S.I. No. 625/2001 - European Communities (Authorization, Placing on The Market, Use and Control of Biocidal Products) Regulations, 2001

Arrangement of regulations

S.I. No. 625 of 2001

EUROPEAN COMMUNITIES (AUTHORIZATION, PLACING ON THE MARKET, USE AND CONTROL OF BIOCIDAL PRODUCTS) REGULATIONS, 2001

I, Joe Walsh, Minister for Agriculture, Food and Rural Development, in exercise of the powers conferred on me by Section 3 of the European Communities Act, 1972 (No 27 of 1972), and for the purpose of giving effect to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998[1] hereby make the following Regulations:

Citation and commencement 1 (1) These Regulations may be cited as the European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) Regulations, 200

(2) These Regulations shall come into operation on the first day of January 2002

Interpretation 2. (1) In these Regulations:

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

"Annex I" (which is set out in Part 1 of the First Schedule) means Annex I to the Directive of 1998;

"Annex IA" (which is set out in Part 2 of the First Schedule) means Annex IA to the Directive of 1998;

"Annex IB" (which is set out in Part 3 of the First Schedule) means Annex IB to the Directive of 1998;

"Annex IIA" (which is set out in Part 4 of the First Schedule) means Annex IIA to the Directive of 1998;

"Annex IIB" (which is set out in Part 5 of the First Schedule) means Annex IIB to the Directive of 1998;

"Annex IIIA" (which is set out in Part 6 of the First Schedule) means Annex IIIA to the Directive of 1998;

"Annex IIIB" (which is set out in Part 7 of the First Schedule) means Annex IIIB to the Directive of 1998;

"Annex IVA" (which is set out in Part 8 of the First Schedule) means Annex IVA to the Directive of 1998;

"Annex IVB" (which is set out in Part 9 of the First Schedule) means Annex IVB to the Directive of 1998;

"Annex V" (which is set out in Part 10 of the First Schedule) means Annex V to the Directive of 1998;

"Annex VI" (which is set out in Part 11 of the First Schedule) means Annex VI to the Directive of 1998;

"aircraft" includes hovercraft;

"authorised officer" means an officer of the Minister appointed in writing by the Minister to be an authorised officer for the purposes of these Regulations;

"authorisation" means an administrative act by which the competent authority authorises, following an application submitted by an applicant, the placing on the market of a biocidal product in the State;

"basic substance" means a substance that is listed in Annex IB whose major use is non-pesticidal but which has some minor use as a biocide, either directly or in a product consisting of the substance and a simple diluent which itself is not a substance of concern and which is not directly marketed for the same biocidal use;

"biocidal products" means active substances and preparations containing one or more active substances, put up in the form in which they are 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. An exhaustive list of 23 product types with an indicative set of descriptions of the products within each type is provided in Annex V;

"Commission" means the Commission of the European Union;

"the competent authority" for the purposes of these Regulations is the Pesticide Control Service of the Department of Agriculture, Food and Rural Development;

"controlled product" means any product, food commodity, article or any other thing that is treated, is in the process of being treated, or has been treated with a biocidal product;

"the Directive of 1967" means Council Directive 67/548/EEC of 27 June[2] , as last amended by Commission Directive 2001/59/EC[3] ;

"the Directive of 1991" means Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[4] ;

"the Directive of 1998" means the Directive of the European Parliament and of the Council No. 98/8/EC of 16 February 1998 on the placing of biocidal products on the market[1] ;

"designated analyst" means any appropriately qualified officer of the Minister who is authorised in writing by the Minister for the purposes of these Regulations;

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

"experimental biocidal product" means a biocidal product intended for use in tests and experiments for the purposes of scientific research and development or process-oriented research and development, that has not been notified, authorised or registered for the particular use or uses concerned in accordance with these Regulations or an active substance intended exclusively for use in a biocidal product intended for use in tests and experiments for the purposes of scientific research and development or process-oriented research and development that has not been notified, authorised or registered in accordance with these Regulations for the use or uses concerned;

"frame formulation" means the specifications for a group of biocidal products having the same use and user type. Each such group of products must contain the same active substance or active substances of the same specification and their composition must present only variations from a previously authorised biocidal product that do not affect the level of risk associated with them and that do not affect their efficacy. In this context, a variation is the allowance of a reduction in the percentage of the active substance and/or an alteration in percentage composition of one or more non-active substances and/or the replacement of one or more pigments, dyes, or perfumes by others presenting the same or a lower risk, and which does not decrease efficacy;

"harmful organism" means any organism that 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, signed by the owner or owners of relevant data protected under the provisions of these Regulations, duly notarised, that states that the data or information to which it refers may be used by the competent authority for the purpose of granting an authorisation, or a registration of a biocidal product in accordance with these Regulations;

"low-risk biocidal product" means a biocidal product that contains one or more active substances listed in Annex IA, that does not contain any substance of concern and that, under the conditions of use poses only a low risk to humans, animals and the environment;

"Member State" means a Member State of the European Union;

"Minister" means the Minister of Agriculture, Food and Rural Development;

"new active substance" means an active substance that was not on the market in the European Union on or before 14 May 2000 for a biocidal purpose other than for the purposes of process-orientated research and development, or scientific research and development;

"notified biocidal product" in the case of a biocidal product on the market on or before the first day of February 2002, means the packaging, including any lab or container used with the package, and basic documentation and information as to the nature and composition and product type of any such biocide, and as t the manufacturer or manufacturers of each such biocide, has been submitted to, and been approved by administrative act of the Minister in accordance with tl Regulations of 2001 and cognate words shall be construed accordingly,

and

in the case of a biocidal product not on the market on or before the first day of February 2002, that contains one or more active substances not yet included ir Annex I or IA of the Directive of 1998 for that product type, and that only contains active substances of biocidal products on the market on or before 14 May 2000 in a Member State of the European Union for purposes other than scientific research and development or process-oriented research and development, means the packaging, including any label or container used with the package, and basic documentation and information as to the nature and composition and product type of any such biocide, and as to the manufacturer or manufacturers of each such biocide as set out in the Second Schedule, has been submitted to and been approved by administrative act of the competent authority and cognate words shall be construed accordingly;

"officially recognised testing facilities and organisations" means testing facilities and organisations which carry out experiments, studies, tests and analyses in accordance with these Regulations;

"officially recognised tests and analyses" means experiments, studies, tests and analyses carried out in accordance with the methodologies and to a standard specified from time to time and issued as guideline documentation;

"placing on the market" means any supply, whether in return for payment or free of charge, or subsequent storage other than storage followed by consignmer from the customs territory of the State or disposal. Importation of a biocidal product into the customs territory of the State shall be deemed to constitute placi on the market for the purposes of these Regulations;

"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;

"registration" means an administrative act by which the competent authority, following an application submitted by an applicant, after verification that the doss meets the relevant requirements of these Regulations, allows the placing on the market of a low-risk biocidal product in the territory of the State;

"the Regulations of 2001" means the European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations, 2001 (**S.I. No. 624 of 2001**);

"residues" means one or more of the substances present in a biocidal product that remains as a result of its use, including the metabolites of such substances a products resulting from their degradation or reaction;

"scientific research and development" means scientific experimentation, analyses 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;

"State Chemist" means the Head of the State Laboratory or a member of the staff of the State Laboratory holding the position of analyst authorised by the Stat Chemist in writing to perform functions assigned to the State Chemist under paragraph 5 of Regulation 37;

"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 that may be separated without affecting the stability of the substance or changing its composition;

"substance of concern" means any substance, other than the active substance, that has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a biocidal product in a concentration sufficient to create such an effect. Such a substance, unless there are other grounds for concern, would normally be a substance classified as dangerous in accordance with the Directive of 1967 that is present in the biocidal product in a concentration that results in the biocidal product being classified as dangerous in accordance with the Regulations of 2001;

"trials permit" means a permit granted under Regulation 17;

In these regulations, unless otherwise indicated:

(a) a reference to a Regulation is a reference to a Regulation of these Regulations;

(b) a reference to a paragraph or subparagraph is a reference to a paragraph or subparagraph of the provision in which the reference occurs;

(c) a reference to a Schedule is a reference to a Schedule to these Regulations

(3) A word or expression that is used in the Directive of 1998 or in any other Directive or Regulation of the European Union mentioned in these Regulations has, unless the contrary intention appears, the meaning in these Regulations that it has in the Directive or Regulation concerned.

(4) In these Regulations, any requirement to submit or provide information in support of an application for the authorisation or registration of a biocidal product o any other information under these Regulations, may be satisfied in whole or in part by either:

(a) the submission of a letter of access in respect of information that the competent authority already holds;

(b) a reference to information that the competent authority already holds and which, by virtue of Regulation 24 or 25, it is entitled to use for the benefit of person other than the person who submitted that information.

(5) 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 Annex I of the Directive of 1967;

(b) if the name is not in Annex I of the Directive of 1967, the name of that substance as given in European Inventory of Existing Chemical Substances (EINECS);

(c) if the name is not listed in Annex I of the Directive of 1967 or given in EINECS, the International Standards Organisation (ISO) common name of that active substance;

(d) if the name is not listed in Annex I of the Directive of 1967 or given in EINECS and there is not ISO common name for that active substance, the chemical designation of that active substance according to the International Union of Pure and Applied Chemistry (IUPAC) rules.

Application

3 (1) These Regulations concern the:

(a) authorisation of biocidal products and registration of low-risk biocidal products;

(b) mutual recognition of the authorisation of biocidal products or the registration of low-risk biocidal products issued by other Member States; and

(c) placing on the market, use and control of biocidal products

These Regulations shall not apply to products that are defined or within the scope of the legal instruments listed in the Third Schedule.

Regulation 30 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

The provisions of these regulations are in addition to, and not in substitution for, the provisions of the Diseases of Animals (Disinfectants) Order, 1975 (S.I. No 273 of 1975) as amended by the Diseases of Animals (Disinfectants) Order 1975 (Amendment) Order (S.I. No. 345 of 1978).

General provisions concerning applications for authorisation and registration of biocidal products and inclusion of active substances in Annex I, IA or IB

4 (1) Every application for:

(a) authorisation of a biocidal product in accordance with the provisions of Regulation 10, 11, 12 or 13;

(b) registration of a biocidal product in accordance with the provisions of Regulation 10, 11, or 12;

(c) inclusion of an active substance in Annex I, IA or IB in accordance with Regulation 7;

(d) authorisation of an experimental biocidal product for experimental and test purposes in accordance with the provisions of Regulation 16;

(e) a trials permit in accordance with the provisions of Regulation 17;

shall be made to the competent authority and shall be accompanied by the appropriate fee specified in Regulation 42.

(2) Every application for authorisation or registration of a biocidal product shall be made by or on behalf of the person responsible for first placing the biocidal product on the market. Every applicant for an authorisation or registration of a biocidal product shall have a business premises in a Member State.

(3) Every application for authorisation or registration of a biocidal product, shall be supported with a dossier for that biocidal product satisfying, in the light of current scientific and technical knowledge:

(a) Annex IIB and where specified the relevant parts of Annex IIIB, for biocidal products that contain chemical active substances; and

(b) Annex IIA and where specified the relevant parts of Annex IIIA for each active substance that is a chemical active substance; or

(c) Annexes IVA and IVB, where the active substance is a fungus, a micro-organism or a virus.

(4) Notwithstanding the provisions of subparagraphs (a) and (c) of paragraph (3) and subject to paragraph (7), each dossier supporting an application for the registration of a low-risk biocidal product:

(a) in the case of a biocidal product that contains one or more chemical active substances, need not satisfy the requirements of Annex IIB and where specified the relevant parts of Annex IIIB;

(b) in the case of a biocidal product that contains an active substance that is a fungus, a micro-organism or a virus, need not satisfy the requirements of Annex IVB;

(c) but shall include the following information and data:

(i) the name and address of the applicant,

(ii) the name and address of the manufacturer of the biocidal product,

(iii) the name and address of the manufacturer of each active substance in the biocidal product, and the location of each manufacturing plant, if different,

(iv) the trade name of the biocidal product,

(v) the identity and minimum content of each active substance as manufactured in the biocidal product, expressed on the basis of pure active substance and on the basis of active substance as manufactured,

(vi) the identity, function and content of other formulants in the biocidal product,

(vii) the detailed specification of each active substance as manufactured in the biocidal product

- minimum content in g/kg of pure active substance
- maximum content in g/kg of inactive isomers
- the ratio of the content of isomers /diastereo-isomers
- maximum content in g/kg of each further component, including by-products and impurities
- content of additives,

(viii) the physical and chemical properties of the biocidal product,

(ix) the product-type and field of use of the biocidal product,

(x) the intended category of user,

(xi) the intended method of use,

(xii) efficacy data,

(xiii) analytical methods,

(xiv) the proposed classification, packaging and labelling of the biocidal product in accordance with Regulation 30, including a draft of the proposed label, and

(xv) the safety data sheet prepared in accordance with the provisions of Regulation 15 of the Regulation of 2001.

(5) Dossiers provided in accordance with paragraphs (3) and (4) shall include a detailed and full description of all studies referred to in each such dossier, the resu of all such studies as well as a detailed and full description of the methods used or a bibliographical reference to such methods. The information included in ea such lossier shall be sufficient to enable the competent authority to ensure compliance with the provisions of paragraph (4) of Regulation 10.

(6) Notwithstanding paragraphs (3) and (4), information that is not necessary owing to the nature of the biocidal product or its proposed uses need not be provide Information that is not scientifically necessary or that cannot technically be supplied need not be provided. In each such case, a justification, deemed acceptab by the competent authority, must be provided.

(7) Where, in the evaluation of a dossier, it becomes apparent that additional information, including data and results from additional tests, is necessary for the purposes of evaluating the risks associated with a biocidal product, the competent authority shall require, that the applicant provide such additional information

(8) Applications referred to in paragraph (1) and any information referred to in paragraph (3), (4) and (7) submitted in support of such applications shall be in the English language.

(9) As a general principle, tests and studies included in dossiers provided in support of applications referred to in paragraph (1) shall be conducted using the methods specified in Annex V of the Directive of 1967. In the event of a method being inappropriate or not described, other test methods used should, wherev possible, be internationally recognised methods and their use must be justified.

(10) Where appropriate, tests must be conducted in accordance with the provisions laid down in Council Directive 86/609/EEC of 24 November 1986[5] and in Cou Directive 87/18/EEC of 18 December 1986[6] .

(11) Where test data exist that were generated before the adoption of the Directive of 1998 using methods other than those specified in Annex V to the Directive of 1967, the adequacy of such data for the purposes of these Regulations and the need to conduct new tests in compliance with the methods specified in Annex shall be decided on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrate animals.

Designation of National Authorities

5 (1) The Pesticide Control Service of the Department of Agriculture, Food and Rural Development is hereby designated the competent authority, responsible for carrying out the duties imposed on the Member States pursuant to the Directive of 1998.

(2) The Poisons Information Centre, Beaumont Hospital, Dublin 9 is hereby designated, the national authority for the purposes of receiving information, including chemical composition, in relation to biocidal products and for making such information available in cases where suspected poisoning arises from exposure to biocidal products.

Placing of

6 (1) Subject to paragraph (2), the placing on the market of a new active substance intended for use in a biocidal product is prohibited unless:

active substances on the market

(a) an application has been made to the competent authority or to the competent authority of another Member State for the inclusion of the active substanc in Annex I, IA or IB and is accompanied by a declaration that the active substance is intended for inclusion in a biocidal product;

(b) the competent authority concerned has in accordance with paragraph 3 of Regulation 8 agreed to the applicant forwarding a summary of the dossiers submitted in support of the application to the Commission and to the other Member States;

(c) it is classified, packaged and labelled in accordance with the provisions of the Directive of 1967.

(2) Paragraph (1) shall not apply to new active substances intended for use in process-orientated research and development or scientific research and developmen in accordance with the provisions of Regulation 15, 16 and 17.

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

7 (1) Every application for inclusion, or the variation of the inclusion, of an active substance in Annex I, IA or IB shall include:

(a) a dossier satisfying the requirements of:

(i) Annexes IIA and, where specified, the relevant parts of Annex IIIA, for each active substance that is a chemical active substance; and

(ii) Annex IVA, where the active substance is a fungus, a micro-organism or a virus;

(b) a dossier satisfying the requirements of paragraphs (2), (3), (5), (6) and (7) of Regulation 4 for at least one biocidal product containing the active substance;

(2) Every application for inclusion of an active substance in Annex I, IA or IB shall be accompanied by the appropriate fee specified in Regulation 42.

Acceptance and evaluation of applications for inclusion, or variation of inclusion, of active substances in Annex I, IA or IB

8 (1) The competent authority on receipt of an application in accordance with Regulation 7, shall:

(a) verify that the dossiers submitted satisfy the requirements specified in Regulation 7;

(b) accept the dossiers if satisfied that they comply with the requirements specified in Regulation 7;

(c) where accepted in accordance with subparagraph (b) agree to the applicant forwarding a summary of the dossiers to the Commission and the other Member States.

(2) Subject to paragraph (5) and the acceptance of the dossiers in accordance with subparagraph (1) (b), the competent authority shall:

(a) within a period of twelve months of accepting the dossiers, evaluate them;

(b) make a recommendation for the inclusion, or otherwise, of the active substance in Annex I, IA or IB; and

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

(3) If when the dossiers are evaluated in accordance with subparagraph (2) (a), it appears that further information is necessary for full evaluation of an active substance, the competent authority shall;

(a) request the applicant to submit such further information concerning the active substance as is considered necessary; and

(b) at the same time inform the Commission and the other Member States of each such request made.

(4) (a) Where a request is made for further information in accordance with paragraph (3) the twelve month period specified in subparagraph (2) (a) shall be suspended from the date the request is made until such time as the information is received and deemed by the competent authority to be acceptable.

(b) Where a request is made for additional information in accordance with paragraph (3), the fee specified in Regulation 42 shall accompany the informatio provided.

(5) (a) Where in circumstances in which a disproportionate number of applications in relation to new active substances are submitted to the competent author following acceptance of dossiers in accordance with subparagraph (1) (b), the competent authority may request that the Commission appoint another Member State to carry out the obligations specified in paragraph (2).

(b) Pending a decision by the Commission concerning a request made by the competent authority in accordance with subparagraph (a), the twelve month period specified in subparagraph (2) (a) shall be suspended from the date the request is made.

Placing on the market and use of biocidal products

9 (1) Subject to paragraphs (4) and (5), the placing on the market and use of a biocidal product after 1 April 2002 is hereby prohibited:

(a) unless it has been notified, authorised or registered in accordance with these Regulations and is placed on the market and used in compliance with any conditions or restrictions associated with such notification, authorisation or registration;

(b) unless it is a commodity substance included in Annex IB; or

(c) where such placing on the market and use has been provisionally prohibited pursuant to the provisions of Regulation 22.

(2) Subject to paragraphs (4) and (5), biocidal products shall be used:

(a) in a proper manner involving the rational combination of physical, biological, chemical or other measures as appropriate, whereby the use of the biocida product is limited to the minimum necessary;

(b) in accordance with the conditions of use established pursuant to Regulation 10 and specified on the label of the biocidal product; and

(c) in accordance with the terms of any restriction established pursuant to Regulation 22.

(3) Biocidal products shall be classified, packaged and labelled in accordance with the provisions of these Regulations.

(4) The provisions of paragraphs (1) and (2) shall not apply to experimental biocidal products intended for use in process-oriented research and development or scientific research and development in accordance with the provisions of Regulation 15, 16 and 17.

(5) The provisions of subparagraph (2) (b) shall not apply to biocidal products placed on the market and used in accordance with the transitional arrangements provided for in paragraphs (1), (2), (3) and (4) of Regulation 14.

(6) Where biocidal products are used in the workplace, such use shall be in accordance with the requirements of legislation in place for the protection of workers

(7) Notwithstanding non-compliance with the provisions of this Regulation, an authorised officer acting on behalf of the Minister, where there is no apparent risk man or to the environment through the placing on the market or use of a non-compliant biocidal product, may, by a notice in writing given to the owner or person in apparent charge or control, permit the controlled placing on the market or use of existing stocks of the biocidal product subject to specified conditio

Authorisation, registration, renewal of authorization and registration of biocidal products

10 (1) Subject to provisions of this Regulation and of paragraph (1) of Regulation 18 the placing on the market and use of a biocidal product may be authorised or registered for a maximum period of 10 years but shall end on a date not later than the date on which the entry or renewed entry in Annex I or IA of any active substance in such biocidal product expires.

