocidal product under paragraph (1) where the new active substance contained in that biocidal product which is not included in Annex IA—

(a) is classified as carcinogenic, mutagenic, sensitising or toxic for reproduction; or

(b) is bioaccumulative and does not readily degrade.

(5) The Executive shall not register a biocidal product under paragraph (1) where the evaluation required by paragraph (2)(*a*) shows that—

(a) under normal conditions under which the new active substance may be used in the biocidal product, there are risks to the health of humans or animals or to the environment which give rise to concern; and

(b) there is another active substance included in Annex I for the same product-type which, having regard to current scientific and technical knowledge, presents significantly less risk than the new active substance to the health of humans or animals or to the environment when used under normal conditions in biocidal products authorised in accordance with these Regulations, provided that—

(i) the chemical diversity of all the active substances included in Annex I is adequate to minimise the occurrence of resistance in organisms targeted by that biocidal product,

(ii) the Executive does not consider that it is necessary to acquire experience of using the new active substance in practice, and

(iii) the active substance included in Annex I can be used on the target organism with similar efficacy as the new active substance without significant economic and practical disadvantages for the user and without an increased risk to the health of humans or animals or to the environment.

(6) The Executive shall not register a biocidal product under paragraph (1) for use by the public, or for placing on the market for use by the public, where that biocidal product is classified as toxic or very toxic.

(7) Paragraphs (4)–(10) of regulation 10 shall apply in the case of an application for a registration granted under paragraph (1) as it applies in the case of an application for a registration granted under paragraph (1) of that regulation, and, in the application of this paragraph, a reference to a low-risk biocidal product in paragraphs (4)–(10) of regulation 10 shall be deemed to be a reference to a biocidal product.

(8) In a registration granted under paragraph (1), the Executive shall specify—

(a) the conditions and restrictions relating to the placing on the market and use of the biocidal product referred to in the registration necessary to ensure—

(i) compliance with any requirements which it has recommended should attach to the inclusion in Annex IA of the new active substance in the biocidal product, and

(ii) that the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3 remain satisfied; and

(b) any other conditions or restrictions subject to which the registration is granted.

(9) If, on the expiry of the period for which a registration has been granted under paragraph (1), a decision has not been taken concerning the inclusion in Annex IA of the new active substance in the biocidal product referred to in that registration, the Executive may register that biocidal product for placing on the market and use for a further period of one year.

(10) Paragraphs (2) to (8) shall apply to an application for a registration under paragraph (9) as they apply to an application for registration under paragraph (1).

(11) The Executive shall inform the Commission and the member States of every registration granted under paragraph (9).

Emergency authorisation

15.—(1) Where a person submits an application to the Executive for the authorisation of an unauthorised biocidal product under this regulation, the Executive may authorise, for a period not exceeding 120 days, the placing on the market of an unauthorised biocidal product for a limited and controlled use if such authorisation appears necessary because of an unforeseen danger which cannot be contained by any other means.

(2) The Executive shall immediately inform the Commission and the member States of an authorisation granted in accordance with paragraph (1) and the justification for it.

(3) An authorisation granted under paragraph (1) shall specify such conditions and restrictions relating to the placing on the market and the use of the biocidal product in question as the Executive considers appropriate.

(4) If there is a Commission decision that—

(a) the period in respect of which an authorisation granted pursuant to paragraph (1) may be extended; or

(b) such an authorisation may be renewed,

the Executive may extend that period or renew that authorisation.

(5) Where the Executive extends the period of, or renews, an authorisation under paragraph (4), it shall at the same time specify any conditions referred to in the Commission decision subject to which the period may be extended or the authorisation may be renewed, as the case may be.

(6) In this regulation, "unauthorised biocidal product" means a biocidal product which—

(a) has not been authorised in accordance with regulation 9, 11, 13 or 17 or registered in accordance with regulation 10, 12 or 14; or

(b) has been authorised in accordance with regulation 9, 11, 13 or 17 or registered in accordance with regulation 10, 12 or 14, but which, by virtue of the conditions or restrictions to which the authorisation, or, as the case may be, the registration, is subject, cannot be used to deal with an unforeseen danger referred to in paragraph (1).

Research and development

16.—(1) This regulation shall not apply to the placing on the market of a relevant product for use in an experiment or test in Northern Ireland which may involve or result in the release into the environment of that relevant product.

(2) A person shall not place on the market a relevant product for use in an experiment or test for the purposes of scientific research and development, or process-orientated research and development, unless that person compiles a dossier containing all available information on the possible effects of the relevant product on human or animal health and on the environment.

(3) A person shall not place on the market a relevant product for use in an experiment or test for the purposes of scientific research and development unless that person draws up and maintains a written record of the following information relating to that relevant product, namely—

(a) its identity;

(b) any data on which the information on its label should be based;

(c) the quantity placed on the market; and

(d) the name and address of the person who receives it.

(4) A person, who places on the market a relevant product for use in an experiment or test for the purposes of scientific research and development, which is to be conducted in Northern Ireland, shall provide to the Executive on request the written record and dossier relating to that relevant product which he is required to compile and maintain in accordance with paragraphs (2) and (3).

(5) A person, who intends to place on the market a relevant product for use in an experiment or test for the purpose of process-orientated research and development in Northern Ireland, shall provide to the Executive before the relevant product is placed on the market—

(a) the dossier relating to the relevant product which he is required to compile in accordance with paragraph (2); and

(b) the following information relating to the relevant product namely—

(i) its identity,

(ii) any data on which the information on its label should be based,

(iii) the quantity of the relevant product to be placed on the market, and

(iv) the name and address of the person who is to receive the relevant product.

(6) If an experiment or test referred to in paragraph (2) or (3) is liable to have harmful effects on human or animal health or an unacceptable adverse influence on the environment, the Executive may—

(a) prohibit the experiment or test; or

(b) impose such conditions regarding the conduct of the experiment or test as it considers necessary to prevent such harmful effects or such adverse influence.