(2) A biocidal product shall not be authorised by the competent authority unless the requirements specified in paragraphs (4) and (5) have been satisfied and, in addition:

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

(b) any other active substance in the biocidal product is included in Annex I or Annex IA at the time the authorisation is granted; and

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

(3) A biocidal product shall not be registered by the competent authority unless the requirements specified in paragraph (4) have been satisfied and, in addition:

(a) each active substance in the biocidal product is included in Annex IA at the time authorization is granted; and

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

(4) The competent authority shall authorise or register a biocidal product only where it has established in the light of current scientific and technical knowledge, a shown on the basis of appraisal of dossiers complying with the requirements of Regulation 4, in accordance with the common principles for the evaluation of dossiers provided in Annex VI;

having regard to:

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

(ii) the way in which a controlled product may be used;

(iii) the consequences arising from use or disposal of the biocidal product;

(iv) the consequences arising from use or disposal of the controlled product;

that the biocidal product:

(i) is sufficiently efficacious;

(ii) has no unacceptable effect on the target organisms such as unacceptable resistance or cross-resistance or unnecessary suffering and pain for

vertebrates;

(iii) has, and its residues have, no unacceptable direct or indirect effects, on human or animal health, (*e.g.* following direct exposure or exposure by means of drinking water, food or feed, indoor air or consequences in the workplace, surface water or ground water;

(iv) has, and its residues have, no unacceptable effects on the environment, having particular regard to:

- its fate and distribution in the environment, including in particular contamination of surface water (including estuarine and marine water), ground water and drinking water;

- its impact on non-target organisms;

(c) that the nature and quantity of the active substances and where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants in the biocidal product, can be determined in accordance with the requirements specified in Annex IIA, IIB, IIIA, IIIB, IVA or IVB;

(d) that the nature and quantity of the residues of toxicological or environmental significance that would result from the use of the biocidal product if such biocidal product was authorised or registered can be determined in accordance with the requirements specified in Annex IIA, IIB, IIIA, IIIB, IVA or IV

(e) that the physical and chemical properties of the biocidal product have been determined and have been deemed acceptable by the competent authority fo the purposes of the intended storage transport and use of the biocidal product.

(5) Biocidal products classified in accordance with the Regulations of 2001 as being very toxic, toxic, carcinogenic (category 1 or 2), mutagenic (category 1 or 2 or toxic for reproduction (category 1 or 2) shall not be authorised for placing on the market or use by the general public.

(6) The competent authority shall subject to Regulation 24, 25 and 42:

(a) where application is made for the authorization of a biocidal product, decide without undue delay whether or not to authorise such a biocidal product; a

(b) where application is made for the registration of a biocidal product, provided that it has the necessary scientific and technical resources at its disposal, decide within 60 days whether or not to register such a biocidal product.

(7) Notwithstanding the provisions of paragraph (6), where additional information is required in accordance with paragraph (7) of Regulation 4, the period of time within which the competent authority must make a decision to grant, or not, an authorisation or registration shall be suspended and shall not recommence unti the additional information is submitted and is deemed complete by the competent authority.

(8) In granting an authorisation or registration, the competent authority shall stipulate the restrictions and conditions, if any, relating to the placing on the market a use of the biocidal product necessary to ensure:

(a) compliance with any requirement laid down in Annex I or IA relating to an active substance in the biocidal product; and

(b) compliance with the provisions of paragraph 4;

and shall make each such authorization or registration conditional upon compliance with all such conditions and restrictions.

(9) Where other Community provisions impose requirements relevant to the conditions for the issue of an authorisation or registration and for use of a biocidal product, and particularly where these are intended to protect the health of distributors, users, workers and consumers or animal health or the environment, the competent authority shall take these into account when issuing an authorisation or registration and where necessary shall issue the authorisation or registration subject to those requirements.

(10) Authorisations or registrations granted may, subject to application being made for such renewal, subject to verification of continued compliance with the provisions of paragraphs (2), (3), (4) and (5), and subject to payment of the appropriate fee specified in Regulation 42, be renewed for a period of 10 years bu shall end on a date not later than the date on which the entry in Annex I or IA of any active substance in the biocidal product expires.

(11) Notwithstanding the provisions of paragraph (10), where application is made for the renewal of an authorisation or registration of a biocidal product, the competent authority may renew that authorisation for such a further period as is required to enable the competent authority to verify that the requirements of paragraphs (2), (3), (4) and (5) continue to be fulfilled.

(12) A certificate in relation to each authorisation or registration granted in accordance with these Regulations shall be issued to the applicant concerned.

Mutual recognition of authorisations and registrations

11 (1) Application may be made to the competent authority for the mutual recognition of an authorisation or registration of a biocidal product that has been authorise or registered in accordance with the Directive of 1998 in another Member State, provided that each active substance contained in any such biocidal product is included in Annex I or IA and conforms to the requirements thereof. Each such application shall include:

(a) where application is made for the mutual recognition of an authorisation of a biocidal product,

(i) in the case of a biocidal product that contains one or more chemical active substances, a summary of the Annex IIB and where specified the relevant parts of Annex IIB dossier submitted in support of the application for authorisation of the biocidal product in the Member State in which authorisation was granted;

(ii) in the case of a biocidal product that contains an active substance that is a fungus, a micro-organism or a virus, a summary of the Annex IVB dossier submitted in support of the application for authorisation of the biocidal product in the Member State in which the authorisation was grante

(b) where application is made for the mutual recognition of a registration of a low-risk biocidal product,

(i) with the exception of efficacy data, the dossier submitted in support of the application for registration of the low-risk biocidal product in the Member State in which the registration was granted;

(ii) a summary of the efficacy data submitted in support of the application for registration of the low-risk biocidal product in the Member State in

which the registration was granted; and

(c) a certified copy of the authorisation or registration issued, for which application for mutual recognition is made.

(2) Where pursuant to paragraph (1), application is made for the mutual recognition of an authorisation or registration of a biocidal product authorised or registere in another Member State, the applicant shall request the competent authority of the other Member State concerned to provide a copy of the file compiled in accordance with Article 8 (10) of the Directive of 1998, together all information necessary for full comprehension of the decisions made in relation to the authorisation of registration granted.

(3) Subject to paragraphs (5), (6), (7) and (8), the competent authority provided that it has the necessary scientific and technical resources at its disposal shall, within 120 days of receiving an application for the mutual recognition of an authorisation and within 60 days of receiving an application for the mutual recognition of a registration, authorise or register such biocidal product, as appropriate. Each such authorisation or registration granted shall be subject to provisions resulting from the implementation of other measures in accordance with Community law, relating to the conditions for distribution and use of biocid products intended to protect the health of the distributors, users and workers concerned.

(4) Notwithstanding paragraphs (1) and (3), applications shall not be accepted and authorisations and registrations based on the mutual recognition of authorisatio and registrations issued by other Member States shall not be granted, where such action is inconsistent with measures taken pursuant to Community law intended to protect the health of workers.

(5) Where it is established that:

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

(b) unacceptable tolerance or resistance of the target organism to a biocidal product occurs;

(c) the relevant circumstances of use, such as climate or breeding period of the target species, differ significantly from those prevailing in the Member Sta that granted the authorisation or registration with which mutual recognition is sought, such that an authorisation or registration without additional conditions may present unacceptable risks to human or animal health or the environment;

the competent authority may require adjustment of the elements listed in paragraph (6) to the different circumstances as a condition of authorisation or registration, to ensure compliance with the provisions of Regulation 10.

(6) In granting an authorisation or registration based on mutual recognition of an authorisation or registration granted by another Member State, the elements that competent authority may require to be adjusted in accordance with paragraph (5), to ensure compliance with Regulation (10), are:

(a) the directions for use of the biocidal product, including its dose rate, expressed in metric units, for each use provided for under the terms of the authorisation;

(b) the interval(s) to be observed between applications of the biocidal product, between application and the next use of the controlled product and the re-entry times for humans or animals to the area where the biocidal product has been used;

(c) the period of time, including contact time, needed for the intended biocidal effect;

(d) details of measures for adequate decontamination or cleaning of application of treatment equipment;

(e) details of means and measures for decontamination of treated areas and duration of necessary ventilation;

(f) directions for safe disposal of the biocidal product and its packaging, including any prohibition on the re-use of packaging;

(g) details concerning precautionary measures to be adopted during use, storage and transport, such as personal protective equipment to be used, measures for protection against fire, removal of food and feedingstuffs and directions to prevent human and animal exposure to the biocidal product;

(h) details of any likely direct or indirect adverse side-effects and any directions relating to first-aid;

(i) details of any specific dangers to the environment, including protection of non-target organisms and avoidance of contamination of water.

(7) Where in relation to a low-risk biocidal product registered by another Member State the competent authority believes that it does not comply with the definitio set out in paragraph (1) of Regulation 2, it shall provisionally refuse registration on the basis of mutual recognition of a registration granted by another Membe State and shall immediately communicate its concerns to the competent authority of the Member State responsible for verification of the dossier. Where withir 90 days, an agreement is not reached between the authorities concerned, the competent authority shall notify the Commission, the other Member States and th applicant of its concerns and shall provide them with an explanatory document containing the name of the product and its specification, the grounds on which believes that the there has been a failure to comply with the definition for a low-risk biocidal product and the outcome of discussions with the competent authority responsible for verification of the dossier.

(8) Where, taking account of the provisions of paragraphs (5) and (6), the competent authority believes that a biocidal product cannot satisfy the requirements specified in paragraph (4) of Regulation 10 and proposes either:

(a) to refuse authorisation or registration; or

(b) to restrict or apply certain conditions to the authorisation or registration to be granted;

it shall notify the Commission, the other Member States and the applicant of its intention and shall provide them with an explanatory document containing the name of the product and its specification, setting out the grounds on which it proposes to refuse or restrict authorisation or registration or proposes to apply certain conditions to the authorisation or registration to be granted.

(9) Where pursuant to Article 27 of the Directive of 1998, the Commission confirms or rejects a proposed decision made pursuant to paragraphs (7) or (8), the competent authority shall without delay grant or refuse authorisation or registration in compliance with the Commission decision made.

Authorisation and 12 (1) Notwithstanding the provisions of Regulation 10, application may be made in accordance with Regulation 4 for the authorisation or registration for a provisior period of the placing on the market and use of a biocidal product containing a new active substance not listed in Annex I or IA.

registration for provisional periods

(2) Subject to paragraph (4) and the provisions of paragraphs (5), (8) and (9) of Regulation 10, the competent authority may grant an authorisation for a provisio period not exceeding three years for a biocidal product referred to in paragraph (1), where following evaluation in accordance with Article 11 of the Directive 1998, it believes that:

(a) the active substance satisfies the requirements of Article 10 of that Directive in relation to its inclusion in Annex I; and

(b) the biocidal product may be expected to satisfy the requirements of paragraph (4) of Regulation 10.

(3) Subject to paragraph (4) and the provisions of paragraphs (5), (8) and (9) of Regulation 10, the competent authority may grant a registration for a provisional period not exceeding three years for a biocidal product referred to in paragraph (1), where following evaluation in accordance with Article 11 of the Directive 1998, it believes that:

(a) the active substance satisfies the requirements of Article 10 of that Directive in relation to its inclusion in Annex IA; and

(b) the biocidal product may be expected to satisfy the requirements of paragraph (4) of Regulation 10.

(4) The competent authority shall not grant an authorisation or registration for a provisional period for a biocidal product where another Member State has made a legitimate objection in accordance with Article 18 (2) of the Directive of 1998 to the completeness of the dossiers and a decision on their completeness has no yet been taken in accordance with Article 28 (2) of that Directive.

(5) Where following application of the procedures specified in Articles 27 and 28 (2) of the Directive of 1998, it is decided that the active substance does not satis the requirements of Article 10 of that Directive each authorisation or registration for a provisional period granted for a biocidal product containing that active substance shall be revoked.

(6) Where, on the expiry of the three years for which an authorisation or registration for a provisional period was granted, a decision has not been taken concerni inclusion of the new active substance concerned in Annex I or IA, the competent authority may grant an authorisation or registration for any such biocidal product for a further provisional period not exceeding one year where there are good reasons to believe that the active substance will satisfy the requirements Article 10 of the Directive of 1998.

(7) The competent authority shall inform the Commission and the other Member States of every authorisation and registration granted in accordance with paragra (6).

Emergency authorisation

13 (1) Notwithstanding the provisions of Regulation 10, 11 and 12, where application is made the competent authority may, subject to Regulation 42, authorise for a period not exceeding 120 days the placing on the market of a biocidal product not complying with the provisions of Regulation 10, 11 or 13, for a limited and controlled use if such authorisation is deemed necessary because of an unforeseen danger which cannot be contained by other means.

(2) The competent authority shall immediately inform the Commission and the other Member States of each authorisation granted in accordance with paragraph (and shall provide a justification for its action.

(3) Each authorisation granted in accordance with paragraph (1) shall be subject to such conditions and restrictions relating to the placing on the market and the u of the biocidal product as the competent authority considers appropriate.

(4) Where following application of the procedure specified in Article 28 (2) of the Directive of 1998, it is decided by the Commission that:

(a) the period for which an authorisation granted pursuant to paragraph (1) might be extended or renewed, the competent authority may extend the period validity of, or renew such authorisation subject to compliance with any conditions specified in the decision; and

(b) an authorisation granted pursuant to paragraph (1) must be revoked, the competent authority shall revoke such authorisation forthwith.

Transitional Arrangements

14 (1) Subject to paragraphs (6) and (7), a biocidal product on the market on or before the first day of February 2002 containing one or more existing active substances, where notified in accordance with subparagraph (3) (b) of regulation 5 of the Regulations of 2001 or cleared in accordance with subparagraph (2) (c) or (2) (d) of Regulation 11 of those Regulations and where classified, packaged and labelled in accordance with those Regulation, may continue to be place on the market and used until 14 May 2010, unless its active substance or active substances are included or refused entry into Annex I or IA.

(2) Subject to paragraphs (6) and (7), a biocidal product not on the market on or before the first day of February 2002, containing one or more existing active substances may be placed on the market and used until 14 May 2010, unless its active substance or active substances are included or refused entry into Annex or IA, provided that:

it is classified, packaged and labelled in accordance with of the Regulations of 2001; and

a notification application and the information, data and documentation as set out in the Second Schedule have been submitted to and been deemed acceptable by the competent authority.

(3) Subject to paragraph (6), a biocidal product not notified in accordance with paragraphs (1) or (2), that is considered identical to a biocidal product notified in accordance with paragraphs (1) or (2), subject to the provisions of Regulation 24 and 25, may be placed on the market and used until 14 May 2010, unless its active substance or active substances are included or refused entry into Annex I or IA, provided that:

(a) it is classified, packaged and labelled in accordance with of the Regulations of 2001; and

(b) evidence that the biocidal product is identical to a notified biocidal product having regard to:

(i) the manufacturer of the biocidal product;

(ii) the specification of the biocidal product;

(iii) the manufacturer of each active substance in the biocidal product;

(iv) the specification of each active substance in the biocidal product;

(v) the manufacturer of each formulant in the biocidal product; and

(vi) the specification of each formulant in the biocidal product;

has been submitted to and deemed acceptable by the competent authority.

(4) Prior to any modification of a notified biocidal product or its packaging and labelling, details of any such proposed changes and of consequential changes in th information, data or documentation submitted in accordance with paragraphs (1) (2) or (4), shall be submitted to and have been deemed acceptable by the competent authority.

(5) (a) Notwithstanding paragraphs (1), (2), (3) and (4) and subject to Regulation 42, where the competent authority is of the opinion, on grounds other than classification, packaging and labelling, that the marketing or use of a biocidal product notified in accordance with paragraphs (1), (2), (3) or (4) may po an unacceptable risk to human or animal health or to the environment, the biocidal product may no longer be placed on the market or used unless a doss in compliance with the provisions of Regulation (4) is submitted to the competent authority by the date as may be specified by the competent authority a is approved by it.

(b) Following examination in accordance with the criteria specified in paragraph (4) of Regulation 10, of a dossier submitted pursuant to subparagraph (a), the competent authority shall as appropriate:

(i) issue a certificate authorising the continued marketing and use of any such product in accordance with specified conditions and restrictions; or

(ii) revoke the notification for any such product.

(c) Where subsequent to the issuing of a certificate or to the revocation of a notification in accordance with subparagraph (b), additional information becomes available and additional facts become apparent that may affect the basis of the decision to issue a certificate or to revoke a notification, each su decision made shall be reviewed on the basis of such additional data and facts.

(6) Following the evaluation of a dossier as provided for in Article 11 (1) (a) of the Directive of 1998, the competent authority, within 6 months of the completion of the evaluation concerned, shall:

(a) where it has been decided that a new active substance not be included in Annex I, IA or IB, cancel any authorisation or registration granted in accordan with Regulation 12 for biocidal products containing the active substance; and

(b) where it has been decided to include a new active substance in Annex I, IA or IB, modify any authorisation or registration granted in accordance with Regulation 12 for biocidal products containing the active substance, such that the conditions and restrictions associated with inclusion of the active substance in Annex I, IA or IB are complied with.

(7) Following the review of an existing active substance in accordance with Article 16 (2) of the Directive of 1998, the competent authority shall:

(a) within 6 months of the completion of each such review, where a decision is taken not to include an active substance in Annex I, IA or IB, in the case o each biocidal products containing the active substance:

(i) revoke notifications for such biocidal products accepted in accordance with paragraphs (1), (2), (3) or (4);

(ii) withdraw authorisations for such biocidal products issued in accordance with paragraph (5);

(b) within 6 months of the completion of each such review, where a decision is taken to include an active substance in Annex I, IA or IB, in the case of ea biocidal product containing the active substance:

(i) revoke notifications for each such biocidal product accepted in accordance with paragraphs (1), (2), (3) or (4), where in accordance with Regulation 24 and 25, information referred to in Article 11 (1) of the Directive of 1998, may not be used to support their authorisation, unless access is demonstrated to equivalent information that can be provided pursuant to subparagraph (c);

(ii) withdraw authorisations for each such biocidal product issued in accordance with paragraph (5), where in accordance with Regulation 24 and 2 information referred to in Article 11 (1) of the Directive of 1998, may not be used to support their authorisation, unless access is demonstrated to equivalent information that can be provided pursuant to subparagraph (c);

(iii) modify notifications accepted in accordance with paragraphs (1), (2), (3) or (4) and modify authorisations issued in accordance with paragraph for each biocidal product concerned, such that the conditions and restrictions associated with inclusion of the active substance in Annex I, IA or are complied with; and

(c) where a decision is taken to include an active substance in Annex I, IA or IB:

(i) require persons marketing any biocidal product that contains the active substance, to make application for its authorisation or registration in accordance with these Regulations, at a time specified by the competent authority;

(ii) examine and authorise or register, or refuse to authorise or register each biocidal product concerned, as appropriate, in accordance with these Regulations, within a period of 2 years following the receipt of a complete application.

Research and development

15 (1) Subject to the provisions of Regulations 16 and 17, the placing on the market of an experimental biocidal product for use in research or development is prohibited unless the persons concerned:

(a) draws up and maintains written records detailing:

(i) the identity of the experimental biocidal product;

(ii) data and information to determine its labelling;

(iii) the quantity placed on the market;

(iv) the names and addresses of those persons receiving the experimental biocidal product; and

(b) compiles a dossier containing all available data and information on the possible effects of the experimental biocidal product on human or animal health o its impact on the environment.

(2) A person, who places an experimental biocidal product on the market for use in an experiment or test for the purpose of scientific research and development shall where requested submit to the competent authority the written record and the dossier relating to that experimental biocidal product which the person is required to compile and maintain in accordance with paragraph (1).

(3) A person, who intends to place on the market an experimental biocidal product for use in an experiment or test for the purpose of process-orientated research and development shall submit to the competent authority before the experimental product is placed on the market the written record and the dossier relating to that experimental biocidal product which the person is required to compile and maintain in accordance with paragraph (1).