(7) A person shall not conduct an experiment or test which the Executive has prohibited under paragraph (6)(*a*).

(8) Where the Executive has imposed conditions regarding the conduct of an experiment or test under paragraph (6)(*b*), the person conducting the experiment or test shall comply with the conditions, or shall ensure that the conditions are complied with.

(9) In this regulation—

(a) "unauthorised biocidal product" means a biocidal product which—

(i) has not been authorised in accordance with regulation 9, 11, 13 or 17 or registered in accordance with regulation 10, 12 or 14, or

(ii) has been authorised in accordance with regulation 9, 11, 13 or 17 or registered in accordance with regulation 10, 12 or 14, but which, by virtue of the conditions or restrictions to which the authorisation, or, as the case may be, the registration is subject, cannot be used in the experiment or test in question;

(b) "relevant product" means—

(i) an unauthorised biocidal product, or

(ii) an active substance intended exclusively for use in a biocidal product.

Experimental authorisation

17.—(1) Subject to the following paragraphs of this regulation, the Executive may authorise a biocidal product, or an active substance intended exclusively for use in a biocidal product, for placing on the market for the purpose of any experiment or test in Northern Ireland which may involve or result in the release into the environment of that biocidal product or active substance, as the case may be.

(2) An authorisation granted under this regulation—

(a) shall contain conditions limiting—

(i) the quantity of biocidal product or active substance, as the case may be, to be used, and

(ii) the area to be treated with that biocidal product or active substance; and

(b) may contain such further conditions, including any conditions necessary to prevent harmful effects on human or animal health or unacceptable adverse influence on the environment, as the Executive considers necessary.

(3) An authorisation granted under this regulation may relate to more than one experiment or test and, if it does so, shall—

(a) be granted to one person;

(b) specify the experiments or tests to which it relates; and

(c) specify the conditions under which those experiments and tests shall be undertaken.

(4) An applicant for an authorisation under this regulation shall submit his application to the Executive together with a dossier setting out, in relation to each experiment or test—

(a) the identity of the biocidal product or active substance in question;

(b) any data on which the information on the label of that biocidal product or active substance should be based;

(c) the quantity of the biocidal product or active substance to be placed on the market;

(d) the name and address of each person who is to receive the biocidal product or active substance in question; and

(e) all available information on the possible effects on human or animal health and on the environment of the biocidal product or active substance concerned.

(5) Subject to regulation 39(2), the Executive shall assess the information provided by the applicant before deciding whether or not to grant an authorisation under this regulation.

Frame-formulations

18.—(1) At the same time the Executive grants an authorisation in respect of a biocidal product under regulation 9 or 13, or grants a registration in respect of a biocidal product under regulation 10 or 14—

(a) it shall, when requested to do so by the applicant for that authorisation or that registration; or

(b) it may, without being requested to do so,

issue a frame-formulation which includes that biocidal product and it shall communicate that frame-formulation to that applicant.

(2) Where an application is made under regulation 9, 10, 13 or 14 in respect of a biocidal product within an issued frame-formulation, the Executive shall take that issued frame-formulation into account in evaluating the dossiers submitted with the application in question.

(3) Where a person makes an application for an authorisation under regulation 9 or 13 and that person has a letter of access in respect of the information relating to the biocidal products within an issued frame-formulation, the Executive shall decide whether or not to grant the authorisation within 60 days of its receiving the application.

(4) In this regulation, "issued frame-formulation" means a frame-formulation issued by the Executive in accordance with paragraph (1).

Revocation of authorisations and registrations

19.—(1) The Executive shall revoke an authorisation granted under regulation 9 or 11 where—

(a) an active substance in the biocidal product to which the authorisation relates—

(i) is removed from Annex I, or

(ii) is removed from Annex IA and that active substance is not included in Annex I; or

(b) a requirement laid down in Annex I or Annex IA in respect of an active substance in the biocidal product to which the authorisation relates is no longer satisfied.

(2) The Executive shall revoke an authorisation—

(a) granted under regulation 9, 11 or 13, where the biocidal product, the subject of the authorisation, no longer satisfies one or more of the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3;

(b) granted under regulation 9, 11, 13, 15 or 17, where false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted.

(3) The Executive shall revoke an authorisation of a biocidal product for use by the public, or for placing on the market for use by the public, where that biocidal product is classified as—

(a) toxic;

(b) very toxic;

(c) carcinogenic category 1;

(d) carcinogenic category 2;

(e) mutagenic category 1;

(f) mutagenic category 2;

(g) toxic for reproduction category 1; or

(h) toxic for reproduction category 2.

(4) The Executive shall revoke a registration granted under regulation 10 or 12 where—

(a) an active substance in the low-risk biocidal product to which the registration relates is removed from Annex IA; or

(b) a requirement laid down in Annex IA in respect of an active substance in the low-risk biocidal product to which the registration relates is no longer satisfied.

(5) The Executive shall revoke a registration granted under regulation 10 if—

(a) there is a Commission decision referred to in regulation 20(4); and

(b) following a review of the registration in accordance with regulation 20(4), the Executive decides that the biocidal product in question is not a low-risk biocidal product.

(6) The Executive shall revoke a registration granted under regulation 10, 12 or 14 where—

(a) the biocidal product, the subject of the registration, no longer satisfies one or more of the requirements referred to in paragraphs 1(*a*)–(*d*) and 4(*b*) of Schedule 3;

(b) false or misleading information was supplied concerning the facts on the basis of which the registration was granted.

(7) The Executive shall revoke a registration of a biocidal product for use by the public or for placing on the market for use by the public, where that low-risk biocidal product is classified as toxic or very toxic.

(8) The Executive shall revoke an authorisation granted under regulation 13 where there is a Commission decision that an active substance in the biocidal product to which the authorisation relates shall not be included in Annex I, and no decision is made to include that active substance in Annex IA.

(9) The Executive shall revoke a registration granted under regulation 14 where there is a Commission decision that an active substance in the biocidal product to which the registration relates shall not be included in Annex IA.

(10) The Executive shall revoke an authorisation granted under regulation 15 where a Commission decision does not uphold it.

(11) The Executive may revoke an authorisation granted under regulation 17 if the experiment or test in question is liable to have harmful effects on human or animal health or an unacceptable adverse effect on the environment.

(12) The Executive may revoke an authorisation or registration granted under these Regulations at the written request of the holder, who shall state the reasons for that request.

(13) Before revoking an authorisation or a registration, except following a request made in accordance with paragraph (12), the Executive shall—

(a) give to the holder a notice in writing stating that—

(i) it is considering revoking that authorisation or registration and the reasons why, and

(ii) within a period specified in the notice, the holder may make written representations to the Executive or, if the holder so requests, may make oral representations to the Executive; and

(b) consider any representations which are duly made and not withdrawn.

(14) Before refusing to revoke an authorisation or a registration following a request made in accordance with paragraph (12), the Executive shall—

(a) give to the holder a notice in writing stating that—

(i) it is considering not revoking that authorisation or that registration and the reasons why, and

(ii) within a period specified in the notice, the holder may make written representations to the Executive or, if the holder so requests, may make oral representations to the Executive; and

(b) consider any representations which are duly made and not withdrawn.

(15) When the Executive revokes—

(a) an authorisation or a registration granted under these Regulations in respect of a biocidal product; or

(b) an authorisation granted under regulation 17 in respect of an active substance intended exclusively for use in a biocidal product,

it may grant a period of grace for the disposal, storage, placing on the market or use of existing stocks of the biocidal product to which the authorisation or the registration relates, or the active substance to which the authorisation relates, as the case may be.

(16) The period of grace referred to in paragraph (15) shall be of a length commensurate with the reason for the revocation, but shall be without prejudice to any period provided for in connection with the removal from Annex I or Annex IA of an active substance in the biocidal product in question or the active substance in question, as the case may be.

(17) In this regulation, "holder" means a person to whom an authorisation or a registration has been granted in accordance with these Regulations.

Modification and review of authorisations and registrations

20.—(1) The Executive shall modify the conditions of use, subject to which an authorisation or a registration is granted under these Regulations, where it considers that, on the basis of developments in scientific and technical knowledge, such modification is necessary to protect human or animal health or the environment.

(2) Subject to regulation 39(3), the Executive may modify the conditions of use, subject to which an authorisation or a registration is granted under these Regulations, at the written request of the holder, who shall state the reasons for that request.

(3) The Executive may review an authorisation of a biocidal product granted under regulation 9, 11 or 13 or a registration of a biocidal product granted under regulation 10, 12 or 14 at any time if there are indications that—

(a) the biocidal product in question no longer satisfies one or more of the requirements referred to in paragraphs 1(*a*)–(*d*) or 4(*b*) of Schedule 3;

(b) there is a change in the classification of the biocidal product; or

(c) the conditions or restrictions, subject to which the biocidal product has been authorised or registered, as the case may be, and imposed to ensure that the requirements referred to in paragraphs 1(*a*)–(*d*) or 4(*b*) of Schedule 3 remain satisfied, are no longer appropriate for ensuring that such requirements remain satisfied.

(4) Where a Commission decision confirms the refusal of a member State to register a biocidal product in respect of which the Executive has granted a registration under regulation 10, if considered appropriate by the Standing Committee, the Executive shall review that registration, taking the refusal of the member State into consideration.

(5) Where the Executive reviews an authorisation or a registration under paragraph (3), or a registration under paragraph (4), the Executive—

(a) may extend the authorisation or registration in question for the period necessary to enable it to complete the review; and

(b) may require the holder to provide further information necessary for the review.

(6) Where the Executive requires further information in accordance with paragraph (5), the Executive shall extend the authorisation or registration for the period necessary to enable the holder to provide such information.

(7) In this regulation—

(a) "holder" has the same meaning as it has in regulation 19;

(b) "the conditions of use" means the conditions relating to the use of a biocidal product, including, but without prejudice to the generality of the foregoing, the manner of use and the amounts used; and

(c) "the Standing Committee" means the Standing Committee on Biocidal Products referred to in Article 28(1).

Notification of new information

21.—(1) A person to whom an authorisation or a registration has been granted in accordance with these Regulations shall immediately notify the Executive of any information of which he is aware or may reasonably be expected to be aware concerning—

(a) the biocidal product; or

(b) an active substance contained in the biocidal product,

to which the authorisation or the registration relates, which may affect that authorisation or registration.

(2) The information referred to in paragraph (1) shall include—

(a) new knowledge or information on the effects of that biocidal product, or the active substance which the biocidal product contains, on humans, animals or the environment;

(b) changes in the source or composition of the active substance which the biocidal product contains;

(c) changes in the composition of the biocidal product;

(d) development of resistance to the biocidal product in the harmful organisms which it is intended to control;

(e) changes of an administrative nature; or

(f) changes in the nature of the packaging.

(3) A notification made pursuant to paragraph (1) shall include—

(a) a statement that the notification is made in compliance with this regulation; and

(b) the number of the authorisation or registration relating to the biocidal product with which the notification is concerned.

(4) The Executive shall immediately notify member States and the Commission of any information it receives by virtue of paragraph (1) relating to—

(a) potentially harmful effects for humans, animals or the environment of—

(i) a biocidal product,

(ii) an active substance, an impurity or a co-formulant which a biocidal product contains, or

(iii) a residue of a biocidal product; and

(b) changes in the composition of a biocidal product, including changes in the active substance which a biocidal product contains.

Emergency prohibition or restriction

22.—(1) The Executive may prohibit or restrict the sale or use of a biocidal product which has been authorised or registered under these Regulations, where it has valid reasons to consider that the biocidal product constitutes an unacceptable risk to human or animal health or to the environment.