Authorisation for experimental and test purposes

16 (1) The placing on the market for use and use of any experimental biocidal product that may involve or could result in its release into the environment is prohibite unless the experimental biocidal product has been authorised for experimental and test purposes in accordance with this Regulation.

(2) Every application for authorisation for experimental and test purposes made under this Regulation shall:

(a) be made by or on behalf of the person responsible for, or on whose behalf, the experiment or experiments, test or tests are to be conducted; and

(b) be submitted to the competent authority at least 45 days before the date which it is intended that the experiment or experiments, test or tests commenc

(3) Every application for authorisation for experimental and test purposes submitted in accordance with this Regulation shall be supported with a dossier setting o in relation to each experiment or test:

(a) the identity of the experimental biocidal product;

(b) data and information to determine its labelling;

(c) the quantity of the experimental biocidal product to be placed on the market;

(d) the name and address of each person who is to receive the experimental biocidal product;

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

(4) Tests and analyses conducted for the purposes of compiling the dossiers referred to in paragraph (3) shall be conducted under conditions, including environmental conditions in which the experimental biocidal product, if authorised for experimental and test purposes, is to be used.

(5) Notwithstanding paragraph (3) and subject to Regulation 24 and 25, applicants shall be exempted from submitting information relevant to the active substance except for that necessary for identifying the active substance, if:

(a) it is already listed in Annex I or IA, taking into account the conditions of inclusion in such Annexes, and is similar in degree of purity and nature of its impurity profile, to the specification of the active substance described in the dossier supporting the inclusion of the active substance in either Annex I, o IA; or

(b) a biocidal product containing the active substance is already authorised in accordance with paragraph (5) of Regulation 14.

(6) The competent authority shall examine every application received for the authorisation for experimental and test purposes of an experimental biocidal product and shall decide thereon within 60 days, provided that it has the necessary scientific and technical resources at its disposal.

(7) Subject to the provisions of paragraphs (9) and (10), the competent authority shall authorise for experimental and test purposes the placing on the market and use of an experimental biocidal product where satisfied that when used in accordance with the conditions and restrictions specified in accordance with paragraph (8), it has no unacceptable effects on human or animal health and no unacceptable effects on the environment.

(8) Each authorisation for experimental and test purposes granted in accordance with paragraph (7), shall:

(a) limit the quantity of experimental biocidal product to be used;

(b) specify the area, space, article, material, product or any other thing to be treated with the experimental biocidal product;

(c) specify particular packaging and labelling requirements;

(d) impose conditions necessary to ensure that the use for experimental and test purposes is controlled and subject to official supervision;

(e) impose restrictions and conditions on use, including any conditions necessary to avoid harmful effects on human health that may arise:

(i) through exposure of consumers:

- in excess of the Acceptable Daily Intake (ADI) of the residues concerned;

- in excess of the Acute Reference Dose (ARfD) of the residues concerned;

- due to residues for which the health risks associated with exposure have yet to be established;

(ii) through direct or indirect exposure of operators, other workers or the general public:

- in excess of the Acceptable Operator Exposure Level (AOEL) for the active substance or substances concerned;

- due to exposure for which the health risks associated with exposure have yet to be established;

(f) impose such further conditions, including conditions necessary to avoid harmful effects on human or animal health or unacceptable adverse influence o the environment, as the competent authority may consider necessary.

(9) Authorisations for experimental and test purposes granted may relate to more than one experiment or test and, and shall:

(a) be granted to the person responsible for, or on whose behalf, the experiments or tests are to be conducted;

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

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

(10) Authorisations for experimental and test purposes granted:

(a) shall be fixed for a period of 12 months;

(b) shall be varied as to any restrictions and conditions attached where an application for such variation is made if the competent authority is satisfied that t provisions of paragraph 7 will be complied with under the changed conditions or restrictions; and

(c) may be renewed for a further fixed period of 12 months where application for such renewal is made and the competent authority is satisfied that the provisions of paragraph 7 continue to be satisfied.

(11) Experiments and tests conducted in accordance with the conditions and restrictions specified in an authorisation for experimental and test purposes granted in accordance with this Regulation are hereby deemed to have been conducted by officially recognised testing facilities or organisations, for the purposes of thes Regulations.

Trials permits 17 (1) Subject to paragraph (2) and notwithstanding the provisions of Regulation 16, a trials permit may be granted by the competent authority to a person, organisation or an official body involved in scientific research and development or process orientated research and development, for specified premises and sit to conduct experiments and tests using experimental biocidal products, where:

(a) the person, organisation or official body makes an application to the competent authority;

(b) the competent authority is satisfied that the requirements specified in paragraph (3) are satisfied.

(2) A person, organisation or official body, that holds a trials permit is hereby exempted from the provisions of Regulation 16, in relation to experiments and tests for which the trials permit is valid, where the experiments and tests are conducted in accordance with the conditions and restrictions of the trials permit, specified pursuant to paragraphs (4) and (5).

(3) A trials permit shall not be granted for particular establishments, premises or sites, unless the applicant:

(a) owns, or has exclusive control of those premises or sites and they are suitable for conducting experiments and tests;

(b) owns, or has available, equipment and other facilities necessary for conducting experiments and tests at each such premises or site; and

(c) holds or an employee of holds, appropriate professional qualifications that are deemed appropriate by the competent authority for the purposes of carry out experiments and tests.

(4) Each trials permit granted shall be subject to the condition that:

(a) where relevant, experiments and tests are conducted in accordance with the provisions of the principles of Good Laboratory Practice (GLP);

(b) in other cases, experiments and tests be conducted by an organisation or laboratory accredited in accordance with International Organisation for Standardisation / International Electrochemical Commission international standard “General requirements for the competence of testing and calibration laboratories” (ISO / IEC 17025) to carry out such tests and experiments.

(5) Each trials permit granted shall be subject to conditions and restrictions such that use of experimental biocidal products in experiments and tests conducted in accordance with the trials permit, have no harmful effect on human and animal health and no unacceptable effects on the environment. The conditions and restrictions specified for each trials permit shall:

(a) restrict its validity to the premises, site or sites specified in the trials permit;

(b) restrict its validity to experiments and tests conducted under the direct supervision of professionally qualified personnel named in the trials permit; and

(c) be conditional on an authorisation for experimental and test purposes being obtained, in accordance with Regulation 16, in each instance in which experiments or tests for which the trials permit is not valid are to be conducted.

(6) A trials permit shall not be valid for experiments and tests involving use of experimental biocidal products unless the nature, proposed use and manner of use i experiments or tests is such that harmful residues are unlikely to occur in or on food, feed or in drinking water.

(7) Subject to the provisions of Regulation 42, trials permits granted:

(a) shall be fixed for periods of 12 months;

(b) may be varied as to any restriction or condition attached, where an application for such variation is made and the competent authority is satisfied that tl provisions of this Regulation will be satisfied under the changed conditions or restrictions; and

(c) may be renewed for further fixed periods of 12 months, where application for such renewal is made.

(8) Experiments and tests conducted in accordance with the conditions and restrictions associated with a trials permit, are hereby deemed to have been conducte by officially recognised testing facilities, for the purposes of these Regulations.

(12) A certificate in relation to each authorisation, registration or trials permit granted in accordance with these Regulations shall be issued to the applicant concern

Cancellation of authorisations and registrations

18 (1) The competent authority shall cancel any authorisation or registration granted pursuant to Regulation 10 or 11 where:

(a) an active substance in the biocidal product to which the authorisation or registration relates is removed from Annex I, or IA;

(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;

(c) the criteria specified in paragraph 4 or Regulation 10 are no longer satisfied; or

(d) it is discovered that false or misleading information was supplied concerning the facts that served as the basis on which the authorisation or registratio was granted.

(2) The competent authority may cancel an authorisation or registration granted in accordance with these Regulations if the authorisation or registration holder so requests and states the reasons for requesting cancellation.

(3) Before cancelling an authorisation or a registration pursuant to paragraph (1), the competent authority shall:

(a) inform the authorisation or registration holder of its intention and the reasons therefor;

(b) provide an opportunity to the authorisation or registration holder to submit a response; and

(c) consider any such response provided.

(4) When an authorisation or a registration granted in accordance with these Regulations is cancelled or withdrawn, a period of grace may be granted 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.

(5) The period of grace referred to in paragraph (4) shall not exceed 12 months and be of a length commensurate with the reason for the cancellation or withdraw 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 prod or the active substance.

Modification of authorisations and registrations

19 (1) Where the competent authority considers it necessary, on the basis of developments in scientific and technical knowledge and to protect human or animal hea or the environment, it shall modify the conditions of use specified in an authorisation or registration granted and in particular the manner of its use and the amounts used.

(2) The competent authority may modify an authorisation or registration granted in accordance with these Regulations if the authorisation or registration holder so requests and states the reasons for requesting the modification.

(3) Subject to continued compliance with the provisions of Regulation 10 and any requirements laid down in Annex I or Annex IA in respect of an active substanc included in the biocidal product concerned, modifications requested in accordance with paragraph (2) shall where the modification concerns an extension of u be accepted and in other cases shall be considered on their merits.

(4) Modifications requested in accordance with paragraph (2) that involve changes in the requirements laid down in Annex I or Annex IA in respect of an active substance included in the biocidal product concerned, shall not be accepted until the requirements concerned have been changed following application of the procedure laid down in Article 11 of the Directive of 1998.

Review of authorisations and registrations

20 (1) An authorisation or registration of a biocidal product granted in accordance with Regulation 10, 11, or 12 or an authorisation granted in accordance with paragraph (5) of Regulation 14 may be reviewed at any time if there are indications (*e.g.* on the basis of information submitted pursuant to Regulation 21) that any of the requirements specified in paragraph (4) of Regulation 10 are no longer satisfied.

(2) Where another Member State refuses to register a biocidal product in respect of which the competent authority pursuant to the provisions Regulation 10 or 11 granted a registration and where in accordance with Article 27 of the Directive of 1998, the refusal is confirmed by the Commission, the competent authority shall review that registration, taking the refusal of the other Member State into consideration.

(3) Where in accordance with the provisions of paragraph (1) a review of an authorisation or registration is to be undertaken, the competent authority may:

(a) if, necessary, extend the validity of the authorisation or registration for the period necessary to enable the review to be completed; and

(b) require that the holder of the authorisation or registration provide further information necessary for the review.

Notification of new

21 (1) A person to whom a notification, authorisation or registration has been granted in accordance with these Regulations shall immediately submit to the competer authority any information of which he/she is aware or may reasonably be expected to be aware concerning an active substance or a biocidal product containin

information

it, that may affect continuing notification, authorisation or registration.

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

(a) any information, including new knowledge or information on the effects of the active substance or biocidal product containing it, that may have a harm effect on human health or the environment;

(b) any changes in the source or composition of any active substance;

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

(d) information concerning the development of resistance to a biocidal product; and

(e) any other changes, such as changes in labelling or in the nature and capacity of the packaging.

(3) Each submission made pursuant to paragraph (1) shall include:

(a) a statement that the submission is made in compliance with this Regulation; and

(b) the reference number allocated by the competent authority (PCS number) to the notification, authorisation or registration for the biocidal product or products to which the submission relates.

(4) The competent authority shall immediately notify the other Member States and the Commission of any information they receive by virtue of paragraph (1) relating to potentially harmful effects for humans or the environment, changes in the composition of a biocidal product, including changes in its active substan or active substances, impurities, formulants or residues.

Emergency prohibition or restriction

22 (1) The competent authority may provisionally prohibit or restrict the placing on the market or use of a biocidal product which has been notified, authorised or registered in accordance with these Regulations, where there are valid reasons to consider that the biocidal product constitutes an unacceptable risk to human animal health or to the environment.

(2) The competent authority shall immediately notify the Commission and the other Member States of each action taken pursuant to paragraph (1) and of the reasons for such action.

Frame-formulations

23 (1) The competent authority shall on request made, or may at its own initiative, when granting an authorisation or registration in accordance with the provisions o Regulation 10 and 12, establish, where appropriate, a frame-formulation and communicate details of any such frame-formulation to the applicant in question.

(2) Subject to the provisions of Regulation 4, 24 and 25, where subsequent application is made pursuant to Regulation 10 or 12 for the authorisation or registratio of a new biocidal product based on a frame-formulation established by the competent authority, and where the applicant has a right of access to the frame-formulation in the form of a letter of access, the competent authority shall decide whether or not to grant the authorisation or registration within 60 days of receiving the application.

Data protection for information concerning active substances

24 (1) In relation to an active substance, information referred to in paragraph (3) of Regulation 4 shall not be used by the competent authority to the benefit of other applicants unless:

(a) each such other applicant has the written agreement of the owner of the information in the form of a letter of access specifying that use may be made o the information concerned by the competent authority to the benefit of such other applicant; or

(b) in the case of a new active substance, a period of 15 years has elapsed from the date of its first inclusion in Annex I or Annex IA; or

(c) in the case of an existing active substance,

(i) a period of 10 years has elapsed from the date of decision in relation to the authorisation of a biocidal product pursuant to paragraph (5) of Regulation 14, subject to the period of protection expiring no later than 14 May 2010; and

(ii) for information 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, a period of 10 years has elapsed from the date of its first inclusion ir either Annex I or Annex IA; or

(d) in the case of further information submitted for the first time for the purpose of:

(i) variation of the conditions, restrictions or other requirements associated with an entry in Annex I or Annex IA; or

(ii) maintenance of an entry in Annex I or Annex IA;

a period of 5 years has elapsed from the date of the decision following receipt of such further information.

(2) Notwithstanding the period of 5 years specified in subparagraph (1) (d), where the 5 year period expires before the periods specified in subparagraphs (1) (b) (1) (c), the 5 year period shall be extended so as to expire on the same date as those periods.

(3) The provisions of subparagraph (1) (c) shall also apply to information submitted in accordance with the provisions of the Regulations of 2001.

Data protection for information concerning biocidal

25 (1) In relation to a biocidal product, information referred to in paragraph (3) of Regulation 4 shall not be used by the competent authority to the benefit of other applicants unless:

products

(a) each such other applicant has the written agreement of owner of the information in the form of a letter of access specifying that use may be made of tl information concerned by the competent authority to the benefit of such other applicant; or

(b) in the case of a biocidal product containing a new active substance, a period of 10 years has elapsed from the date on which first authorised or registered, in any Member State; or

(c) in the case of a biocidal product containing an existing active substance,

(i) a period of 10 years has elapsed from the date of decision in relation to the authorisation of a biocidal product pursuant to paragraph (5) of Regulation 14, subject to the period of protection expiring no later than 14 May 2010; and

(ii) for information submitted for the first time in support of an application for the inclusion in Annex I or Annex IA of that existing active substance of an additional product-type for that existing active substance, a period of 10 years has elapsed from the date of inclusion in either Annex I or Annex IA; or

(d) in the case of further information submitted for the first time for the purpose of:

(i) variation of the conditions of authorisation or registration of a biocidal product; or

(ii) maintenance of an entry in Annex I or Annex IA;

a period of 5 years has elapsed from the-date of first receipt of such information.

(2) Notwithstanding the period of 5 years specified in subparagrpah (1) (d), where the 5 year period expires before the periods specified in subparagraphs (1) (b) (1) (c), the 5 year period shall be extended so as to expire on the same date as those periods.

(3) The provisions of subparagraph (1) (c) shall also apply to information submitted in accordance with the provisions of the Regulations of 2001.

Confidentiality 26 (1) Without prejudice to Council Directive 90/313/EEC[7] , an applicant may indicate in writing to the competent authority the information provided in accordance with these Regulations that the applicant considers to be commercially sensitive and disclosure of which might harm the applicant industrially or commercially and which the applicant therefore wishes to be kept confidential from all persons other than the competent authorities of the Member States and the Commission. Requests made to keep certain information confidential shall be supported by a full written justification in relation to the request made.

(2) The competent authority shall decide, on the basis of documentary evidence produced by the applicant, which information shall be kept confidential and shall ensure that information referred to in paragraph (1) is treated as confidential where such treatment is warranted. The competent authority shall keep informatic confidential that has been accepted as being confidential by another competent authority that received the information.

(3) Following the notification, authorisation or registration of a biocidal product in accordance with these Regulations, confidentiality shall not apply to:

(a) the name and address of the applicant;

(b) the name and address of the manufacturer of the biocidal product;

(c) the name and address of the manufacturer of the active substance;

(d) the names and content of the active substance or substances in the biocidal product and the name of the biocidal product;

(e) the names of other substances regarded as dangerous within the meaning of the Directive of 1967 that contribute to the classification of the biocidal product;

(f) physical and chemical data concerning the biocidal product and the active substance or active substances contained in that biocidal product;

(g) any means of rendering the active substance or biocidal product containing it harmless;

(h) a summary of the results of the tests included in dossiers submitted in accordance with Regulation 4, to establish in relation to an active substance or biocidal product:

(i) its efficacy;

(ii) its effects on humans, animals and the environment; and

(iii) where applicable, its ability to promote resistance;

(i) the recommended methods and precautions to reduce dangers from handling, storage, transport and use as well as from fire or other hazards;

(j) safety data sheets;

(k) the methods of analysis referred to in subparagraph (4) (c) and (4) (d) of Regulation 10;

(l) the methods of disposal of the biocidal product and of its packaging;

(m) the procedures to be followed and measures to be taken in the event of spillage or leakage;

(n) first aid and medical advice to be given in the case of injury to persons.

(4) If the applicant for a notification, authorisation or registration of a biocidal product or the manufacturer or the importer of that biocidal product or of an active

substance contained in that biocidal product discloses previously confidential information, the applicant, manufacturer or imported shall inform the competent authority of such disclosure and such information shall no longer be treated as being confidential for the purposes of these Regulations.

Treatment of confidential information

27 Information to be kept confidential in accordance with the provisions of Regulation 26, shall not be disclosed by the competent authority except to:

(a) the Commission or a competent authority of another Member State;

(b) persons involved in administrative proceedings to enable the competent authority to process applications made and to control active substances, biocidal products and controlled products in accordance with the provisions of these Regulations; or

(c) persons involved in, or who are to participate or be heard in, legal proceedings involving sanctions undertaken for the purpose of controlling active substance biocidal products or controlled products placed on the market and/or used.

Co-operation in the use of information

28 (1) Subject to the provisions of Regulation 24 and 25, the competent authority may agree that a second or subsequent applicant for authorisation or registration o biocidal product, may refer to data provided by the first applicant in relation to a biocidal product authorised or registered in accordance with the provisions of Regulation 10, in so far as the second or subsequent applicant can provide evidence, to the satisfaction of the competent authority, that the biocidal product fo which application is made is similar to, and its active substance is or active substances are the same as that already authorised or registered, including degree o purity and nature of impurities.

(2) Notwithstanding the provisions of paragraph (3) of Regulation 4, a prospective applicant for authorisation or registration of a biocidal product shall, before carrying out experimentation involving vertebrate animals, enquire of the competent authority:

(a) whether the biocidal product for which application is to be made is similar to a biocidal product for which authorisation or registration has been granted and

(b) as to the name and address of the holder or holders of any such authorisation or registration.

(3) Each enquiry made pursuant to paragraph (2), shall be supported with evidence to demonstrate that:

(a) the prospective applicant intends to apply on his or her own behalf for an authorisation or registration of a biocidal product; and

(b) the other information specified in accordance with the provisions of paragraph (3) of Regulation 4 is available to the prospective applicant for submissi

(4) The competent authority, where satisfied in relation to evidence provided by a prospective applicant pursuant to paragraph (3), shall provide such applicant wi the name and address of the holder or holders of relevant authorisations and registrations and shall inform the authorisation or registration holders concerned o the name and address of the prospective applicant.

(5) Authorisation or registration holders and prospective applicants referred to in paragraph (4) 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.

(6) The competent authority shall encourage information and data holders and prospective applicants to co-operate in the provision of information, with a view to limiting the duplication of testing on vertebrate animals.

Information exchange

29 (1) Within a period of one month from the end of each quarter the competent authority shall inform the competent authorities of the other Member States and the Commission of every biocidal product in respect of which, in that quarter, a notification, an authorisation or a registration, has been granted, refused, modifiec renewed or revoked in accordance with these Regulations, indicating at least:

(a) the name of the applicant for, or the holder of the notification, authorisation or registration;

(b) the trade name of the biocidal product;

(c) the name and amount of each active substance which the biocidal product contains;

(d) the name, amount and classification of other substances regarded as dangerous within the meaning of the Directive of 1967 which the biocidal product contains;

(e) the product-type for the biocidal product and the use for which it is notified, authorised or registered;

(f) the type of formulation of the biocidal product;

(g) any proposed residues limits which have been established;

(h) the conditions subject to which notification, authorisation or registration was granted;

(i) the reasons for any modification or cancellation of a notification, authorisation or registration;

(j) an indication as to whether the biocidal product is of a special type (*e.g.* a low-risk biocidal product or within a frame-formulation).

(2) When the competent authority receives a summary of a dossier submitted in support of an application made to any Member State for inclusion of an active substance in Annex I, IA or IB or for modification of the conditions or restrictions associated with any such inclusion and the competent authority believes tha the dossier is incomplete, it shall:

(a) immediately communicate that opinion to the competent authority of the Member State that is responsible for the evaluation on behalf of the Commissic of that dossier; and

(b) without undue delay inform the Commission and the competent authorities of the other Member States of that opinion.

(3) The competent authority shall draw up an annual list of the biocidal products notified, authorised or registered in accordance with these Regulations and shall send a copy of the list to the Commission and to the competent authorities of the other Member States.

Classification packaging and labelling of biocidal products

30 (1) Biocidal products shall be classified in accordance with the provisions of the Regulations of 2001.

(2) Biocidal products shall be packaged in accordance with the provisions of the Regulations of 2001 and in addition where a biocidal product:

(a) may be mistaken for food, drink, or feedingstuffs, it shall be packaged in a manner that serves to minimise the likelihood of such a mistake being made; and

(b) that is available to the general public, may be mistaken for food, drink or feedingstuffs, it shall contain components to discourage consumption of any such biocidal product.

(3) Biocidal products shall be labelled in accordance with the provisions of the Regulations of 2001 and in addition, the label of each biocidal product:

(a) shall not be misleading or give an exaggerated impression of the product and, in any case, shall not include the indications such as "low-risk biocidal product", "non-toxic", "harmless" or other similar indications;

(b) shall show clearly and indelibly the following:

(i) the identity of every active substance and its concentration in metric units;

(ii) the notification, authorisation or registration number allocated to the biocidal product by the competent authority;

(iii) the type of preparation (*e.g.* liquid concentrate, granule, wettable powder, *etc.*);

(iv) the use or uses (as set out in column 2 of Annex V) for which the biocidal product is notified, authorised or registered;

(v) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the notification, authorisation or registration;

(vi) particulars of likely direct or indirect adverse side effects and any directions for first aid;

(vii) if accompanied by a leaflet, the sentence "Read attached instructions before use";

(viii) directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging;

(ix) the formulation batch number or designation and the expiry date relevant to normal conditions of storage;

(x) the period of time needed for the biocidal to take effect;

(xi) the interval to be observed between applications of the biocidal product or between application and the next use of the treated product, or the nex access by man or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas;

(xii) particulars for adequate cleaning of equipment;

(xiii) particulars concerning precautionary measures during use, storage and transport (*e.g.* personal protective clothing and equipment, measures for protection against fire, covering of furniture, removal of food and feedingstuffs and directions to prevent animals from being exposed); and

(c) where applicable, shall show clearly and indelibly the following:

(i) the categories of users to which the biocidal product is restricted;

(ii) information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contaminatio of water;

(iii) for microbiological biocidal products, labelling requirements according to Council Directive 90/679/EEC of 26 November 1990 on the protection workers from risks related to exposure to biological agents at work[8] .

(4) The information specified in paragraph (3) included on labels on or attached to packaging mentioned in paragraph (2) shall be in the Irish language, or the English language, or in both the Irish and English languages,

(5) Information specified in subparagraph (3) (b) (i), (3) (b) (ii), and (3) (b) (ii), and (3) (b) (iv) and where applicable, subparagraph (3) (b) (vii) and (3) (c) (i) sl always appear on the label of the biocidal product.

(6) Information cited in subparagraph (3) (b) (iii), (3) (b) (v), (3) (b) (vi), (3) (b) (viii), (3) (b) (ix), (3) (b) (x), (3) (b) (xi), (3) (b) (xii), (3) (b) (xiii) and (3) (c) (ii) may be carried elsewhere on the packaging or on an accompanying leaflet integral to the packaging. Where not included on the label of a biocidal product, information cited in this paragraph shall nevertheless be regarded as label information for the purposes of these Regulations.

Samples, drafts and models

31 When requested by the competent authority, an applicant for the notification, authorisation or registration of a biocidal product or the holder of a notification, authorisation or registration for a biocidal product shall submit:

(a) a sample of the biocidal product;

(b) a sample of the active substance or active substances contained in the biocidal product;

(c) a sample of each formulant (other than active substance) in the biocidal product;

(d) analytical standards for each active substance in the biocidal product;

(e) analytical standards for any impurity of toxicological or ecotoxicological significance in the biocidal product;

(f) analytical standards for transformation products of the active substance included in the residue definition for the active substance;

(g) a sample or model of the packaging of the biocidal product or where requested a detailed specification of the packaging of the biocidal product;

(h) a sample or a draft of the label of the biocidal product, in written and electronic form; and

(i) a sample or a draft of any accompanying leaflets.

Safety data sheets 32 (1) Persons responsible for placing biocidal products on the market shall prepare safety data sheets and on request provide them to professional and industrial use and, as appropriate, other users of biocidal products to enable them to take necessary measures for the protection of the environment and health as well as hea and safety at the workplace.

(2) Safety data sheets made available pursuant to the provisions of paragraph (1) shall comply with the provisions of Commission Directive 2001/58/EC amending for the second time Directive 91/155/EEC[9] and shall be prepared:

(a) for active substances used exclusively in biocidal products; and

(b) for biocide products that:

(i) contain at least one dangerous substance;

(ii) are classified as dangerous in accordance with the Regulations of 2001; or

(iii) although not classified as dangerous in accordance with the Regulations of 2001, contain in individual concentration of 1% or more by weight in the case of non-gaseous biocidal products and 0.2% or more by volume for gaseous biocidal products at least:

- one substance posing health or environmental hazards, or

- one substance for which there is one or more EU workplace exposure limit or acceptable operator exposure level (AOEL).

(4) Safety data sheets may be supplied written on paper, or provided the person requesting the safety data sheet has means necessary for its retrieval, in electronic format.

Advertisements 33 (1) Persons responsible for placing biocidal products on the market shall ensure that every advertisement for such a biocidal product:

(a) is accompanied by the following sentences presented such that they are clearly distinguishable in relation to the whole advertisement:

- "Use biocides safely"

- "Always read the label and product information before use";

(b) does not refer to the biocidal product in a manner that is likely to mislead with respect to the risks exposure to the biocidal product involves for human animal health or the environment; and

(c) excludes indications such as "low-risk biocidal product", "non-toxic", "harmless" or other similar indication.

(2) Advertisers may replace the word "Biocides" in the first prescribed sentence specified in subparagraph (1) (a) with an accurate description of the product type being advertised, for example, wood preservative, disinfectant, rodenticide, anti-fouling product, etc.

Poisons control 34 (1) Persons responsible for placing biocidal products on the market shall ensure that for each such biocidal product, the following information is provided to the national authority specified in paragraph (2) of Regulation 5, in the form specified from time to time by that authority:

(a) the name of the biocidal product;

(b) the use or uses, for which it is so authorised, registered or notified;

(c) it's chemical composition;

(d) its physico-chemical effects;

(e) its health effects;

(f) the target organs and mode of toxic action;

(g) the symptoms and time-course of poisoning;

(h) the estimated threshold dose for toxic effects;

(i) diagnostic measures;

(j) therapeutic regimes and their effectiveness, including information on the use of antidotes, where available;

(k) contact person or persons (name, address and telephone number);

(i) for further information; and

(ii) for use in emergency situations.

(2) Information provided in accordance with paragraph (1):

(i) may only be used to meet any medical demand by means of the formulation, where necessary, and dissemination of information concerning preventativ or curative measures, in particular in emergency situations;

(ii) shall be treated in confidence and shall not be use for other purposes.

(3) Persons that provide information pursuant to paragraph (1) shall notify the competent authority of the biocidal products for which such information has been provided.

Files on applications

35 (1) The competent authority shall ensure that a file is compiled on each application for notification, authorisation or registration, of a biocidal product.

(2) Each file shall contain at least:

(a) a copy of the application;

(b) a record of the administrative decisions taken by the competent authority concerning the application;

(c) a record of the administrative decisions taken by the competent authority concerning dossiers submitted in accordance with paragraph (3) of Regulatio 4; and

(d) a summary of the administrative decisions referred to in subparagraph (c).

(3) The competent authority shall, on request, make available to the competent authorities of the other Member States and to the Commission the files provided fo in paragraph (1) in relation to applications for authorisation or registration of biocidal products, and shall supply to them, on request, all information necessary for full comprehension of decisions made in relation to such applications, and shall, where requested, ensure that the applicants concerned provide them with a copy of the technical documentation submitted in accordance with paragraph (3) of Regulation 4 in support of any such applications.

Notification of imports and exports

36 Persons that import biocidal products to which these Regulations apply into the State or export such biocidal products from the State, shall by the 1 June of each ye provide an annual return of all such imports and exports during the previous calendar year to the competent authority. Annual returns of imports and exports provide shall include the following information for each biocidal product: -

(a) the brand name of the biocidal product;

(b) the notification, authorisation or registration number allocated to the biocidal product by the competent authority;

(c) the number of packages of each size (specify package size by reference to volume or weight of contents); and

(d) the total quantity (specify quantity by reference to volume or weight) imported and exported for the year for which returns are provided.

Inspections, sampling, tests and examinations

37 (1) Subject to paragraph (5), an authorised officer may at any reasonable time enter:

(a) any place or premises in which the authorised officer has reasonable grounds for believing that:

(i) an active substance of a biocidal product is being manufactured, packaged, labelled, placed on the market, stored or used;

(ii) a biocidal product is being manufactured, packaged, labelled, placed on the market, stored or used;

(iii) a controlled product is being produced, placed on the market, processed, stored or used;

(iv) the place or premises is to be treated, is being treated or has been treated with a biocidal product;

(b) any railway wagon, vehicle, ship, vessel, aircraft, container or other thing in which the authorised officer has reasonable grounds for believing that an active substance of a biocidal product, a biocidal product or a controlled product is being transported, stored or used;

(c) any premises in which the authorised officer has reasonable grounds for believing that there are any books, documents or records, including electronic records, relating to any business whose activities consist of or include:

(i) the manufacture, packaging, labelling, placing on the market, storage, transport or use of an active substance of a biocidal product or of a biocid product, as the case may be;

(ii) the production, placing on the market, processing, storage, transport or use of any controlled product;

and there or at any other place:

(d) make such examinations, tests and inspections; and

(e) take samples in accordance with internationally accepted sampling procedures of any active substance of a biocidal product or of any biocidal product that the authorised officer finds in the course of the inspection and which the authorised officer believes is or may be an active substance or a biocidal product to which these Regulations apply; and

(f) take samples in accordance with:

(i) Commission Directive 79/700/EEC[10] ; or

(ii) the Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, recommended method of sampling for the determination of Pesticide Residues (Volume 2a, Codex Alimentarius, Food & Agriculture Organisation of the United Nations, World Health Organisation, "Pesticid Residues in Food, Methods of Analysis and Sampling" 2nd edition, Rome 2000), where appropriate, or

(iii) in accordance with other internationally recognised accepted procedures in other cases;

of any controlled product, or of any article, commodity, soil, effluent or thing that the authorised officer finds in the course of the inspection and which the authorised officer believes is or may be a controlled product to which these Regulations apply or believes has or may have been contaminated with a biocidal product to which these Regulations apply;

as the authorised officer considers appropriate and provided the quantity that a sample taken pursuant to this Regulation comprises is reasonable.

(2) A person who has in any place, on any premises, or in any railway wagon, vehicle, ship, vessel, aircraft, container or other thing, an active substance of a biocidal product, a biocidal product or a controlled product to which these Regulations apply, shall at all reasonable times:

(a) afford an authorised officer such facilities and assistance as are reasonably necessary for an inspection and for the taking of samples pursuant to this Regulation;

(b) give an authorised officer any information which he or she may reasonably require regarding the manufacture, purchase, importation, packaging, labelling, storage, transport, sale, supply or use of any such active substance or biocidal product or regarding the production, purchase, importation, processing, transport, storage, sale, supply or use of any controlled product, which is within the person's knowledge or procurement;

(c) produce to an authorised officer any document or any electronic information relating to the raw materials used in the manufacture of any such active substance or biocidal product or relating to the production of any controlled product which the authorised officer may reasonably require and when produced permit the officer to inspect and take extracts from or make a copy (including an electronic copy) of any such document or to make a copy (including an electronic copy) of any such electronic data.

(3) Any person who carries on a business involving the manufacture, purchase, importation, packaging, labelling, sale, supply, transport, storage or use of an acti substance of a biocidal product or of a biocidal product or involving the production, purchase, importation, processing, sale, supply, transport, storage or use a controlled product, shall:

(a) keep records of all transactions relating to any such active substance, biocidal product or controlled product;

(b) produce at the request of an authorised officer any records, books, other documents or electronic data relating to such business which are in his or her possession or under his or her control;

(c) permit an authorised officer to inspect and take extracts from or make copies (including electronic copies) of such records, books, other documents o electronic data and give to the authorised officer any information which is within his or her knowledge or under his or her control and which the authorised officer may reasonably require in relation to any entries therein;

(d) afford to an authorised officer such facilities and assistance as are reasonably necessary for inspecting the stock of any active substance or biocidal product, or of any controlled product on any premises on which such person carries on such a business; and

(e) give to such an authorised officer any information he or she may reasonably require in relation to such transactions, including, in particular, informatio which he or she may reasonably require regarding any active substance, biocidal product, or any controlled product specified by him or her.

(4) Where a sample is taken pursuant to this Regulation, the authorised officer concerned shall:

(a) either:

(i) divide the sample into three or more parts, each of which he or she shall seal and mark, or

(ii) where the procedure specified in subparagraph (i) would or could result in the division of individual units, identify 3 or more units of the batch o material to be sampled, or 3 or more packages or containers containing material from the batch of material to be sampled, as appropriate, each un package or container of which shall constitute a part which he or she shall seal and mark;

(b) give, deliver to, or send by registered post one part thereof to a designated analyst for analysis in accordance with paragraph (5);

(c) leave with, deliver to, or send by registered post to the defendant or prospective defendant or his or her agent, a second part thereof;

(d) where there is more than one defendant or prospective defendant, leave with, deliver to, or send by registered post to such defendant or prospective defendant or agent of such defendant or prospective defendant, one or more further parts thereof; and

(e) leave with, deliver to, or send by registered post to the State Chemist the remaining part thereof for analysis in accordance with paragraph 5.

(5) Where a designated analyst or the State Chemist receives a sample from an authorized officer in pursuance of these Regulations he or she shall make analyses thereof using appropriate analytical methods.

(6) (a) In any proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or any report on, a sample taken pursuant this Regulation shall not be adduced unless, before the proceedings were instituted, one of the parts into which the sample was divided (as required by paragraph (4)) was left with, delivered to, or sent by registered post to the defendant or his or her agent.

(b) In any proceedings for an offence under these Regulations, evidence of the presence of traces of an active substance of a biocidal product or of a biocidal product to which the Regulations apply, in or on machinery, plant or other equipment capable of use for application of the biocidal product or f treatment of a controlled product with the biocidal product, shall be evidence, until the contrary is proved, of the use of the biocidal product by the own or person in possession or in charge of the machinery, plant or equipment;

(c) In any proceedings for an offence under these Regulations, evidence of the presence of a residue of an active substance of a biocidal product or of a biocidal product to which the Regulations apply, in or on a controlled product, article, or any other thing which may have been treated with or exposed a biocidal product, shall be evidence, until the contrary is proved, of the use of the biocidal product by the owner, occupier or person in possession or i charge of the controlled product, article or other thing, as the case may be.

(d) In any proceedings for an offence under these Regulations, a certificate in the form set out in the Fourth Schedule showing the results of an analysis shall, until the contrary is shown, be sufficient evidence of the facts certified therein in relation to:

(i) the presence in a biocidal product of any active substance, impurity or formulant, and the level of any such presence;

(ii) the presence of a residue of a biocidal product and the level of such residue in or on any controlled product, article, commodity, soil, effluent or other thing; and

a document purporting to be such a certificate shall be deemed, until the contrary is shown, to be such a certificate.

(e) In any proceedings for an offence under these Regulations, each of the documents referred to in subparagraph (1) (f) may be proved by the production of a copy thereof purporting to have been published in the Official Journal of European Communities, or by the Food and Agriculture Organisation of th United Nations, as appropriate.

(f) For the purpose of these Regulations, the presence of an active substance of a biocidal product or of a biocidal product, to which these Regulations app on any premises (including any store), shall, until the contrary is shown, be sufficient evidence that the active substance or biocidal product in question or was being placed on the market by the owner or by the occupier of such premises.

(7) An authorised officer shall be furnished with a certificate of his or her appointment as an authorised officer and when exercising any power conferred on him her by these Regulations shall, if requested by any person affected, produce the certificate to that person.

(8) A designated analyst shall be furnished with a certificate of appointment by the Minister to carry out analyses as required by these Regulations.

Seizure, retention, removal and disposal

38 (1) An authorised officer may seize and retain, or seize, remove and retain an active substance of a biocidal product, a biocidal product or any controlled product which he or she believes is an active substance, biocidal product or controlled product to which these Regulations apply and in relation to which the authorised officer has reasonable grounds for suspecting that there is or has been a failure to comply with any provision of these Regulations.

(2) An authorised officer may, by a notice in writing given to the owner or to the person in apparent charge or control of an active substance of a biocidal produc or a controlled product that has been seized under this Regulation:

(a) require things specified in the notice to be done in relation to the active substance, biocidal product or controlled product before it is released by an authorised officer;

(b) in the case of an active substance or biocidal product:

(i) require the disposal of the active substance or biocidal product by the owner or person in apparent charge of the active substance or biocidal product, in a manner and within a time specified in the notice and at the expense of the owner; or

(ii) indicate the authorised officer's intention of disposing of the active substance or the biocidal product at the expense of the owner;

such disposal to be, in either case, such as will prevent the said active substance or biocidal product from being placed on the market or used.

(c) In the case of a controlled product require the disposal of the controlled product by the owner, or person in apparent charge or control of the controlle product, in a manner and within a time specified in the notice and at the expense of the owner, such disposal to be such as will prevent the said controll product from being placed on the market, used or consumed;

and in case a notice given under this paragraph that requires specified things to be done in relation to an active substance, a biocidal product or controlled product, the authorised officer shall retain control of the active substance, biocidal product or controlled product to which the notice relates until the requirements of the notice have been complied with.

(3) Where a notice is given under this Regulation, a person shall not, without the consent of the authorised officer by whom the notice was given sell, use, move, dispose of or otherwise interfere with the active substance, biocidal product or a controlled product in any way pending compliance with the requirements of t notice.

(4) Any person who is aggrieved by a notice given under paragraph (2) in relation to an active substance or a biocidal product may, not later than the expiration o period of seven days beginning on the date of the notice, appeal against the notice to the District Court in the District Court District in which the notice has be served.

(5) Disposal of an active substance or a biocidal product, pursuant to a notice given under paragraph (2), shall not take place until:

(a) the period during which an appeal under paragraph (4) may be taken against the notice has expired; or

(b) an appeal under that paragraph is determined or withdrawn.

(6) (a) Where an appeal is made to the District Court under paragraph (4), that Court, if it is satisfied that:

(i) the active substance or biocidal product to which the relevant notice relates is one to which these Regulations apply; and

(ii) if the active substance or biocidal product were to be released, it might be placed on the market or used for purposes not notified, authorised, or registered in accordance with these Regulations; or

(iii) there has been a failure to comply with the provisions of these Regulations,

shall order that the active substance, or biocidal product be disposed of in the manner specified in the notice, or in such other manner as may be specifi in the Court's order and which, in the opinion of the Court, will prevent the active substance or biocidal product from being placed on the market or use

(b) Where an order made by the District Court under this paragraph requires an active substance or biocidal product to which it relates to be disposed of b an authorised officer, the cost of such disposal shall be recoverable by the Minister as a simple contract debt in any Court of competent jurisdiction fror the person who is either the owner or the person in apparent charge or control of the active substance or biocidal product, as the case may be, at the tir of its seizure under this Regulation.