(2) Where the Executive prohibits or restricts the sale or use of a biocidal product pursuant to paragraph (1), it shall immediately inform the Commission and member States of that prohibition or restriction and of the reasons for it.

(3) A person shall not sell a biocidal product—

(a) whose sale has been prohibited pursuant to paragraph (1); or

(b) in a manner which contravenes any restriction on the sale of that biocidal product imposed pursuant to paragraph (1).

(4) A person shall not use a biocidal product—

(a) whose use has been prohibited pursuant to paragraph (1); or

(b) in a manner which contravenes any restriction on the use of that biocidal product imposed pursuant to paragraph (1).

(5) The Executive shall revoke a prohibition or restriction issued under this regulation where a decision made in accordance with the procedures set out in Article 28(3) does not uphold the prohibition or restriction.

Part IV

Use of Information

Data protection for active substances

23.—(1) Subject to the following paragraphs, the Executive shall not make use of relevant information relating to an active substance for the benefit of a person making an application under these Regulations other than—

(a) the person who submitted; or

(b) the person on whose behalf was submitted,

that relevant information.

(2) The Executive may make use of relevant information relating to an active substance for the benefit of a person making an application under these Regulations who has a letter of access to that relevant information.

(3) In the case of relevant information relating to a new active substance which was submitted other than for a purpose referred to in paragraph (4), paragraph (1) shall not apply after the expiry of the period of 15 years from the date on which that new active substance was first included in either Annex I or Annex IA.

(4) In the case of relevant information relating to a new active substance which was submitted for the first time for the purpose of an application under regulation 7 to renew the inclusion of that new active substance in Annex I or Annex IA or to vary the requirements subject to which the new active substance was included in Annex I or Annex IA, paragraph (1) shall not apply after either—

(a) the expiry of the period of 5 years from the date of the decision relating to the application under regulation 7; or

(b) the expiry of the period of 15 years from the date on which that new active substance was first included in either Annex I or Annex IA,

whichever is the later.

(5) In the case of relevant information relating to an existing active substance which was also submitted in support of an application for an approval (except an approval in the form of an experimental permit) under the 1987 Regulations, paragraph (1) shall not apply after either—

(a) the expiry of the period of 10 years from the date on which the approval was first given on the basis of that relevant information; or

(b) 14th May 2010,

whichever is the sooner.

(6) Subject to paragraph (10), in the case of relevant information relating to an existing active substance which was also submitted in response to a requirement imposed under section 16(11) of the 1985 Act to supply information relating to the review, revocation or suspension of, or the

amendment of the conditions of, an approval given under the 1987 Regulations (except an approval in the form of an experimental permit), paragraph (1) shall not apply after either—

(a) the expiry of the period of 5 years from the date of the decision to continue, revoke or suspend, or amend the conditions of, the approval in question; or

(b) 14th May 2010,

whichever is the sooner.

(7) Subject to paragraph (11), in the case of relevant information relating to an existing active substance which was also submitted in support of an application for approval in the form of an experimental permit under the 1987 Regulations, paragraph (1) shall not apply after 14th May 2010.

(8) In the case of relevant information relating to an existing active substance which was not submitted in the specified circumstances but which was submitted for the first time in support of an application for the first inclusion in Annex I or Annex IA of that existing active substance or of an additional product-type for that existing active substance, paragraph (1) shall not apply after the expiry of the period of 10 years from the date on which that existing active substance, or additional product-type for that existing substance, as the case may be, was first included in either Annex I or Annex IA.

(9) In the case of relevant information relating to an existing active substance which was not submitted in the specified circumstances but which was submitted for the first time for the purpose of an application under regulation 7 to renew the inclusion of that existing active substance in Annex I or Annex IA, or to vary the requirements subject to which the existing active substance was included in Annex I or Annex IA, paragraph (1) shall not apply after either—

(a) the expiry of the period of 5 years from the date of the decision relating to the application under regulation 7; or

(b) the expiry of the period of 10 years from the date on which that existing active substance was first included in either Annex I or Annex IA,

whichever is the later.

(10) Paragraph (6) shall not apply where the relevant information submitted in response to a requirement imposed under section 16(11) of the 1985 Act is also submitted in support of an application referred to in paragraph (5).

(11) Paragraph (7) shall not apply where the relevant information submitted in support of an application referred to in that paragraph is also submitted in support of an application referred to in paragraph (5).

(12) In this regulation—

(a) "the 1985 Act" means the Food and Environment Protection Act 1985(**12**);

(b) "the 1987 Regulations" means the Control of Pesticides Regulations (Northern Ireland) 1987(**13**);

(c) "submitted in the specified circumstances" means—

(i) submitted under the 1987 Regulations, as described in paragraphs (5) or (7), or

(ii) submitted in response to a requirement imposed under section 16(11) of the 1985 Act, as described in paragraph (6); and

(d) "relevant information" means information submitted to the Executive under these Regulations.

(**12**) 1985 c. 48, as amended by 1989 c. 27 and 1998 c. 26
(**13**) S.R. 1987 No. 414, as amended by S.R. 1991 No. 203 and S.R. 1997 No. 469

Data protection for biocidal products

24.—(1) Subject to the following paragraphs, the Executive shall not make use of relevant information relating to a biocidal product for the benefit of a person making an application under these Regulations other than—

(a) the person who submitted; or

(b) the person on whose behalf was submitted,

that relevant information.

(2) The Executive may make use of relevant information relating to a biocidal product for the benefit of a person making an application under these Regulations who has a letter of access to that relevant information.

(3) In the case of relevant information relating to a biocidal product containing a new active substance which was submitted other than for a purpose referred to in paragraph (4), paragraph (1) shall not apply after the expiry of the period of 10 years from the date on which that biocidal product was first authorised or registered, as the case may be, under these Regulations.