(7) Notwithstanding paragraph (2) and the requirements of these Regulations, the method of disposal specified in a notice given under paragraph (2) may include use subject to such conditions as the authorised officer may specify in the notice, provided that the authorised officer is satisfied that there is no unacceptable risk to human and animal health or adverse effect on the environment by such proposed use.

(8) In the case of a notice given under paragraph (2) which indicates an intention to dispose of an active substance or a biocidal product, the ownership of such active substance or biocidal product shall, in the absence of an appeal by the owner against the notice to the District Court, vest in the Minister on the expiratic of a period of 7 days beginning on the date of the notice. In the event of an appeal by the owner against the notice to the District Court, ownership of the activ substance or biocidal product shall vest in the Minister if the Court makes an order under paragraph (6) that requires the active substance or biocidal product t be disposed of by an authorised officer.

(9) In the case of a notice under paragraph (2) that requires the disposal at the expense of the owner of an active substance or of a biocidal product that has been seized under this Regulation and where there has been a failure to pay, the cost of such disposal shall be recoverable by the Minister as a simple contract debt any Court of competent jurisdiction from the person who was either the owner or the person in apparent charge or control of the active substance or biocidal product at the time of its seizure under this Regulation.

(10) Where there has been failure to comply with a requirement of a notice given under paragraph (2) with respect to a controlled product, an authorised officer w in pursuance of this Regulation has seized such a controlled product may, on giving notice in writing to the owner, or the person in apparent charge or control the controlled product of his or her intention to do so, apply to the District Court in the District Court district in which the notice has been served for an order directing that the controlled product be disposed of (by destruction or otherwise) in a manner, specified in the order, that will prevent the controlled product being placed on the market, used or consumed, as the case may be.

(11) Where an application is made under paragraph (10) to the District Court for an order directing the disposal of a controlled product, the Court, if it is satisfied that:

(a) the controlled product to which the notice relates contains within it or on it a residue of a biocidal product in excess of the maximum residue limit (MR specified on inclusion of an active substance in Annex I, Annex IA or Annex IB; or

(b) the controlled product to which the notice relates is intended or may be used for human or animal consumption, contains within it or on it residues of a biocidal product and if consumed may constitute a danger to human or animal health; or

(c) the controlled product to which the notice relates contains within it or on it a residue of a biocidal product and if placed on the market or used may constitute a danger to human or animal health or the environment;

shall order that the controlled product be disposed of (by destruction or otherwise) in a manner, specified in the order, that will prevent its being placed on the market, used or consumed, as the case may be.

(12) Where an order is made by the District Court under paragraph (11), the order may provide that the controlled product to which it relates shall be disposed of i the manner specified in the notice given under paragraph (2), or in such other manner as may be specified in the Court's order and which, in the opinion of the Court, will prevent the controlled product being placed on the market, used or consumed, as the case may be.

Where an order made by the District Court under paragraph (11) requires that a controlled product to which it relates be disposed of by an authorised officer, the cost of disposing of the controlled product concerned, pursuant to and in accordance with the order shall be recoverable by the Minister as a simple contra debt in any Court of competent jurisdiction from the person who was either the owner, or in apparent charge or control of the controlled product, at the time was seized.

General offences

39 (1) A person who contravenes Regulation 6 or 9, paragraph (1) of Regulation 15, paragraph (1) of Regulation 16 or Regulation 22 shall be guilty of an offence an shall be liable on summary conviction to a fine not exceeding €1,905 to imprisonment for a term not exceeding six months, or to both.

(2) If any person:

(a) tampers with an active substance or a biocidal product so as to procure that any sample of it taken pursuant to Regulation 37 does not correctly repres the active substance or the biocidal product; or

(b) tampers with any controlled product, article, commodity, soil, effluent, or thing treated with or contaminated with a biocidal product so as to procure t any sample of it taken pursuant to Regulation 37 does not correctly represent the controlled product, article, commodity, soil, effluent, or thing; or

(c) tampers or interferes with any sample taken pursuant to these Regulations,

he or she shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €1,905 or to imprisonment for a term not exceeding si months or to both.

(3) A person who:

fails to comply with the requirements of Regulation 4 or 7, paragraphs (1), (2), (3), (4) or (5) of Regulation 14, paragraphs (2) or (3) of Regulation 15, paragraph (2), (3), (4) or (5) of Regulation 16, paragraphs (2), (4) or (5) of Regulation 17, paragraph (1) of Regulation 19, Regulation 21, paragraph (4

of Regulation 26, paragraphs (2) or (5) of Regulation 28, Regulation 30, 31, 32, 33, 34 or 36, paragraphs (2) or (3) of Regulation 37 or paragraph (3) o Regulation 38;

(b) obstructs or interferes with an authorised officer in the course of exercising a power conferred on him or her by Regulation 37 or 38 or paragraph (9) Regulation 42; or

(c) in the context of Regulation 4 or 7, paragraph (1) of Regulation 11, paragraphs (2), (3), (4) or (5) of Regulation 14, paragraphs (2) or (3) of Regulatio 15, paragraphs (2), (3), (4), or (5) of Regulation 16, paragraph (1) of Regulation 17, paragraph (2) of Regulation 19, paragraph (3) of Regulation 20, Regulation 21, paragraph (1) of Regulation 26, paragraph (3) of Regulation 28, or Regulation 34 or 36 submits false or misleading information, or who gives false information when requested to provide information under paragraphs (2) or (3) of Regulation 37 or paragraph (9) of Regulation 42;

shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €1,905, to imprisonment for a term not exceeding six months, o to both.

(4) Where an offence under these Regulations has been committed by a body corporate and is proved to have been so committed with the consent, or connivance of, or to be attributable to any neglect on the part of any director, manager, secretary or other officer of the body corporate, or a person who was purporting act in any such capacity, that person as well as the body corporate, shall be guilty of an offence and shall be liable to be proceeded against as if he or she were guilty of the first mentioned offence.

(5) On summary conviction of an offence, the defendant shall be liable for the cost of any analysis carried out by a designated analyst or by the State Chemist und paragraph (5) of Regulation 37.

Prosecutions and specific rules of evidence

40 (1) The Minister may prosecute an offence under these Regulations.

(2) In proceedings for an offence under Regulation 39 (1), evidence that claims have been made that a substance, preparation or product renders harmless, destroys, deters, gives protection against, or prevents the action of, or otherwise exerts a controlling effect on any harmful organisms by chemical or biologic means, shall, until the contrary is shown, be sufficient evidence that it is a biocidal product to which these Regulations apply.

Referee analyses

41 (1) Where an appeal is made to the District Court concerning the results of any analysis made by a designated analyst under paragraph (5) of Regulation 37, the results of analysis of the third or subsequent part of the sample made by the State Chemist, in the form of a certificate set out in the Fifth Schedule, shall if the Court or the defendant so requests, be made available by the State Chemist.

(2) Where in accordance with paragraph (1), the State Chemist is requested to make the results of an analysis carried out by him or her available, copies of the certificate in the form set out in the Fifth Schedule shall be provided to the defendant and to the designated analyst concerned.

Fees

42 (1) (a) The acceptance and consideration of each application for:

(i) inclusion or variation of the inclusion of an active substance in Annex I, or IA or IB;

(ii) authorisation or registration or renewal of authorisation or registration of a biocidal product;

(iii) mutual recognition of an authorisation or registration of a biocidal product that has been authorised or registered by another Member State;

(iv) modification of an authorisation or registration of a biocidal product;

(v) review of an authorisation or registration of a biocidal product;

(vi) authorisation or registration for a provisional period of a biocidal product or renewal of authorisation or registration for a provisional period of a biocidal product;

(vii) authorisation for experimental and test purposes, renewal of authorisation for experimental and test purposes, or variation in the conditions or restrictions attached to an authorisation for experimental and test purposes of a biocidal product;

(viii) a trials permit, renewal of a trials permit, or variation in the conditions or restrictions attached to a trials permit;

(ix) emergency authorisation of a biocidal product;

(x) notification of a biocidal product or modification of a notification of a biocidal product;

(b) the acceptance and consideration of additional data and information submitted in relation to an application for authorisation or registration of a biocidal product or in relation to the inclusion of an active substance in Annex I, IA or IB; and

(c) the provision of certified copies of certificates of authorisation, registration or notification for biocidal products;

shall be subject to the payment of the fees specified in the following paragraphs.

(2) The acceptance and consideration of every application for:

(a) (i) inclusion of an active substance in Annex I, IA or IB;

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

(iii) variation of any such inclusion,

shall be subject to the payment of the fee, or fees as appropriate, set out in column (2) of Part 1 of the Sixth Schedule, payable to the Minister in respec of the evaluation of the dossiers set out in column (1) of Part 1 thereof;

(b) authorisation or registration or renewal of an authorisation or registration of a biocidal product in accordance with Regulation 10 or 12, paragraph (5) o Regulation 14 or Regulation 20, shall be subject to the payment of the fee, or fees as appropriate, set out in column 2 of Part 2 the Sixth Schedule, paya to the Minister in respect of the evaluation of the dossiers set out in column (1) of Part 2 thereof;

mutual recognition of an authorisation or registration of a biocidal product that has been authorised or registered **[illegible]** another Member State, in accordance with Regulation 11 shall be subject to payment of a fee payable to the Minister in an amount as he may by order determine;

modification of an authorisation or registration of a biocidal product in accordance with Regulation 19, shall be subject to payment of the fee, or fees as appropriate, set out in column 2 of Part 3 of the Sixth Schedule, payable to the Minister in respect of each such modification in relation to a category se out in column (1) of the said Part 3 thereof;

minor amendment of the packaging and labelling of a biocidal product or of the information provided in support an authorisation or registration granted i accordance with Regulations 10, 11, or 12 for a biocidal product, shall be subject to payment of a fee of €190 payable to the Minister; and

emergency authorisation of a biocidal product in accordance with Regulation 13 shall be subject to payment of a fee payable to the Minister in an amour as he may by order determine.

(3) Where in relation to the consideration of an application for inclusion, variation of the inclusion or renewal of the inclusion of an active substance in Annex I, o IA or IB, or in relation to the consideration of an application for authorisation or registration or renewal of authorisation or registration of a biocidal product, it necessary to request the submission of further information in accordance with paragraph (7) of Regulation 4 or paragraph (3) of Regulation 8, the considerati of such further information shall be subject to payment of a fee payable to the Minister in an amount as he may by order determine.

(4) The provision in response to requests received of certified copies of certificates of notification, authorisation or registration for biocidal products shall be subj to payment of a fee payable to the Minister in an amount as he may by order determine.

(5) (a) The acceptance and consideration of every application for notification of a biocidal product not on the market on or before the first day of February 20 in accordance with paragraph (2) of Regulation 14, shall be subject to payment of a fee of € 254 payable to the Minister.

(b) The acceptance and consideration of every application for notification of a biocidal product not on the market on or before the first day of February 20 that is identical to a biocidal product already notified in accordance with paragraph (3) of Regulation 14, shall be subject to payment of a fee of € 254 payable to the Minister.

(c) The acceptance and consideration of every application for modification of a notification in accordance with paragraph (4) of Regulation 14 shall be subject to payment of a fee of €190 payable to the Minister.

(6) (a) The acceptance and consideration of every application for the authorisation for experimental and test purposes of a biocidal product in accordance with Regulation 16 shall be subject to the payment of a fee payable to the Minister in an amount as he may by order determine.

(b) The acceptance and consideration of every application for renewal of an authorization for experimental and test purposes of a biocidal product in accordance with Regulation 16 shall be subject to the payment of a fee payable to the Minister in an amount as he may by order determine.

(c) The acceptance and consideration of every application for variation of the conditions or restrictions attached to an authorization for experimental and te purposes of a biocidal product in accordance with Regulation 16 shall be subject to the payment of a fee payable to the Minister in an amount as he may by order determine.

(7) (a) The acceptance and consideration of every application for a trials permit in accordance with Regulation 17 shall be subject to the payment of a fee payable to the Minister in an amount as he may by order determine.

(b) The acceptance and consideration of every application for renewal of a trials permit in accordance with Regulation 17 shall be subject to the payment o fee payable to the Minister in an amount as he may by order determine.

(c) The acceptance and consideration of every application for variation of the conditions or restrictions attached to a trials permit in accordance with Regulation 17 shall be subject to the payment of a fee payable to the Minister in an amount as he may by order determine.

(8) (a) Authorisation or registration, whether or not, for a provisional period, or notification, granted in accordance with the requirements of these Regulations notification or clearance granted before the first day of February 2002 in accordance with the provisions of the Regulations of 2001 shall be revoked if there is a failure to pay the annual fee set out in Part 4 of the Sixth Schedule, within 30 days of the annual fee falling due, but renewal of authorization, registration, notification or clearance, as appropriate, may be granted where application is made more than 30 days but not more than 60 days after the annual fee fell due, on payment to the Minister of the late annual fee set out in Part 4 of the Sixth Schedule.

(b) The annual fees payable in accordance with subparagraphs (a) shall be paid by 1 September of each year.

(c) In the case of a biocidal product already on the market for a period of a year or more prior to the calendar year for which the annual fee is payable, the Minister may reduce the level of the annual fee payable to the Minister under this paragraph for particular biocidal products, where, on the basis of an auditor's certificate furnished to him, he is satisfied that the wholesale sales of the biocidal product during the previous calendar year did not exceed -

(i) in the case of biocidal products for household use €6,350; and

(ii) in the case of other biocidal products, €19,050;

but in all such cases, the minimum fee payable for each such biocidal product shall be €65.

(d) In the case of a biocidal product on the market for less than one year prior to the calendar year for which the annual fee is payable, the Minister may refund part of the annual fee payable in accordance with this paragraph, on a request being made to him in that behalf, where, on the basis of an auditor certificate furnished to him, he is satisfied that the wholesale sales of the biocidal product during the year for which the annual fee was paid, did not exceed -

(i) in the case of biocidal product for household use, € 6,350; and

(ii) in the case of other biocidal products, € 19,050;

but in all such cases, any refund made shall be such that for each such biocidal product, the minimum fee payable shall be € 65.

(9) A person who makes a claim for a reduction or a refund of fees in accordance with subparagraphs (8) (c) or (8) (d) shall, at all reasonable times -

(a) produce, at the request of an authorised officer, any records, books or other documents which are in his possession or under his control which substantiate such a claim,

(b) permit an authorised officer to inspect and take extracts from such records, books or other documents and give to the authorised officer any informati which is within his knowledge or under his control and which such officer may reasonably require for the purpose of verifying the claim,

(c) afford to such an authorised officer such facilities and assistance as are reasonably necessary for inspecting the stock of the relevant biocidal product i the authorised officer considers such inspection is necessary for the purpose of verifying the claim.

(10) A fee payable under these Regulations may be recovered by the Minister as a simple contract debt in any Court of competent jurisdiction.

Civil and criminal liability

43 The acceptance of a notification for a biocidal product submitted by any person, the granting to any person of an authorisation or registration for a biocidal product, the granting to any person of an authorisation for experimental and test purposes for a biocidal product or the granting to any person of a trials permit in accordance with the provisions of these Regulations, shall be without prejudice to general civil and criminal liability of the manufacturer, and where applicable, the person responsible for placing the biocidal product on the market or for using it.

Exemptions from certain provisions of the Regulations of 2001

44 Biocidal products placed on the market in compliance with the provisions of these Regulations are hereby exempted from the provisions of paragraph (5) of Regulati 5 and Regulation 15, 18 and 25 of the Regulations of 2001.

FIRST SCHEDULE

Part 1

Annex I

LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL FOR INCLUSION IN BIOCIDAL PRODUCTS

(Active substances to be included from time to time as may by order be determined by the Minister)

Part 2

Annex IA

LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL FOR INCLUSION IN LOW-RISK BIOCIDAL PRODUCTS

(Active substances to be included from time to time as may by order be determined by the Minister)

Part 3

Annex IB

LIST OF BASIC SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL

(Basic substances to be included from time to time as may by order be determined by the Minister)

Part 4

Annex IIA

COMMON CORE DATA SET FOR ACTIVE SUBSTANCES

CHEMICAL SUBSTANCES

1 Dossiers on active substances must address at least all the points listed under “Dossier requirements”. Responses provided must be supported by data. Dossier requirements must be interpreted in accordance with developments in science and technology.

2 Information that is not necessary owing to the nature of the biocidal product or its proposed uses need not be supplied. Similarly where it is not scientifically necessary or technically possible to supply information, it need not be supplied. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

Dossier requirements

I Applicant

II. Identity of the active substance

III Physical and chemical properties of the active substance

IV Methods of detection and identification

V Effectiveness against target organisms and intended uses

VI Toxicological profile for man and animals including metabolism

VII Ecotoxicological profile including environmental fate and behaviour

VIII Measures necessary to protect man, animals and the environment

IX Classification and labelling

X Summary and evaluation of Sections II to IX

The following data are required to support a submission on the points listed above

I APPLICANT

1.1 Name and address, *etc.*

1.1 Name and address, *etc.*

1.2 Active substance manufacturer (name, address, location of plant)

II IDENTITY

Common name proposed or accepted by ISO and synonyms

Chemical name (IUPAC nomenclature)

Manufacturer's development code number(s)

CAS and EC numbers (if available)

Molecular and structural formula (including full details of isomeric composition), molecular mass

Method of manufacture (syntheses pathway in summary form) of active substance

Specification of purity of the active substance in g/kg or g/l, as appropriate

Identity of impurities and additives (*e.g.* stabilisers), together with their structural formulas and the possible ranges of their content expressed as g/kg or g/l, as appropriate

Origin of natural active substance(s) or their precursor(s) *e.g.* an extract of a flower

Exposure data in conformity with Annex VIIA to Directive of 1967 i.e. exposure estimates relevant to practical conditions of use for:

- the working environment
- the environment

III PHYSICAL AND CHEMICAL PROPERTIES

3.1 Melting point, boiling point, relative density of purified active substance of stated specification

3.2 Vapour pressure (in Pa) of purified active substance of stated specification

3.3 Appearance (physical state, colour) of active substance of stated specification

3.4 Absorption spectra (UV/VIS, IR, NMR), and mass spectrum, molar extinction at relevant wavelengths, where relevant, of purified active substance of stated specification

3.5 Solubility in water including effect of pH (5 to 9) and temperature on solubility, where relevant, of purified active substance of stated specification

3.6 Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature of purified active substance of stated specification

3.7 Thermal stability, identity of relevant breakdown products

3.8 Flammability including auto-flammability and identity of combustion products

3.9 Flash-point

3.10 Surface tension

3.11 Explosive properties

3.12 Oxidising properties

3.13 Reactivity towards container material

IV ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

4.1 Analytical methods for the determination of pure active substance and, where appropriate, relevant degradation products, isomers and impurities of the active substance and additives (*e.g.* stabilisers)

4.2 Analytical methods, recovery rates and limits of determination for the active substance, and for residues thereof, where relevant in / on the following:

(a) soil

(b) air

(c) water: the applicant should confirm that the substance and any of its degradation products which fall within the definition of pesticides given for parameter 55 in Annex I to Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption[11] can be estimated with adequate reliability at the MAC specified in that Directive for individual pesticides

(d) animal and human body fluids and tissues

V EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES

5.1 Function *e.g.* fungicide, rodenticide, insecticide, bactericide

5.2 Organism(s) to be controlled and products, organisms or objects to be protected

5.3 Effects on target organisms, and likely concentration at which the active substance will be used

5.4 Mode of action (including time delay)

5.5 Field of use envisaged

5.6 User: - industrial, professional, general public (non-professional)

5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies

5.8 Likely tonnage to be placed on the market per year

VI TOXICOLOGICAL AND METABOLIC STUDIES

6.1 Acute toxicity

For studies specified at points 6.1.1 to 6.1.3, substances other than gases shall be administered *via* at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the substance and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route.

6.1.1 Oral

6.1.2 Dermal

6.1.3 Inhalation

6.1.4 Skin and eye irritation

Eye irritation testing is not necessary where the active substance has been shown to have potential corrosive properties

6.1.5 Skin sensitisation

6.2 Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study

For the studies specified at point 6.3 (where necessary), points 6.4, 6.5, 6.7 and point 6.8, the required route of administration is the oral route unless it can be justified that an alternative route is more appropriate

6.3 Short-term repeated does toxicity (28 days)

This study is not required when a sub-chronic toxicity study is available in a rodent

Sub-chronic toxicity 90-day study, two species, one rodent and one non-rodent

Chronic toxicity in a rodent and one other mammalian species.

Studies concerning the long-term toxicity of an active substance may not be required where a full justification demonstrates that these tests are not necessary

6.6 Mutagenicity studies

T□ *In-vitro* gene mutation study in bacteria

T□ *In-vitro* cytogenicity study in mammalian cells

T□ *In-vitro* gene mutation assay in mammalian cells

T□ If positive results are obtained on testing as specified at points 6.6.1, 6.6.2 or 6.6.3, an *in-vivo* mutagenicity study is required (bone marrow assay for chromosomal damage or a micronucleus test)

T□ If negative results are obtained on testing as specified in point 6.6.4 but positive results were obtained *in-vitro* tests, a second *in-vivo* study must be undertaker determine if mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow

T□ If positive results are obtained on testing as specified in point 6.6.4, a test to assess possible germ cell effects may be required

6.7 Carcinogenicity study in a rodent and one other mammalian species.

These studies may be combined with those specified at point 6.5. Studies concerning the carcinogenicity of an active substance may not be required where a full justification demonstrates that these tests are not necessary

6.8 Reproductive toxicity

If, in exceptional circumstances, it is claimed that such testing is unnecessary, that claim must be fully justified.

6.8.1 Teratogenicity test - rabbit and one rodent species

6.8.2 Fertility study - at least two generations, one species, male and female

6.9 Medical data in anonymous form

6.9.1 Medical surveillance data on manufacturing plant personnel, if available

6.9.2 Direct observation *e.g.* clinical cases, poisoning incidents if available

6.9.3 Health records, both from industry and any other available sources

6.9.4 Epidemiological studies on the general population, if available

6.9.5 Diagnosis of poisoning including specific signs of poisoning and clinical tests, if available

6.9.6 Sensitisation / allergenicity observations, if available

6.9.7 Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known

6.9.8 Prognosis following poisoning

6.10 Summary of mammalian toxicology and conclusions, including no observed adverse effect level (NOAEL), no observed effect level (NOEL), overall evaluation w regard to all toxicological data and any other information concerning the active substance. Where identified, details of suggested worker protection measures shou be included in summary form

VII ECOTOXICOLOGICAL STUDIES

7.1 Acute toxicity to fish

7.2 Acute toxicity to *Daphnia magna*

7.3 Growth inhibition test on algae

7.4 Inhibition of microbiological activity

7.5 Bioconcentration

Fate and behaviour in the environment

7.6 Degradation

7.6.1 Biotic degradation

7.6.1.1 Ready biodegradability

7.6.1.2 Inherent biodegradability, where appropriate

7.6.2 Abiotic degradation

7.6.2.1 Hydrolysis as a function of pH and identification of breakdown products

7.6.2.2 Phototransformation in water of purified active substance of stated specification, including identity of the products of transformation

7.7 Adsorption / desorption screening test

Depending on the results obtained, testing in accordance with point 1.2 and / or point 2.2 of Section XII of Annex IIIA is required

7.8 Summary of ecotoxicological effects and fate and behaviour in the environment

VIII MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire

8.2 In case of fire, nature of reaction products, combustion gases, *etc.*

8.3 Emergency measures in case of an accident

8.4 Possibility of destruction or decontamination following release in or on the following:

8.4.1 air

8.4.2 water, including drinking water

8.4.3 soil

8.5 Procedures for waste management of the active substance for industry or for professional users

8.5.1 Possibility of re-use or recycling

8.5.2 Possibility of neutralisation of effects

8.5.3 Conditions for controlled discharge and quality of leachate for disposal

8.5.4 Conditions for controlled incineration

8.6 Observations on undesirable or unintended side-effects *e.g.* on beneficial and other non-target organisms

IX CLASSIFICATION AND LABELLING

Proposals including justification for the proposals for the classification and labelling of the active substance in accordance with the Directive of 1967

Hazard symbol(s)

Indications of danger

Risk phrases

Safety phrases

X SUMMARY AND EVALUATION OF SECTIONS II TO IX

Part 5

Annex IIB

COMMON CORE DATA SET FOR BIOCIDAL PRODUCTS

CHEMICAL PRODUCTS

1 Dossiers on biocidal products must address at least all the points listed under “Dossier requirements”. Responses provided must be supported by data. Dossier requirements must be interpreted in accordance with developments in science and technology.

2 Information that is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. Similarly where it is not scientifically necessary or technically possible to supply information, it need not be supplied. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3 Where a justification acceptable to the competent authority is provided, information may be derived from existing data. In particular, the conventional methods of classification provided for in the Regulations of 2001 should be used wherever possible to minimise animal testing.

Dossier requirements

I Applicant

II Identity of the biocidal product

III Physical and chemical properties of the biocidal product

IV Methods for identification and analysis of the biocidal product

V Intended uses of the biocidal product and efficacy for these uses

VI Toxicology data for the biocidal product (additional to that for the active substance)

VII Ecotoxicology data for the biocidal product (additional to that for the active substance)

VIII Measures necessary to protect man, animals and the environment

IX Classification, packaging and labelling

X Summary and evaluation of Sections II to IX

The following data are required to support a submission on the points listed above

I APPLICANT

1.1 Name and address, *etc.*

1.2 Formulator of the biocidal product and manufacturer of the active substance(s) (names, addresses, including location of plant(s))

II IDENTITY

2.1 Trade name or proposed trade name, and manufacturer's development code number of the preparation, if appropriate

2.2 Detailed quantitative and qualitative information on the composition of the biocidal product, *e.g.* active substance(s), impurities, adjuvants, inert components

2.3 Physical state and nature of the biocidal product *e.g.* emulsifiable concentrate, wettable powder, solution

III PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES

3.1 Appearance (physical state, colour)

3.2 Explosive properties

3.3 Oxidising properties

3.4 Flash-point and other indications of flammability or spontaneous ignition

3.5 Acidity / alkalinity and if necessary pH value (1 % in water)

3.6 Relative density

3.7 Storage stability - stability and shelf life.

Effects of light, temperature and humidity on the technical characteristics of the biocidal product

Reactivity towards container material

3.8 Technical characteristics of the biocidal product *e.g.* wettability, persistent foaming, flowability, pourability and dustability

3.9 Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised

IV METHODS OF IDENTIFICATION AND ANALYSIS

4.1 Analytical method for determination of the concentration of the active substance(s) in the biocidal product

4.2 In so far as not covered by point 4.2 of Annex IIA, analytical methods, recovery rates and limits of determination for toxicologically and ecotoxicologically releva components of the biocidal product and / or residues thereof, where relevant in or on the following:

(a) soil

(b) air

(c) water (including drinking water)

(d) animal and human body fluids and tissues

(e) treated food or feedingstuffs

V INTENDED USES AND EFFICACY

5.1 Product type and field of use envisaged

5.2 Method of application including description of system used

5.3 Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used *e.g.* cooling water, surface water, water used for heating purposes

5.4 Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals

5.5 Function *e.g.* fungicide, rodenticide, insecticide, bactericide

5.6 Pest organism(s) to be controlled and products, organisms or objects to be protected

5.7 Effects on target organisms

5.8 Mode of action (including time delay) in so far as not covered by point 5.4 of Annex IIA

5.9 User: industrial, professional, general public (non-professional)

Efficacy data

5.10 The proposed label claims for the product and efficacy data to support those claims, including any available standard protocols used and details of laboratory tests or field trials carried out, where appropriate

5.11 Any other known limitations on efficacy including resistance

VI TOXICOLOGICAL STUDIES

6.1 Acute toxicity

For studies specified at points 6.1.1 to 6.1.3, biocidal products other than gases shall be administered *via* at least two routes, one of which should be the oral rout The choice of the second route will depend on the nature of the product and the likely route of human exposure. Gases and volatile liquids should be administered the inhalation route

6.1.1 Oral

6.1.2 Dermal

6.1.3 Inhalation

6.1.4 For biocidal products to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate

6.2 Skin and eye irritation

Eye irritation testing is not necessary where the biocidal product has been shown to have potential corrosive properties

6.3 Skin sensitisation

6.4 Information on dermal absorption

6.5 Available toxicological data on toxicologically relevant non-active substances (*i.e.* substances of concern)

6.6 Information concerning exposure to the biocidal product for man and the operator

Where necessary, the test(s) described in Annex IIA, shall be required for toxicologically relevant non-active substances in the preparation

VII ECOTOXICOLOGICAL STUDIES

7.1 Foreseeable routes of entry into the environment on the basis of the use(s) envisaged

7.2 Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information submitted on the active substanc itself

7.3 Available ecotoxicological information on ecotoxicologically relevant non-active substances (*i.e.* substances of concern), such as information from safety data sheets

VIII MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire

8.2 Specific procedures in case of an accident in so far as not covered by point 8.3 of Annex IIA

e.g. first-aid measures, antidotes, medical treatment if available;

emergency measures to protect the environment;

8.3 Procedures, if any, for cleaning application equipment

8.4 Identity of relevant combustion products in cases of fire

8.5 Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public (non-professional users) *e.g.* possibility of reuse, recycling or neutralisation, conditions for controlled discharge and for incineration

8.6 Possibility of destruction or decontamination following release in or on the following:

air

water, including drinking water

soil

8.7 Observations on undesirable or unintended side effects, *e.g.* on beneficial and other non-target organisms

8.8 Details of any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms

IX CLASSIFICATION, PACKAGING AND LABELLING

Proposals for packaging and labelling

Proposals for safety-data sheets, where appropriate

Justification for the proposed classification and labelling in accordance with the provisions of Regulation 30

- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases
- Packaging (type, materials, size, *etc.*) and compatibility of the preparation with proposed packaging materials

X SUMMARY AND EVALUATION OF SECTIONS II TO IX

Part 6

Annex IIIA

ADDITIONAL DATA SET FOR ACTIVE SUBSTANCES

CHEMICAL SUBSTANCES

1 Dossiers on active substances are required to address at least all the points listed under “Dossier requirements”. Responses provided must be supported by data. Dossier requirements must be interpreted in accordance with developments in science and technology.

2 Information that is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. Similarly where it is not scientifically necessary or technically possible to supply information, it need not be supplied. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

III PHYSICAL AND CHEMICAL PROPERTIES

1 Solubility in organic solvents, including effect of temperature on solubility of purified active substance of stated specification

2 Stability in organic solvents of active substance of stated specification used in biocidal products and identity of relevant breakdown products on solubility

IV ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

1 Analytical methods, recovery rates and limits of determination for the active substance, and for residues thereof, in and on food, feedingstuffs and other products where relevant

VI TOXICOLOGICAL AND METABOLIC STUDIES

1 Neurotoxicity study

If the active substance is an organophosphorus compound or if there are any other indications that the active substance may have neurotoxic properties then neurotoxicity studies are required. The adult hen shall be used as test species unless another test species is justified as being more appropriate. Where appropriate, delayed neurotoxicity tests are required. Where anticholinesterase activity is detected a test for response to reactivating agents should be considered

2 Toxic effects on livestock and pets

3 Studies concerning exposure of humans to the active substance

4 Food and feedingstuffs

If the active substance is to be used in preparations for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored the tests referred to in points 1.1 to 1.9 of Section XI are required

5 If any other tests relating to exposure of humans to the active substance deriving from exposure to biocidal products are considered necessary, the test(s) referre to in point 2 of Section XI, are required

6 If the active substance is to be used in products for treatment of plants, tests to assess the toxic effects of metabolites, if any, found in treated plants, that are different to those formed and identified in animals, are required

7 Mechanistic study - any studies necessary to clarify effects reported in toxicity studies

VII ECOTOXICOLOGICAL STUDIES

1 Acute toxicity test on one other non-aquatic non-target organism

2 If the results of ecotoxicological studies provided in accordance with Section VII of Annex IIA and if the intended use(s) of the active substance are such as to indicate a danger for the environment, the tests described in Sections XII and XIII are required

3 If the results of testing in accordance with point 7.6.1.2 of Annex IIA are negative and if the likely means of disposal of the active substance includes sewage treatment, the test described in point 4.1 of Section XIII, is required

4 Any other biodegradability tests that on the basis of the results of testing in accordance with points 7.6.1.1 and 7.6.1.2 of Annex IIA, are relevant

5 Phototransformation in air (estimation method) of purified active substance of stated specification, including identification of breakdown products

6 If the results of testing in accordance with points 7.6.1.2 in Annex IIA or of testing in accordance with point 4, above, indicate the need to do so, or the active substance undergoes little or no abiotic degradation, the tests described in points 1.1 and 2.1 and where appropriate point 3 of Section XII, are required

VIII MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

1 Identity of substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused certain dangerous substances[12]

XI FURTHER HUMAN HEALTH-RELATED STUDIES

1 Food and feedingstuffs studies

1.1 Identity of degradation, reaction products and metabolites of the active substance in treated or contaminated foods or feedingstuffs

1.2 Behaviour of the residue of the active substance, its degradation products and where relevant its metabolites on treated or contaminated food or feedingstuffs, including kinetics of disappearance

1.3 Overall material balance for the active substance.

Sufficient residue data from supervised trials are required to demonstrate that residues likely to arise from the proposed use would not be of concern for human o animal health

1.4 Estimation of potential or actual exposure of the active substance to humans through diet and other means

1.5 If residues of the active substance remain on feedingstuffs for a significant period of time, feeding and metabolism studies in livestock are required to permit evaluation of residues in food of animal origin

1.6 Effects of industrial processing and / or domestic preparation on the nature and magnitude of residues of the active substance

1.7 Proposed acceptable residue levels and justification of their acceptability

1.8 Any other available information that is relevant

1.9 Summary and evaluation of data submitted under points 1.1 to 1.8

2 Other test(s) in relation to exposure of humans

Suitable test results and a reasoned case in relation to the level of human exposure are required

XII FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1 Fate and behaviour in soil

1.1 Rate and route of degradation including identification of the processes involved and of metabolites and degradation products formed in at least three soil types unc appropriate conditions

1.2 Absorption and desorption in at least three soil types and, where relevant, absorption and desorption of metabolites and degradation products

1.3 Mobility in at least three soil types and where relevant mobility of metabolites and degradation products

1.4 Extent and nature of bound residues

2 Fate and behaviour in water

2.1 Rate and route of degradation in aquatic systems (as far as is not covered by point 7.6 of Annex IIA) including identification of metabolites and degradation products

2.2 Absorption and desorption in water / soil sediment systems and, where relevant, absorption and desorption of metabolites and degradation products

3 Fate and behaviour in air

If the active substance is to be used in preparations for fumigation, if it is to be applied by a spray method, if it is volatile, or if any other information indicates that such testing is relevant, the rate and route of degradation of the active substance in air shall be determined in as far as not covered by point 5 of Section VII

4 Summary and evaluation of point 1, 2 and 3

XIII FURTHER ECOTOXICOLOGICAL STUDIES

1 Effects on birds

1.1 Acute oral toxicity - this need not be done if an avian species was selected for study in accordance with point 1 of Section VII

1.2 Short-term toxicity - eight-day dietary study in at least one species (other than chickens)

1.3 Effects on reproduction

2 Effects on aquatic organisms

2.1 Prolonged toxicity to an appropriate species of fish

2.2 Effects on reproduction and growth rate in an appropriate species of fish

2.3 Bioaccumulation in an appropriate species of fish

2.4 *Daphnia magna* reproduction and growth rate

3 Effects on other non-target organisms

3.1 Acute toxicity to honeybees and other beneficial arthropods, *e.g.* predators.

A different test organism must be chosen to that used in accordance with point 1 of Section VII

3.2 Toxicity to earthworms and to other soil non-target macro-organisms

3.3 Effects on soil non-target micro-organisms

3.4 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

4 Other effects

4.1 Activated sludge respiration inhibition test

5 Summary and evaluation of points 1, 2, 3 and 4

Part 7

Annex IIIB

ADDITIONAL DATA SET FOR BIOCIDAL PRODUCTS

CHEMICAL PRODUCTS

1 Dossiers on biocidal products must address at least all the points listed under “Dossier requirements”. Responses provided must be supported by data. Dossier requirements must be interpreted in accordance with developments in science and technology.

2 Information that is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. Similarly where it is not scientifically necessary or technically possible to supply information, it need not be supplied. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3 Where a justification acceptable to the competent authority is provided, information may be derived from existing data. In particular, the conventional methods of classification provided for in the Regulations of 2001 should be used wherever possible to minimise animal testing.

XI FURTHER HUMAN HEALTH-RELATED STUDIES

1 Food and feedingstuffs studies

1.1 If residues of the biocidal product remain on feedingstuffs for a significant period of time, feeding and metabolism studies in livestock are required to permit evaluation of residues in food of animal origin

1.2 Effects of industrial processing and / or domestic preparation on the nature and magnitude of residues of the biocidal product

2 Other test(s) in relation to exposure of humans

Suitable test(s) and a reasoned case in relation to the level of human exposure are required for the biocidal product

XII FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1 Where relevant, the information specified in accordance with Section XII of Annex IIIA is required for ecotoxicologically relevant components of the biocidal product

2 Testing of ecotoxicologically relevant components of the biocidal product for distribution and dissipation in:

(a) soil

(b) water

(c) air

XIII FURTHER ECOTOXICOLOGICAL STUDIES

1 Effects on birds

1.1 Acute oral toxicity, if not already provided in accordance with the requirements of Section VII of Annex IIB

2 Effects on aquatic organisms

2.1 In case of application on, in, or near surface waters

2.1.1 Particular studies with fish and other aquatic organisms

2.1.2 Residue data in fish in relation to the active substance and toxicologically relevant metabolites

2.1.3 Where necessary, the studies referred to in points 2.1, 2.2, 2.3 and 2.4 of Section XIII of Annex IIIA, for relevant components of the biocidal product

2.2 If the biocidal product is to be sprayed near surface waters, an overspray study may be required to permit assessment of risks to aquatic organisms under field conditions

3 Effects on other non-target organisms

3.1 Toxicity to terrestrial vertebrates other than birds

3.2 Acute toxicity to honeybees

3.3 Effects on beneficial arthropods other than bees

3.4 Effects on earthworms and other soil non-target macro-organisms, believed to be at risk

3.5 Effects on soil non-target micro-organisms

3.6 Effects on any other specific non-target organisms (flora and fauna) believed to be at risk

3.7 If the biocidal product is in the form of bait or granules

3.7.1 Supervised trials to assess risks to non-target organisms under field conditions

3.7.2 Studies on acceptance by ingestion of the biocidal product by non-target organisms thought to be at risk

4 Summary and evaluation of points 1, 2, and 3

Part 8

Annex IVA

DATA SET FOR ACTIVE SUBSTANCES

FUNGI, MICRO-ORGANISMS AND VIRUSES

1 Dossiers on active organisms must address at least all the points listed under “Dossier requirements”. Responses provided must be supported by data. Dossier requirements must be interpreted in accordance with developments in science and technology.

2 Information that is not necessary owing to the nature of the biocidal product or its proposed uses need not be supplied. Similarly where it is not scientifically necessary or technically possible to supply information, it need not be supplied. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

Dossier requirements

I Applicant details

II Identity of the active organism

III Source of active organism

IV Methods of detection and identification

V Biological properties of active organism including pathogenicity and infectivity for target and non-target organisms including man

VI Effectiveness and intended uses

VII Toxicological profile for man and animals including metabolism of toxins

VIII Ecotoxicological profile including environmental fate and behaviour of the organisms and of toxins produced

IX Measures necessary to protect man, non-target organisms and the environment

X Classification and labelling

XI Summary and evaluation of Sections II to X

The following data will be required to support a submission on the points listed above

I APPLICANT

1.1 Name and address, *etc.*

1.2 Active substance manufacturer (name, address, location of plant)

II IDENTITY OF THE ORGANISM

2.1 Common name of the organism (including alternative and superseded names)

2.2 Taxonomic name and strain and an indication as to whether it is a stock variant or a mutant strain

For viruses, the taxonomic designation of the agent, serotype, strain or mutant

2.3 Collection and culture reference number where the culture is deposited

2.4 Methods, procedures and criteria used to establish the presence and identity of the organism (*e.g.* morphology, biochemistry, serology, *etc.*)

III SOURCE OF THE ORGANISM

3.1 Occurrence in nature or otherwise

3.2 Isolation methods for organism or active strain

3.3 Culture methods

3.4 Production methods including details of containment and procedure to maintain quality and ensure a uniform source of active organism.