(4) In the case of relevant information relating to a biocidal product containing a new active substance which was submitted for the first time in connection with a modification under regulation 20 of a condition of use subject to which was granted the authorisation or registration, as the case may be, relating to that biocidal product, or for the first time in connection with an application under regulation 7 to renew the inclusion of that new active substance in Annex I or Annex IA, paragraph (1) shall not apply after either—

(a) the expiry of the period of 5 years from the date on which the Executive first received that relevant information, or

(b) the expiry of the period of 10 years from the date on which that biocidal product was first authorised or registered, as the case may be, under the Regulations,

whichever is the later.

(5) In the case of relevant information relating to a biocidal product containing an existing active substance which was also submitted in support of an application for an approval (except an approval in the form of an experimental permit) under the 1987 Regulations, paragraph (1) shall not apply after either—

(a) the expiry of the period of 10 years from the date on which the approval was first given on the basis of that relevant information; or

(b) 14th May 2010,

whichever is the sooner.

(6) Subject to paragraph (10), in the case of relevant information relating to a biocidal product containing an existing active substance which was also submitted in support of an application for approval in the form of an experimental permit under the 1987 Regulations, paragraph (1) shall not apply after 14th May 2010.

(7) In the case of relevant information relating to a biocidal product containing an existing active substance which was not submitted under the 1987 Regulations as described in paragraphs (5) or (6) but which was submitted for the first time in support of an application for the first inclusion in Annex I or Annex IA of that existing active substance or of an additional product-type for that existing active substance, paragraph (1) shall not apply after the expiry of the period of 10 years from the date on which that existing active substance, or additional product-type for that existing substance, as the case may be, was first included in either Annex I or Annex IA.

(8) In the case of relevant information relating to a biocidal product containing an existing active substance which—

(a) was not submitted under the 1987 Regulations as described in paragraphs (5) or (6); nor

(b) submitted for the first time in support of an application for the first inclusion in Annex I or Annex IA of that existing active substance or of an additional product-type for that existing active substance,

but which was submitted in support of an application for the grant of an authorisation or a registration under these Regulations, paragraph (1) shall not apply after 14th May 2010.

(9) In the case of relevant information relating to a biocidal product containing an existing active substance which was not submitted under the 1987 Regulations as described in paragraphs (5) or (6), but which was submitted for the first time in connection with a modification under regulation 20 of a condition of use subject to which was granted the authorisation or registration, as the case may be, relating to that biocidal product, or for the first time in connection with an application under regulation 7 to renew the inclusion of that existing active substance in Annex I or Annex IA, paragraph (1) shall not apply after either—

(a) the expiry of the period of 5 years from the date on which the Executive first received that relevant information; or

(b) after the expiry of the period of 10 years from the date on which that existing active substance was first included in either Annex I or Annex IA,

whichever is the later.

(10) Paragraph (6) shall not apply where the relevant information submitted in support of an application referred to in that paragraph was also submitted in support of an application referred to in paragraph (5).

(11) In this regulation, "the 1987 Regulations" and "relevant information" have the same meaning as they have in regulation 23.

Co-operation in the use of information

25.—(1) Subject to paragraph (2), the Executive may give its consent to a new applicant referring to the information contained in the dossiers included in the application submitted to the Executive in respect of an approved biocidal product.

(2) The Executive shall not give its consent under paragraph (1) unless—

(a) the new applicant can provide evidence to the satisfaction of the Executive that—

(i) the biocidal product to which his application relates is sufficiently similar to, and

(ii) the active substance contained in that biocidal product is the same as that contained in,

the approved biocidal product, including in relation to the degree of purity and the nature of the impurities; and

(b) the information referred to in paragraph (1) is information—

(i) in respect of which the new applicant has a letter of access, or

(ii) which the Executive already holds and, by virtue of regulation 23 or 24, is entitled to use for the benefit of that new applicant.

(3) Notwithstanding the obligations contained in these Regulations to submit dossiers in support of an application for the authorisation of a biocidal product under regulation 9, 11, 13 or 17, or the registration of a biocidal product under regulation 10, 12 or 14, before carrying out an experiment on vertebrate animals, a new applicant shall ask the Executive—

(a) whether an authorisation or registration has been granted under these Regulations in respect of a biocidal product similar to that which the new applicant intends to use in such an experiment (whether or not that authorisation or registration has been revoked); and

(b) for the name and address of the authorisation holder in respect of that biocidal product.

(4) When a new applicant makes an enquiry pursuant to paragraph (2), he shall provide evidence that—

(a) he intends to apply on his own behalf for an authorisation of a biocidal product under regulation 9, 11, 13 or 17 or a registration of a biocidal product under regulation 10, 12 or 14; and

(b) the other information, which he has to provide with such an application in accordance with these Regulations, is available.

(5) If the Executive is satisfied that the new applicant intends to apply for an authorisation or a registration referred to in paragraph (4)(a), it shall provide him with the name and address of the authorisation holder and shall inform the authorisation holder of the name and address of the new applicant.

(6) The authorisation holder and the new applicant shall take all reasonable steps to reach agreement on the sharing of information in order to avoid, if possible, the duplication of testing on vertebrate animals.

(7) The Executive shall encourage the authorisation holder to co-operate in the provision of information, with a view to limiting the duplication of testing on vertebrate animals.

(8) In this regulation—

(a) "approved biocidal product" means a biocidal product which has been authorised under regulation 9, 11 or 13 or registered under regulation 10, 12 or 14;

(b) "authorisation holder" means the person to whom—

(i) an authorisation of a biocidal product has been granted under regulation 9, 11, 13 or 17, or

(ii) a registration of a biocidal product has been granted under regulation 10, 12 or 14,

as the case may be;

(c) "dossier" includes a summary of a dossier;

(d) "new applicant" means a person who intends to apply for an authorisation or registration of a biocidal product under these Regulations.