For mutant strains detailed information must be provided on production methods and isolation procedures, together with details of all known differences between mutant strains and patent and naturally occurring strains

3.5 Composition of the final active organism material *i.e.* nature, purity, identity, properties, content of any impurities and extraneous organisms

3.6 Methods to prevent contamination of seed stock and loss of virulence of seed stock

3.7 Procedures for waste management

IV METHODS OF DETECTION AND IDENTIFICATION

4.1 Methods for establishing the presence and identity of the organism

4.2 Methods for establishing the identity and purity of seed stock from which batches are produced and results obtained, including information on variability

4.3 Methods to show the microbiological purity of the final product and to show that contaminants have been controlled to an acceptable level, the results obtained ar information on variability

4.4 Methods used to show that there are no human or other mammalian pathogens present as contaminants in the active agent, including in the case of protozoa and fungi, the effects of temperature (35°C and other relevant temperatures)

4.5 Methods to determine viable and non-viable (*e.g.* toxins) residues in or on treated products, foodstuffs, feedingstuffs, animal and human body fluids and tissues, soil, water and air, where relevant

V BIOLOGICAL PROPERTIES OF THE ORGANISM

5.1 History of the organism and its uses including in as far as is known its general natural history and, if relevant, its geographical distribution

5.2 Relationship to existing pathogens of vertebrates, invertebrates, plants or other organisms

5.3 Effects on target organism

Pathogenicity or type of antagonism to the host. Details of host specificity range should be included

5.4 Transmissibility, infective dose and mode of action including information on presence, absence or production of toxins with, if appropriate, information on their nature, identity, chemical structure, stability and potency

5.5 Possible effects on non-target organisms closely related to the target organism including infectivity, pathogenicity and transmissibility

5.6 Transmissibility to other non-target organisms

5.7 Any other biological effects on non-target organisms when properly used

5.8 Infectivity and physical stability when properly used

5.9 Genetic stability under environmental conditions of proposed use

5.10 Pathogenicity and infectivity to man and animals under conditions of immunosuppression

5.11 Pathogenicity and infectivity for known parasites / predators of the target species

VI EFFECTIVENESS AND INTENDED USES

6.1 Harmful organisms controlled and materials, substances, organisms or products to be treated or protected

6.2 Uses envisaged (*e.g.* insecticide, disinfectant, anti-fouling product, *etc.*)

6.3 Information or observations on undersirable or unintended side effects

6.4 Information on the occurrence or possible occurrence of the development of resistance and possible management strategies to deal with the development of resistance

6.5 Effects on target organisms

6.6 Category of user

VII TOXICOLOGICAL AND METABOLIC STUDIES

7.1 Acute toxicity

In cases where a single does is not appropriate, a set of range finding tests must be carried out to reveal highly toxic agents and infectivity

7.1.1 Oral

7.1.2 Dermal

7.1.3 Inhalation

7.1.4 Skin and where necessary eye irritation

7.1.5 Skin sensitisation and, where necessary, respiratory sensitisation and

7.1.6 For viruses and viroids, cell culture studies using purified infective virus and primary cell cultures of mammalian, avian and fish cells

7.2 Sub-chronic toxicity

40-day study, two species, one rodent, one non-rodent

7.2.1 Oral administration

7.2.2 Other routes (inhalation, dermal) as appropriate

7.2.3 For viruses and viroids, test for infectivity carried out by bio-assay or on a suitable cell culture maintained for at least seven days after administration to test anim

7.3 Chronic toxicity

Studies on two species, a rodent and one other mammalian species are required, with oral administration unless another route is more appropriate

7.4 Carcinogenicity study

May be combined with studies conducted in accordance with point in 7.3. Studies on one rodent and one other mammalian species are required

7.5 Mutagenicity studies

Tests as specified point 6.6 of Section VI of Annex IIA are required

7.6 Reproductive toxicity

Teratogenicity test - rabbit and one rodent species.

Fertility study - at least two generations, one species, male and female

7.7 Metabolism studies

Basic toxicokinetic studies - absorption (including dermal absorption) distribution and excretion in mammals including elucidation of metabolic pathways

7.8 Neurotoxicity studies

Required where there is any indication of anticholinesterase activity or other neurotoxic effects. Where appropriate, delayed neurotoxicity tests using adult hens should be performed

7.9 Immunotoxicity studies (*e.g.* allergenicity)

7.10 Incidental exposure studies

Required where the active substance is contained in products for use where human food or animal feedingstuffs are prepared, consumed or stored and / or where humans, livestock or pets are likely to be exposed to treated areas or materials

7.11 Data relating to human exposure including:

7.11.1 Medical data in anonymous form (if available)

7.11.2 Health records, medical surveillance data on manufacturing plants personnel (if available)

7.11.3 Epidemiological data (if available)

7.11.4 Poisoning incidents data

7.11.5 Diagnosis of poisoning (signs, symptoms) including details of any analytical tests

7.11.6 Proposed treatment of poisoning and prognoses

7.12 Summary of mammalian toxicology and conclusions, including no observed adverse effect level (NOAEL), no effect level (NOEL) and if appropriate an acceptab daily intake level (ADI), overall evaluation with regard to all toxicological, pathogenicity and infectivity data and any other information concerning the active organism. Where identified, details of suggested user protection measures should be included in summary form

VIII ECOTOXICOLOGICAL STUDIES

8.1 Acute toxicity to fish

8.2 Acute toxicity to *Daphnia magna*

8.3 Effects on algae growth (inhibition test)

8.4 Acute toxicity on one other, non-aquatic, non-target organism

8.5 Pathogenicity and infectivity for honeybees and earthworms

8.6 Acute toxicity and / or pathogenicity and infectivity for other non-target organisms believed to be at risk

8.7 Effects (if any) on other flora and fauna

8.8 In cases where toxins are produced, testing as specified in points 7.1 to 7.5 of Section VII of Annex IIA is required

Fate and behaviour in the environment

8.9 Spread, mobility, multiplication and persistence in air, soil and water

8.10 In cases where toxins are produced, testing as specified in points 7.6 to 7.8 of Section VII of Annex IIA is required

IX MEASURES NECESSARY TO PROTECT HUMANS, NON-TARGET ORGANISMS AND THE ENVIRONMENT

9.1 Methods and precautions to be taken for storage, handling, transport and use or in the event of fire or other likely incident

9.2 Any circumstances or environmental conditions under which the active organism should not be used

9.3 The possibility of rendering the active organism non-infective and any method for doing this

9.4 Consequences of the contamination of air, soil and water, particularly drinking water

9.5 Emergency measures in case of accident

9.6 Procedures for waste management of the active organism including specification of leachate qualities on disposal

9.7 Possibility of destruction or decontamination following release in or into air, water, soil, or other release

X CLASSIFICATION AND LABELLING

Proposals for allocation to one of the risk groups outlined in Article 2(d) of Directive 90/679/EEC[13] together with justifications for the proposals made and proposals in relation on the need for products to carry the biohazard sign specified in Annex II to Directive 90/679/EEC

XI SUMMARY AND EVALUATION OF SECTIONS II TO X

Part 9

Annex IVB

DATA SET FOR BIOCIDAL PRODUCTS

FUNGI, MICRO-ORGANISMS AND VIRUSES

1 Dossiers on biocidal products must address at least all the points listed under "Dossier requirements". Responses provided must be supported by data. Dossier requirements must be interpreted in accordance with developments in science and technology.

2 Information that is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. Similarly where it is not scientifically necessary or technically possible to supply information, it need not be supplied. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3 Where a justification acceptable to the competent authority is provided, information may be derived from existing data. In particular, the conventional methods of classification provided for in the Regulations of 2001 should be used wherever possible to minimise animal testing.

Dossier requirements

I Applicant

II Identity and composition of the biocidal product

III Technical properties of the biocidal product and any biocidal properties additional to those of the active organism

IV Methods for identification and analysis of the biocidal product

V Intended uses and efficacy for those uses

VI Toxicological information (additional to that for the active organism)

VII Ecotoxicological information (additional to that for the active organism)

VIII Measures to be adopted to protect humans, non-target organisms and the environment

IX Classification, packaging and labelling of the biocidal product

XII Summary of Sections II to IX

The following data will be required to support a submission on the points listed above

I APPLICANT

1.1 Name and address, *etc.*

1.2 Manufacturers of biocidal product and active organism(s) including location of plants

II IDENTITY OF BIOCIDAL PRODUCT

2.1 Trade name or proposed trade name and manufacturer's development code number of the biocidal product, if appropriate

2.2 Detailed quantitative and qualitative information on the composition of the biocidal product *e.g.* active organisms, inert components, extraneous organisms, *etc.*

2.3 Physical state and nature of the biocidal product *e.g.* emulsifiable concentrate, wettable powder, *etc.*

2.4 Concentration of active organism in material used

III TECHNICAL AND BIOLOGICAL PROPERTIES

3.1 Appearance (colour and odour)

3.2 Storage - stability and shelf-life.

Effects of temperature, method of packaging and storage, *etc.* on retention of biological activity

3.3 Methods for establishing storage and shelf-life stability

3.4 Technical characteristics of the biocidal product

3.4.1 Wettability

3.4.2 Persistent foaming

3.4.3 Suspensibility and suspension stability

3.4.4 Wet sieve test and dry sieve test

3.4.5 Particle size distribution, content of dust / fines, attrition and friability

3.4.6 In the case of granules, sieve test and indication of weight distribution of granules, at least of the fraction with particle sizes bigger than 1 mm

3.4.7 Content of active substance in or on bait particles, granules or treated material

3.4.8 Emulsifiability, re-emulsifiability, emulsion stability

3.4.9 Flowability, pourability and dustability

3.5 Physical and chemical compatibility with other products including biocidal products with which its use is to be authorised

3.6 Wetting, adherence and distribution following application

3.7 Any changes to the biological properties of the organism as a result of formulation, in particular changes in pathogenicity or infectivity

IV METHOD FOR IDENTIFICATION AND ANALYSIS

4.1 Analytical methods for determination of the composition of the biocidal product

4.2 Methods for determining residues (*e.g.* biotest)

4.3 Methods used to show the microbiological purity of the biocidal product

4.4 Methods used to show the biocidal product to be free from any human and other mammalian pathogens or, if need be, from pathogens harmful to non-target organisms and the environment

4.5 Techniques used to ensure a uniform product and assay methods for its standardisation

V INTENDED USES AND EFFICACY FOR THESE USES

5.1 Use

Product-type (*e.g.* wood preservative, insecticide, *etc.*)

5.2 Details of intended use (*e.g.* types of harmful organism controlled, materials to be treated, *etc.*)

5.3 Application rate

5.4 Where necessary, in the light of test results, any specific circumstances or environmental conditions under which the product may or may not be used

5.5 Method of application

5.6 Number and timing of applications

5.7 Proposed instructions for use

Efficacy data

5.8 Preliminary range-finding tests

5.9 Field experimentation

5.10 Information on the possible occurrence of the development of resistance

5.11 Effects on the quality of materials or products treated

VI TOXICITY INFORMATION ADDITIONAL TO THAT REQUIRED FOR THE ACTIVE ORGANISM

6.1 Oral single dose

6.2 Percutaneous single dose

6.3 Inhalation

6.4 Skin and where relevant eye irritation

6.5 Skin sensitisation

6.6 Available toxicological data relating to non-active substances

6.7 Operator exposure

6.7.1 Percutaneous absorption / inhalation depending on formulation and method of application

6.7.2 Likely operator exposure under field conditions, including where relevant quantitative measurement of operator exposure

VII ECOTOXICITY INFORMATION ADDITIONAL TO THAT REQUIRED FOR THE ACTIVE ORGANISM

7.1 Observations concerning undesirable or unintended side-effects *e.g.* on beneficial and other non-target organisms or concerning persistence in the environment

VIII MEASURES TO BE ADOPTED TO PROTECT MAN, NON-TARGET ORGANISMS AND THE ENVIRONMENT

8.1 Recommended methods and precautions concerning handling, storage, transport and use

8.2 Re-entry periods, necessary waiting periods or other precautions to protect humans and animals

8.3 Emergency measures in case of an accident

8.4 Procedures for destruction or decontamination of the biocidal product and its packaging

IX CLASSIFICATION, PACKAGING AND LABELLING

Proposals including justification for the proposals submitted for classification, packaging and labelling

9.1.1 Proposals relating to non-biological components of the product, in accordance with the Regulations of 2001

- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases

9.1.2 Proposals relating to the active organisms, labelling in accordance with the appropriate risk group as outlined in Article 2(d) of Directive 90/679/EEC together witl proposals concerning the need for the product to carry the biohazard sign specified in that Directive, as appropriate

9.2 Packaging type (materials, size, *etc.*) and compatibility of the biocidal product with the proposed packaging materials

9.3 Specimens of proposed packaging

X SUMMARY OF SECTIONS II to IX

Part 10

Annex V

BIOCIDAL PRODUCT TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN PARAGRAPH (1) OF REGULATION 2

These product types exclude products regulated in accordance with the legal instruments listed in the Third Schedule.

MAIN GROUP 1	**Disinfectants and general biocidal products**	
Product type 1	Human hygiene biocidal products	Biocidal products used for human hygiene purposes
Product type 2	Private area and public health area disinfectants and other biocidal products	Biocidal products used for disinfection of air, surfaces, materials, equipment and furniture (excluding uses involving direct contact with food or feed), in private, public, and industrial areas including hospitals and products used as algaecides Usage areas include *inter alia* use in swimming pools, aquariums, bathing and other waters, air conditioning systems, walls and floors in health and other institutions, chemical toilets, waste water, hospital waste, soil or

		other substrates (in playgrounds)
Product type 3	Veterinary hygiene biocidal products	Biocidal products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported
Product type 4	Food and feed area disinfectants	Biocidal products used for the disinfection of equipment, containers, consumption **[illegible]**, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals
Product type 5	Drinking water disinfectants	Biocidal products used for disinfection of drinking water for humans and animals
MAIN GROUP 2	**Preservatives**	
Product type 6	In-can preservatives	Biocidal products used for preservation of manufactured products other than foodstuffs or feedingstuffs, in containers, *via* control of microbial deterioration to ensure their shelf life
Product type 7	Film preservatives	Biocidal products used for the preservation of films or coatings by the control of microbial deterioration in orc to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works
Product type 8	Wood preservatives	Biocidal products used for the preservation of wood, from and including the saw-mill stage, or wood product by the control of wood-destroying or wood-disfiguring organisms
		This product type includes both preventative and curative products
Product type 9	Fibre, leather, rubber and polymerised materials preservatives	Biocidal products used for the preservation of fibrous or polymerised materials, such as leather, rubber or pap or textile products and rubber by the control of microbiological deterioration
Product type 10	Masonry preservatives	Biocidal products used for the preservation and remedial treatment of masonry or other construction materials (excluding wood) by the control of microbiological and algal attack
Product type 11	Preservatives for liquid-cooling and processing systems	Biocidal products used for the preservation of water or other liquids used in cooling and processing systems b the control of harmful organisms such as microbes, algae and mussels
		Biocidal product used for the preservation of drinking water are not included in this product type
Product type 12	Slimicides	Biocidal products used for the prevention or control of slime growth on materials, equipment and structures used in industrial processes *e.g.* on wood and paper pulp, porous sand strata in oil extraction
Product type 13	Metalworking-fluid preservatives	Biocidal products used for the preservation of metalworking fluids by the control of microbial deterioration
MAIN GROUP 3	**Pest control**	
Product type 14	Rodenticides	Biocidal products used for the control of mice, rats or other rodents
Product type 15	Avicides	Biocidal products used for the control of birds
Product type 16	Molluscicides	Biocidal products used for the control of molluses
Product type 17	Piscicides	Biocidal products used for the control of fish
		Products for the treatment of fish diseases are not included in this product type
Product type 18	Insecticides, acaricides and products to control other arthropods	Biocidal products used for the control of arthropods (*e.g.* insects, arachnids and crustaceans)
Product type 19	Repellents and attractants	Biocidal products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), b repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectl
MAIN GROUP 4	**Other biocidal products**	
Product type 20	Preservatives for food or feedstocks	Biocidal products used for the preservation of food or feedstocks by the control of harmful organisms
Product type 21	Antifouling products	Biocidal products used to control the growth and settlement of fouling organisms (microbes and higher forms plant or animal species) on vessels, aquaculture equipment or other structures used in water
Product type 22	Embalming and taxidermist fluids	Biocidal products used for the disinfection and preservation of human or animal corpses, or parts thereof
Product type 23	Control of other vertebrates	Biocidal products used for the control of vermin

Part 11

Annex VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

CONTENTS

DEFINITIONS

(a) *Hazard identification*

The identification of the adverse effects that a biocidal product inherently has the capacity to cause.

(b) *Dose (concentration) - response (effect) assessment*

Estimation of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

(c) *Exposure assessment*

Determination of the emissions, pathways and rates of movement of an active substance or a substance of concern in a biocidal product and its transformation or degradation in order to estimate the concentration / doses to which human populations, animals or environmental compartments are or may be exposed.

(d) *Risk characterisation*

Estimation of the incidence and severity of the adverse effects likely to occur in a human population, animals or environmental compartments as a consequence of actual or predicted exposure to any active substance or substance of concern in a biocidal product. It may include 'risk estimation' *i.e.* the quantification of the likelihood of the occurrence of adverse effects.

(e) *Environment*

Water, including sediment, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms.

INTRODUCTION

1 This Annex lays down principles to ensure that evaluations made and decisions taken by competent authorities of the Member States concerning the authorisation or registration of any biocidal product, providing that it is a chemical preparation, result in a harmonised high level of protection for humans, animals and the environme throughout the European Union.

2 To ensure a high and harmonised level of protection for human and animal health and for the environment, any risks arising from use of a biocidal product shall be identified. To that end a risk assessment shall be conducted to determine the acceptability or otherwise of any risks identified in relation to the proposed normal use o the biocidal product. The risk assessment carried out shall include assessment of the risks associated with exposure to relevant individual components of the biocidal product.

3 A risk assessment in relation to the active substance or substances present in the biocidal product is always required. Such an assessment will have been carried out for the purpose of inclusion of the active substance or substances in Annexes I, IA or IB. The risk assessment carried out shall entail hazard identification and, as appropriate, dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be ma a qualitative risk assessment shall be produced.

4 Where relevant for the use(s) of the biocidal product, additional risk assessments as described in the preceding paragraph, shall be carried out, for any other substar of concern present in the biocidal product.

5 Data are necessary to permit a risk assessment to be made. Details of the data required are provided in Annexes II, III and IV. Since there are a wide variety of product types, the data requirements specified are flexible and shall be adjusted in accordance with the biocidal product type being considered and its associated risks The data required in individual cases are the minimum necessary to carry out an appropriate risk assessment. The competent authority shall have due regard to the requirements of Regulations 24, 25 and 28 in order to avoid duplication in generation and submission of data. The minimum set of data required for an active substar in any biocidal product type, however, shall be that detailed in Annex VIIA to the Directive of 1967, data that will have been submitted and assessed as part of the ris assessment required for entry of the active substance into Annex I, IA or IB. Data may also be required in relation to any substance of concern present in a biocidal product.

6 The results of risk assessments carried out on an active substance and on substances of concern present in a biocidal product shall be integrated to produce an over assessment for the biocidal product itself.

7 When making evaluations and taking decisions concerning the authorisation or registration of a biocidal product the competent authority shall:

(a) take into consideration other relevant technical and scientific information which is reasonably available to it with regard to the properties of the biocidal produ its components, metabolites, or residues; and

(b) evaluate, where relevant, justifications submitted by the applicant for not supplying certain data.