Confidentiality

26.—(1) Information provided to the Executive under these Regulations shall not be treated as relevant information for the purposes of Article 30 of the 1978 Order.

(2) Subject to the following paragraphs, where a person indicates to the Executive in writing that information provided by him to it under these Regulations should be kept confidential because the disclosure of that information might harm his industrial and commercial position—

(a) he shall provide to the Executive full written justification for that indication; and

(b) the Executive shall decide which information shall be kept confidential on the basis of that justification.

(3) Information which a person has indicated should be kept confidential and in relation to which the Executive has not made a decision under paragraph (2)(*b*) shall not be disclosed except—

(a) to a Government Department, the Great Britain Executive, the Commission or to a competent authority;

(b) where the information is provided in support of an application made under these Regulations, to the extent necessary to enable the Executive to deal with the application in question.

(4) Where the Executive has made a decision under paragraph (2)(*b*) that certain information shall not be kept confidential, that information shall not be disclosed until there has elapsed a period of 14 days following the day on which the Executive informed the person providing the information of its decision except—

(a) to a Government Department, the Great Britain Executive, the Commission or to a competent authority;

(b) where the information is provided in support of an application made under these Regulations, to the extent necessary to enable the Executive to deal with the application in question.

(5) A person who receives information by virtue of paragraph (3)(*b*), (4)(*b*) or (11)(*b*) shall not use that information except for the purposes of the Executive.

(6) After a biocidal product has been authorised or registered under these Regulations, the Executive shall not keep the information specified in Schedule 6 relating to that biocidal product confidential.

(7) If—

(a) the applicant for the authorisation or registration of a biocidal product; or

(b) the manufacturer or the importer of that biocidal product or an active substance contained in that biocidal product,

discloses any information relating to that biocidal product or that active substance which the Executive has decided under paragraph (2)(*b*) shall be kept confidential, that applicant shall inform the Executive accordingly, and such information shall no longer be treated as being confidential for the purposes of these Regulations.

(8) Subject to paragraph (9), where, pursuant to paragraph (2), a person has indicated that he has provided confidential information, he shall forthwith inform the Executive in writing of any change in circumstances which may affect the justification given by him under paragraph (2)(*a*).

(9) Paragraph (8) shall not apply if the Executive has informed the person in question that the information he has provided shall not be kept confidential.

(10) Where—

(a) the Executive has decided to keep information confidential pursuant to paragraph (2)(*b*); and

(b) a person has informed it of a change in circumstances pursuant to paragraph (8),

after consulting that person as appropriate, the Executive shall review whether the information in question should continue to be kept confidential and shall inform that person of the result of that review.

(11) If, following a review referred to in paragraph (10), the Executive decides that the information in question shall not be kept confidential, that information shall not be disclosed until there has elapsed a period of 14 days following the day on which the Executive informed the person providing the information of its decision except—

(a) to a Government Department, the Great Britain Executive, the Commission or to a competent authority;

(b) where—

(i) the information is provided in support of an application made under these Regulations, and

(ii) the Executive has not finally disposed of that application,

to the extent necessary to enable the Executive to deal with the application.

(12) This regulation is without prejudice to the provisions of the Environmental Information Regulations (Northern Ireland) 1993(**14**).

Treatment of confidential information

27.—(1) The Executive shall inform the competent authorities and the Commission of the information it has decided shall be kept confidential in accordance with regulation 26.

(2) When the Executive receives information from a competent authority which that competent authority has decided shall be kept confidential, it shall treat that information as confidential and shall not disclose it except to the Commission or to another competent authority.

Exchange of information

28.—(1) The Executive shall inform the Commission and the competent authorities within one month from the end of each quarter of the information, including the information specified in Schedule 7, relating to every biocidal product in respect of which, in that quarter, an authorisation or, as the case may be, a registration has been granted, refused, modified, renewed or revoked under these Regulations.

(2) Where the Executive receives a summary of a dossier submitted in support of an application in a member State for inclusion, or for changes to the inclusion, of an active substance in Annex I, IA or IB and is of the opinion that the dossier is incomplete, it shall—

(a) immediately communicate that opinion to the competent authority which is responsible for the evaluation of that dossier; and

(b) without undue delay inform the Commission and the member States of that opinion.

(3) The Executive shall draw up annually a list of the biocidal products authorised or registered under these Regulations and shall send a copy of that list to the Commission and the member States.

(4) In this regulation, "quarter" means the periods in each year—

(a) commencing on 1st January and ending on 31st March;

(b) commencing on 1st April and ending on 30th June;

(c) commencing on 1st July and ending on 30th September;

(d) commencing on 1st October and ending on 31st December,

and "end of each quarter" shall be construed accordingly.

Notification of information to the Poison Information Service

29.—(1) This regulation shall not apply to a biocidal product on the market in Northern Ireland on 14th May 2000 until 6th May 2003.

(2) The person responsible for first placing a biocidal product on the market in Northern Ireland shall submit to the Poison Information Service written notification of the information specified in Schedule 8 relating to that biocidal product.

(3) Subject to paragraph (4), the notification referred to in paragraph (2) shall be submitted to the Poison Information Service—

(a) within three months after the date on which these Regulations come into operation; or

(b) within one month after the date on which the biocidal product in question was first placed on the market in Northern Ireland,

whichever is the later.

(**14**) S.R. 1993 No. 45, as amended by S.R. 1998 No. 238

(4) In the case of a biocidal product which is on the market in Northern Ireland on 14th May 2000, the notification referred to in paragraph (2) shall be submitted to the Poison Information Service by 13th May 2003.

(5) A person who has submitted a notification under paragraph (2) shall also submit to the Poison Information Service written notification of any change to the information notified by him in accordance with that paragraph.

(6) Notifications to be submitted in accordance with this regulation shall be sent to the Poison Information Service at the Royal Victoria Hospital, Grosvenor Road, Belfast BT12 6BA.

(7) In the event of an emergency referred to in paragraph (4)(*c*) of Schedule 8, the individual to be contacted shall provide such further information relating to the biocidal product in question as the Poison Information Service may require.

(8) The Poison Information Service shall not disclose any information notified to it in pursuance of this regulation except to, and at the request of—

(a) a registered medical practitioner; or

(b) a person working under the direction of a registered medical practitioner,

in connection with the medical treatment of a person who may have been affected by the biocidal product in question.

Part V

Packaging, Labelling and Advertisements

Packaging

30.—(1) A person shall not place on the market an authorised biocidal product which may be mistaken for food, drink or feedingstuff unless—

(a) it is packaged to minimise the likelihood of such a mistake being made; and

(b) where that authorised biocidal product is available to the public, it contains a substance or preparation to discourage its consumption.

(2) In this regulation, "authorised biocidal product" means a biocidal product which has been authorised or registered in accordance with these Regulations or the Great Britain Regulations.

Labelling

31.—(1) A person shall not place on the market a biocidal product whose label—

(a) is misleading or gives an exaggerated impression of the authorised biocidal product; or

(b) contains, in relation to the authorised biocidal product, the descriptions "low-risk biocidal product", "non-toxic" or "harmless", or similar descriptions.

(2) Subject to paragraph (3), a person shall not place on the market an authorised biocidal product unless—

(a) that authorised biocidal product is labelled clearly and indelibly with the information specified in Schedule 9; and

(b) that information is in English, whether or not it is also in any other language.

(3) Subject to paragraph (4), the information referred to in sub-paragraphs 3, 5 to 12 and 14 of Schedule 9 may be given on the packaging of the authorised biocidal product or in an accompanying leaflet integral to the packaging of that authorised biocidal product.

(4) Where any information referred to in paragraph (3) is given in an accompanying leaflet, the authorised biocidal product shall be labelled clearly and indelibly with the words "Read attached instructions before use.".

(5) In this regulation, "authorised biocidal product" has the same meaning as it has in regulation 30.

Samples, models and drafts

32. When required to do so by the Executive, a person who has submitted an application under regulations 9 to 15 or 17 or a person who places, or has placed, a biocidal product on the market shall provide it with—

(a) a sample or model of the packaging of, or a sample or draft of the labelling of, the biocidal product in question;

(b) a sample or draft of any accompanying leaflet integral to the packaging of the biocidal product in question.

Advertisements

33.—(1) A person who places a biocidal product on the market shall ensure that—

(a) any advertisement of that biocidal product—

(i) subject to paragraph (2), contains the sentences "Use biocides safely. Always read the label and product information before use.",

(ii) does not refer to the biocidal product in a manner likely to mislead in respect of the risks of that biocidal product to humans, animals or the environment,

(iii) does not contain, in relation to the biocidal product, the descriptions "low-risk biocidal product", "non-toxic" nor "harmless", nor similar descriptions; and

(b) the sentences referred to in sub-paragraph (*a*)(i) shall be clearly distinguishable from the rest of the advertisement.

(2) The word "biocides" in the first sentence required by paragraph (1)(*a*)(i) may be replaced by the product-type of the biocidal product being advertised.

Part VI

Miscellaneous and General

General provisions on applications for authorisations and registrations

34.—(1) An application for—

(a) an authorisation of a biocidal product under regulation 9, 11, 13, 15 or 17; and

(b) a registration of a biocidal product under regulation 10, 12 or 14,

shall be made to the Executive by, or on behalf of, the person responsible for first placing the biocidal product in question on the market in Northern Ireland.

(2) An application referred to in paragraph (1), and information submitted in support of such an application, shall be in English.

(3) An applicant shall have a permanent office within the Community.

(4) When requested to do so by the Executive, an applicant shall submit to it samples of—

(a) the biocidal product in question; and

(b) its ingredients.

(5) The Executive shall communicate its decision in respect of an application referred to in paragraph (1) to the applicant.

(6) Every authorisation and every registration granted under these Regulations shall be in writing.

(7) In this regulation, "applicant" means an applicant for—

(a) an authorisation of a biocidal product under regulation 9, 11, 13, 15 or 17; or

(b) a registration of a biocidal product under regulation 10, 12 or 14.

Files on applications

35.—(1) The Executive shall ensure that a file is compiled in respect of each application made under regulations 9 to 15 and 17.

(2) A file referred to in paragraph (1) shall include—

(a) a copy of the application to which it relates;

(b) a record of the decision relating to the application taken by the Executive;

(c) a record of the decision concerning the dossiers submitted in support of that application taken by the Executive; and

(d) a summary of those dossiers.

(3) The Executive shall, on request, make available to the competent authorities and the Commission—

(a) a copy of a file compiled in accordance with paragraph (1); and

(b) all information necessary for the full comprehension of the application to which the file relates.

(4) When requested to do so by a competent authority or the Commission, the Executive shall require an applicant under regulations 9 to 15 and 17, to forward copies of the dossiers submitted in support of his application to that competent authority or to the Commission, as the case may be and the applicant shall comply with that requirement.

Appeals

36.—(1) Subject to paragraph (3), a person may appeal to the Department of Enterprise, Trade and Investment if that person is aggrieved by a decision of the Executive—

(a) not to grant his application for—

(i) the authorisation, or the renewal of an authorisation, of a biocidal product under regulation 9 or 13,

(ii) the authorisation of a biocidal product under regulation 17, or

(iii) the registration, or the renewal of a registration, of a biocidal product under regulation 10 or 14;

(b) to impose a condition or restriction when granting his application for—

(i) an authorisation of a biocidal product under regulation 9, 13 or 17, or

(ii) a registration of a biocidal product under regulation 10 or 14;

(c) made pursuant to regulation 16(6), to prohibit him from conducting an experiment or test or to impose conditions regarding the conduct by him of an experiment or test;

(d) made pursuant to regulation 20(1), to modify a condition of use subject to which an authorisation or registration has been granted to him under regulations 9 to 15 or 17;

(e) not to modify a condition of use, subject to which an authorisation or registration has been granted to him under regulations 9 to 15 or 17, when requested by him to do so under regulation 20(2);

(f) made pursuant to regulation 19, other than paragraph (12) of that regulation, to revoke an authorisation or a registration granted to him under regulations 9 to 15 or 17;

(g) not to revoke an authorisation or registration granted to him under regulation 9 to 15 or 17, when requested by him to do so under regulation 19(12);

(h) not to issue a frame-formulation, when requested by him to do so under regulation 18(1)(*a*);

(i) made pursuant to regulation 25, not to give its consent to him referring to information;

(j) made pursuant to regulation 26(2)(*b*), not to keep confidential information submitted by him to the Executive.

(2) A person may appeal to the Department of Enterprise, Trade and Investment if that person is aggrieved by a decision of the Executive—

(a) not to grant him a period of time longer than 3 months in which to make an application under regulation 9, 10, 11 or 12 pursuant to paragraphs 5 or 8 of Schedule 12;

(b) not to grant him a certificate of exemption;

(c) to impose a condition when granting him a certificate of exemption;

(d) to revoke a certificate of exemption granted to him;

(e) relating to the period of time for which a certificate of exemption is granted to him,

and in this paragraph, "certificate of exemption" means a certificate of exemption referred to in Schedule 12.

(3) Paragraph (1) shall not apply where the decision of the Executive in question is made to give effect to a Commission decision.

(4) Chapter I of the Schedule to the Deregulation (Model Appeal Provisions) Order (Northern Ireland) 1997(**15**) shall apply where an aggrieved person appeals to the Department of Enterprise, Trade and Investment.

(5) Where an appeal is brought under paragraphs (1)(*d*), (1)(*f*) or (2)(*d*), the decision in question shall be suspended pending the final determination of the appeal.

(6) Where an appeal is brought under paragraph (1)(*j*), pending final determination of the appeal, the Executive shall not disclose the information except—

(a) to a Government Department, the Great Britain Executive, the Commission or to a competent authority; and

(b) to the extent necessary to enable the Executive to deal with the application in question made under these Regulations.

(7) A person who receives information by virtue of paragraph (6)(*b*) shall not use that information except for the purposes of the Executive.

Tests

37. Every test carried out in support of an application under regulations 9 to 15 and 17 shall be conducted in accordance with such guidance as may be issued by the Executive.

(**15**) S.R. 1997 No. 269

Enforcement, offences and civil liability

38. Schedule 10 shall have effect.

Fees

39.—(1) Schedule 11 shall have effect.

(2) The period of time within which the Executive must—

(a) comply with the provisions of regulation 6(2) when dealing with an application under regulation 5, 7(1) or 7(2);

(b) make a decision relating to an application submitted under regulations 9 to 14 or 17; or

(c) comply with the provisions of regulation 6(6) or 7(5),

shall not begin until there have been paid all fees payable under these Regulations in respect of the application or evaluation in question, other than those fees payable in accordance with paragraph 10 of Schedule 11.

(3) The Executive shall not be bound to consider a request made under regulation 20(2) until there have been paid the fee or fees payable under paragraph (6) of Schedule 11, other than those payable in accordance with paragraph 10 of that Schedule.

Transitional provisions

40. Schedule 12 shall have effect.

Application within territorial waters

41. Within territorial waters these Regulations shall apply only to and in relation to the premises and activities mentioned in paragraphs 2 to 6 of Schedule 13.

Amendments

42.—(1) At the end of regulation 3(2) of the Control of Pesticides Regulations (Northern Ireland) 1987 there shall be added the following sub-paragraph—

"(j) any biocidal product—

(i) authorised or registered under the 2001 Regulations,

(ii) placed on the market for use in an experiment or test in accordance with regulation 16 of the 2001 Regulations, or

(iii) the placing on the market and use of which are subject to any of the prohibitions specified in regulation 8 of the 2001 Regulations,

and in this sub-paragraph, "the 2001 Regulations" means the Biocidal Products Regulations (Northern Ireland) 2001, and "biocidal product" shall have the meaning assigned to it in regulation 2(1) of the 2001 Regulations.".

(2) For sub-paragraph (*d*) of regulation 3(2) of the Notification of New Substances Regulations (Northern Ireland) 1994(**16**) there shall be substituted the following sub-paragraph—

"(d) a new substance which is placed on the market exclusively for use as an active substance in one or more of the following, namely—

(i) a biocidal product to which the Biocidal Products Regulations (Northern Ireland) 2001 apply,

(**16**) S.R. 1994 No. 6, to which there are amendments not relevant to these Regulations

(ii) a biocidal product to which the Biocidal Products Regulations (Northern Ireland) 2001 would have applied but for regulation 3(2) of those Regulations,

(iii) a plant protection product to which the Plant Protection Products Regulations (Northern Ireland) 1995(**17**) apply, or

(iv) a pesticide to which the Control of Pesticides Regulations (Northern Ireland) 1987 apply."(**18**).

(3) In regulation 5(6) of the 1995 Regulations, after the words "the Food and Environment Protection Act 1985", there shall be inserted the words "or a biocidal product which has been authorised or registered under the Biocidal Products Regulations (Northern Ireland) 2001.".

Sealed with the Official Seal of the Department of Enterprise, Trade and Investment on 5th December 2001.

L.S.

Michael J. Bohill
A senior officer of the
Department of Enterprise, Trade and Investment

(**17**) S.R. 1995 No. 371, as amended by S.R. 1996 No. 456, S.R. 1997 No. 471, S.R. 1997 No. 507, S.R. 1999 No. 57 and S.R. 1999 No. 282

(**18**) S.R. 1987 No. 414, as amended by S.R. 1991 No. 203 and S.R. 1997 No. 469