8 The competent authority shall comply with and have regard to requirements concerning the mutual recognition of an authorisation or registration granted by another Member State as set out in Regulation 11.

9 Since in relation to their composition, many biocidal products differ in only a minor way from other biocidal products, this should be taken into account when evaluating dossiers submitted in support of their authorisation or registration and where relevant 'frame-formulations' should be identified and / or be used as a basis for authorisation or registration, as appropriate, in accordance with the provisions of Regulation 23.

10 Since certain biocidal products are considered to pose only a low risk, such biocidal products, while complying with the requirements of this Annex, are subject to a simplified procedure (registration procedure) as provided for in paragraph (4) of Regulation 4 and paragraph (3) of Regulation 10.

11 The application of these common principles shall be the basis on which the competent authority decides whether or not a biocidal product can be authorised or registered, and where a biocidal product is to be authorised or registered shall be the basis for selection of the restrictions on use or other conditions to be associated with any such authorisation or registration. In certain cases the competent authority may conclude that more data are required before a decision can be made.

12 During the process of evaluation and decision-making, the competent authority and applicants shall co-operate:

- to resolve any questions in relation to data requirements quickly;

- to identify at an early stage any additional studies required;

- to amend any proposed conditions for the use of the biocidal product in order to ensure full compliance with the requirements of these Common Principles and these Regulations; or

- to modify the nature or composition of the biocidal product in order to ensure full compliance with the requirements of these Common Principles or of these Regulations.

The administrative burden, especially for small and medium-sized enterprises (SMEs), shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.

13 Judgements made by the competent authority during the evaluation and decision-making process shall be based on scientific principles, preferably recognised at international level and shall be made with the benefit of expert advice.

EVALUATION

General principles

14 Data submitted in support of an application for the authorisation or registration of a biocidal product shall be examined for completeness and overall scientific value b the competent authority. On acceptance of an application, the competent authority shall utilise the data provided to carry out a risk assessment based on the propose use of the biocidal product.

15 A risk assessment on the active substance or substances present in the biocidal product shall always be carried out. In addition, if there are any substances of conce present in the biocidal product, a risk assessment shall be carried out for each of these. Risk assessments undertaken shall relate to the proposed normal use of the biocidal product. In addition a risk assessment involving a realistic worst-case scenario shall be made. Relevant production and disposal issues in relation to the biocid product and any material treated with it shall be taken into account in the risk assessment undertaken.

16 For each active substance and each substance of concern present in the biocidal product, the risk assessment shall include hazard identification and the establishmen of appropriate no adverse effect levels (NOAEL), where possible. The risk assessment shall also include, as appropriate, a dose (concentration) - response (effect) assessment, together with exposure assessment and risk characterisation.

17 The results achieved on comparison of level of exposure to the no-effect level concentrations for each of the active substances and any substances of concern shall integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available the results of qualitative assessments shall be integrated in a similar manner.

18 The risk assessment carried out shall:

(a) determine the risks to humans and animals;

(b) determine the risks to the environment; and

(c) identify the measures necessary to protect humans, animals and the general environment during both the proposed normal use of the biocidal product and in a realistic worst-case situation.

19 In certain cases it may be concluded that further data are required before a risk assessment can be completed. Any such additional data requested shall be the minimum necessary to complete such a risk assessment.

Effects on humans

20 Each risk assessment shall take account of the populations liable to exposure and of the potential effects arising from the use of the biocidal product.

21 The potential effects resulting from the properties of the active substance and any substance of concern present, to be taken into account shall include the following

- acute and chronic toxicity,
- irritation,
- corrosivity,
- sensitisation,
- repeated dose toxicity,
- mutagenicity,
- carcinogenicity,
- reproduction toxicity,
- neurotoxicity,
- any other special properties of the active substance or substance of concern,
- other effects due to physico-chemical properties

22 The populations liable to exposure to be taken into account shall include the following:

- professional users,
- non-professional users,
- humans exposed indirectly *via* the environment.

23 Hazard identification undertaken shall include consideration of the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. Dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation shall be undertaken if the properties of the biocidal product are such that it warrants classification in accordance with Regulation 30.

24 Where on the basis of appropriate testing for the purposes of hazard identification in relation to a particular effect of an active substance or of a substance of concern present in a biocidal product, classification is not warranted, risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern, *e.g.* adverse environmental effects or unacceptable residues.

25 The competent authority shall apply paragraphs 26 to 29 when carrying out a dose (concentration) - response (effect) assessment on an active substance or a substance of concern present in a biocidal product.

26 For the purposes of repeated dose toxicity and reproductive toxicity assessments, the dose response relationship shall be assessed for each active substance or substance of concern tested and, where possible, the no-observed-adverse-effect level (NOAEL) shall be identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified.

27 For the purposes of acute toxicity, corrosivity and irritation assessments, it is not usually possible to derive a NOAEL or a LOAEL on the basis of tests conducted in accordance with the requirements of these Regulations. In the case of acute toxicity, the LD_{50} (median lethal dose) or LC_{50} (median lethal concentration) value or, where the fixed dose procedure has been used, the discriminating dose shall be derived. For the purposes of corrosivity and irritation assessments it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the product.

28 For the purposes of mutagenicity and carcinogenicity assessments, it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product. However, if it can be demonstrated that an active substance or a substance of concern identified as a carcinogen is non-genotoxic, it will be appropriate to identify a NOAEL or LOAEL as specified in paragraph 26.

29 With regard to skin sensitisation and respiratory sensitisation, since there is no consensus on the possibility of identifying a dose / concentration below which adverse effects are unlikely to occur in a subject already sensitised to a given substance, it shall be sufficient to evaluate whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product.

30 Where toxicity data derived from observations of human exposure, *e.g.* information gained from exposure during manufacture, from Poison Centres or from epidemiology surveys, are available, special consideration shall be given by the competent authority to such data when carrying out risk assessments.

31 An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed indirectly *via* the environment) for which exposure to a biocidal product occurs or can reasonably be foreseen. The purpose of assessments made shall be to make a quantitative or qualitative estimate of the dose / concentration of each active substance or substance of concern to which a population is, or may be exposed during use of the biocidal product.

32 Exposure assessments undertaken shall be based on the information in the technical dossier provided in accordance with Regulation 4 and on any other available and relevant information. Particular account shall be taken, as appropriate, of:

- adequately measured exposure data,
- the form in which the product is marketed,
- the type of biocidal product,
- the application method and application rate,
- the physico-chemical properties of the product,
- the likely routes of exposure and potential for absorption,
- the frequency and duration of exposure,
- the type and size of specific exposed populations where such information is available.

33 Where a sufficient quantity of representative measured exposure data is available, special consideration shall be given to such data when conducting exposure assessments. Where calculation methods are used for the estimation of exposure levels, the models used shall be suitable for that purpose.

The models used shall:

- permit making a best possible estimation of all relevant processes taking into account realistic parameters and assumptions,
- be subjected to an analysis taking into account possible elements of uncertainty,
- be reliably validated with measurements carried out under circumstances relevant for the use of the model,
- be relevant to conditions in the area of use of the biocidal product.

Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties shall also be considered.

34 Where for any of the effects set out in paragraph 21, a NOAEL or LOAEL has been identified, risk characterisation shall entail comparison of the NOAEL or LOAEL with the dose / concentration to which the population will be exposed. Where a NOAEL or LOAEL cannot be established a qualitative comparison shall be made.

Effects on animals

35 Using as relevant, the same principles as described in the section dealing with effects on humans, the competent authority shall consider the risks posed to animals from exposure to the biocidal product.

Effects on the environment

36 Each risk assessment shall take account of any adverse effects arising in any of the three environmental compartments air, soil and water (including sediment) and of any adverse effects for relevant biota following use of the biocidal product.

37 Hazard identification undertaken shall include consideration of the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. Dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation shall be undertaken if the properties of the biocidal product are such that it warrants classification in accordance with Regulation 30.

38 Where on the basis of appropriate testing for the purposes of hazard identification in relation to a particular effect of an active substance or of a substance of concern present in a biocidal product, classification of the biocidal product is not warranted, risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern. Such grounds may derive from the properties and effects of an active substance or substance of concern in the biocidal product, and include:

- indications of bioaccumulation potential,
- persistence characteristics,
- the shape of the toxicity / time curve in ecotoxicity testing,
- indications of other adverse effects identified in toxicity studies (*e.g.* classification as a mutagen),
- data on structurally analogous substances, or
- endocrine effects.

39 Dose (concentration) - response (effect) assessments shall be carried out to predict the concentration below which adverse effects in the environmental compartments of concern are not expected to occur. Assessments shall be carried out for the active substance and for any substance of concern present in the biocidal product. The concentration thus identified is the predicted no-effect concentration (PNEC). If in some cases, it is not possible to establish a PNEC value, a qualitative estimation of the dose (concentration) - response (effect) relationship shall be carried out.

40 The PNEC value for a biocidal product shall be determined on the basis of data concerning effects on organisms and the ecotoxicity studies submitted in accordance with requirements of Regulation 4. It shall be calculated by means of application of an assessment factor to the values resulting from tests on organisms *e.g.* LD_{50} (median lethal dose), LC_{50} (median lethal concentration), EC_{50} (median effective concentration), IC_{50} (concentration causing 50 % inhibition of a given parameter *e.* growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)).

41 An assessment factor is an expression of the degree of uncertainty arising in extrapolations made using test data based upon a limited number of species to the real environment. In general, the more extensive the data base and the longer the duration of testing, the smaller the degree of uncertainty arising and therefore the smalle the assessment factor.

Specifications for the assessment factors to be used will be elaborated in the notes for technical guidance, which shall be based particularly on the indications provid in Commission Directive 93/67/EEC[14] .

42 For each environmental compartment an exposure assessment shall be carried out, to permit prediction of the concentration likely to be found in each compartment each active substance or substance of concern present in the biocidal product. The concentration thus estimated is the predicted environmental concentration (PEC). in some cases it is not possible to establish a PEC value, a qualitative estimate of exposure shall be made.

43 A PEC value, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions including contributions from material treated with biocidal products, are known to occur or can reasonably be foreseen.

44 PEC values, or qualitative estimations of exposure, shall be determined taking account of, as appropriate:

- adequately measured exposure data,
- the form in which the product is marketed,
- the type of biocidal product,
- the application method and application rate for the biocidal product,
- physico-chemical properties of the biocidal product, of its active substance(s) and of substances of concern present in the biocidal product,
- breakdown / transformation products of the active substance(s) and of substances of concern present in the biocidal product,
- likely pathways to environmental compartments and potential for adsorption / desorption and degradation,
- frequency and duration of exposure.

45 Where a sufficient quantity of representative measured exposure data is available, special consideration shall be given to such data when conducting exposure assessments. Where calculation methods are used for the estimation of exposure levels, the models used shall be suitable for the purpose. The characteristics of models used shall be as listed in paragraph 33. Where appropriate and on a case-by-case basis, relevant monitoring data concerning substances having analogous use and exposure patterns or analogous properties should also be considered.

46 For any given environmental compartment, risk characterisation shall, in as far as is possible, entail comparison of the PEC value with the PNEC value such that a P / PNEC ratio can be derived.

47 Where it is not possible to derive a PEC / PNEC ratio, risk characterisation shall entail a qualitative evaluation of the likelihood that an effect occurs or will occur unc the existing or expected conditions of exposure.

Unacceptable effects

48 Data shall be submitted to and be evaluated by the competent authority in relation to any unnecessary suffering caused to target vertebrate species as a consequence use of a biocidal product. Evaluations shall include examination of the mechanism by which the effect is obtained and assessment of the observed effects on the behaviour and health of target vertebrate species. Where the intended effect is to kill target animals, the time necessary to obtain death and the conditions under whic death occurs shall be evaluated.

49 The competent authority shall, where relevant, evaluate the possibility of the development of resistance to an active substance in the biocidal product by the target organism.

50 If there are indications that any other unacceptable effects may occur the competent authority shall evaluate the possibility of such effects occurring. An example of such an unacceptable effect would be an adverse reaction in fastenings and fittings used in wood following the application of a wood preservative.

Efficacy

51 Data shall be submitted to and be evaluated by the competent authority to ascertain whether or not efficacy claims made for the biocidal product have been substantiated. Data submitted by the applicant or held by the competent authority must be sufficient to demonstrate the efficacy of the biocidal product under norma conditions of use against the target organism(s) for which label claims are proposed, taking account of the conditions to be attached to any authorisation or registrat granted.

52 Where available and applicable, testing should be carried out in accordance with Community guidelines. Relevant field data of acceptable quality can be used. Other t methods, if appropriate, can be used:

- ISO, CEN or other international standard methods,
- national standard methods,
- industry standard methods (accepted by the competent authority),
- individual producer standard methods (accepted by the competent authority),

- methods used in the development of the biocidal product (accepted by the competent authority).

Summary

53 In each of the areas for which risk assessments have been carried out (*i.e.* effects on man, animals, and the environment), the competent authority shall combine th results obtained for the active substance and the results for any substance of concern to produce an overall risk assessment for the biocidal product. This risk assessment should take account of any likely synergistic effects of the active substance(s) and substances of concern in the biocidal product.

54 For biocidal products containing more than one active substance, the results obtained shall be combined to produce an overall risk assessment for the biocidal produ

DECISION MAKING

General principles

55 Subject to paragraph 96, the competent authority shall come to a decision regarding the authorisation or registration of a biocidal product following integration of the risk assessments for each active substance together with the risk assessments for each substance of concern present in the biocidal product. The risk assessments relied upon shall relate to both normal conditions of use of the biocidal product together and a realistic worst-case scenario and shall include relevant disposal issues concerning the biocidal product and any material treated with it.

56 In decision-making concerning authorisation or registration of a biocidal product, the competent authority shall arrive at one of the following conclusions for each product type and for each area of use of the biocidal product for which application has been made:

- the biocidal product cannot be authorised or registered,
- the biocidal product can be authorised or registered subject to specific conditions / restrictions, or
- more data is required before a decision can be made concerning authorisation or registration of the biocidal product.

57 If the conclusion reached by the competent authority is that additional information or data are required before an authorisation or registration decision can be made, t need for any such information or data shall be justified. Any additional information or data required shall be the minimum necessary to carry out a further risk assessment, as appropriate.

58 The competent authority shall have regard to and comply with the provisions concerning mutual recognition of authorisation or registrations granted by another Member State, set out in Regulation **[illegible]**.

59 The competent authority shall give effect to the provisions of Regulation 23 concerning 'frame formulations' for the purposes of decision-making concerning authorisation or registration of a biocidal product.

60 The competent authority shall have regard to and comply with the provisions of paragraph (3) of Regulation 10 for the purposes of decision-making in relation to th registration of "low risk" products.

61 The competent authority shall only grant authorisation or registration for a biocidal product that when used in accordance with the conditions or restrictions to be attached to any such authorisation or registration, does not present an unacceptable risk to humans, animals or the environment, is efficacious and which contains active substances permitted at Community level for use in such biocidal products.

62 The competent authority shall, where appropriate, impose conditions and /or restrictions to be associated with an authorisation or registration granted for a biocidal product. The nature and severity of any such conditions and restrictions shall be selected on the basis of, be appropriate to, and reflect the nature and extent of the advantages expected and the risks likely to arise from the use of the biocidal product.

63 In the decision-making process the competent authority shall take into consideration the following:

- the results of risk assessments undertaken, in particular the relationship between exposure and effects,
- the nature and severity of the effects observed,
- risk management measures that can be applied,
- the field of use of the biocidal product,
- the efficacy of the biocidal product,
- the physical properties of the biocidal product, and
- the benefits likely to arise from use of the biocidal product.

64 The competent authority shall, when making a decision concerning the authorisation or registration of a biocidal product, take into account uncertainty arising becau of variability in the data used in the evaluation and decision-making process.

65 The competent authority shall prescribe that each biocidal product be used properly. Proper use shall include application at an efficacious dose and minimisation of u where possible.

66 The competent authority shall take the necessary measures to ensure that applicants submit a proposal for the content and presentation (format) of each biocidal product label and, where relevant, for the safety-data sheet for the biocidal product which:

- complies with the requirements of Regulations 30 and 32,
- contains that information on the protection of users that is required by Community legislation concerning worker protection,

- specifies the conditions and / or restrictions under which the biocidal product may or may not be used.

Before issuing an authorisation the competent authority shall confirm that these requirements have been satisfied.

67 The competent authority shall take the necessary measures to ensure that applicants submit a proposal for the packaging and, where appropriate, for the procedures for destruction or decontamination of the biocidal product and its packaging or any other relevant material associated with the biocidal product. Any destruction and decontamination procedures proposed must conform to relevant regulatory provisions.

Effects on humans

68 The competent authority shall not authorise or register a biocidal product if the risk assessments undertaken confirm that, following normal conditions of use or following use in accordance with a realistic worst possible scenario, the biocidal product presents an unacceptable risk to humans.

69 The competent authority shall consider possible effects on all relevant population groups when making a decision with regard to the authorisation or registration of a biocidal product *i.e.* namely professional users, non-professional users and humans exposed directly or indirectly through the environment.

70 The competent authority shall examine the relationship between exposure and effect, and use this relationship in the decision-making process. Factors that must be considered when examining the exposure / effect relationship include the nature of the adverse effects - acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, reproduction toxicity, effects deriving from physico-chemical properties, and any other adverse propertie of the active substance or substance of concern.

71 The competent authority shall, where possible, compare results obtained with those obtained from previous risk assessments for an identical or similar adverse effec and decide on an appropriate margin of safety (MOS) when making an authorisation or registration decision.

An appropriate MOS is typically 100 but an MOS higher or lower than 100 may be appropriate depending on, among other things, the nature of the critical toxicological effect being considered.

72 The competent authority shall, if appropriate, impose, as a condition of authorisation or registration, the wearing of personal protective equipment such as respirator breathing-masks, overalls, gloves and goggles in order to reduce exposure for professional operators. Where such a condition is imposed, the equipment specified m be readily available to such professional operators.

73 Where in the case of use by non-professional users, the wearing of personal protective equipment would be the only method available for reducing exposure to acceptable levels, the product shall not normally be authorised or registered for such use.

74 If the relationship between exposure and effect cannot be reduced to an acceptable ratio, the competent authority shall refuse authorisation or registration for the biocidal product concerned.

75 The competent authority shall not authorise or register for use by the general public a biocidal product classified in accordance with Regulation 30 as being:

- toxic,
- very toxic,
- a category 1 or 2 carcinogen,
- a category 1 or 2 mutagen, or
- toxic for reproduction category 1 or 2.

Effects on animals

76 The competent authority shall not authorise or register a biocidal product if on the basis of the risk assessments undertaken, it is concluded that in normal use the biocidal product presents an unacceptable risk to non-target animals.

77 Using as relevant, the same principles as described in the section dealing with effects on humans, the competent authority shall consider the risks posed to animals from exposure to the biocidal product when making authorisation or registration decisions.

Effects on the environment

78 The competent authority shall not authorise a biocidal product if the risk assessments undertaken confirm that the active substance, or any substance of concern, or any degradation, or reaction product formed presents an unacceptable risk in any of the environmental compartments, water (including sediment), soil or air. The ris assessments concerned shall include the assessment of risks to non-target organisms in these compartments.

In considering whether there is an unacceptable risk, the competent authority shall, when coming to a final decision in accordance with paragraph 96, have regard tc the criteria specified in paragraphs 81 to 91.

79 The basic tool for use in the decision-making process is the PEC / PNEC ratio or if not available, a qualitative estimation of the dose (concentration) - response (effe relationship. Due consideration shall be given to the accuracy of this ratio taking into account the variability of the data used for measurement and estimation of concentrations.

In the determination of the PEC value, the most appropriate model should be used for the purpose, taking into account fate and behaviour of the biocidal product in t environment.

80 Where for any given environmental compartment it is found that the PEC / PNEC ratio is equal to or less than 1, the risk shall be characterised as follows - 'no furtl information and / or testing are necessary'.

Where the PEC / PNEC ratio is greater than 1, the competent authority, depending on the size of that ratio and on other relevant factors listed in paragraph 38, shall make a judgement as to whether or not:

- further information and / or testing are required to clarify the concern,

- risk reduction measures are necessary, or

- the product can be authorised or registered.

Water

81 The competent authority shall not authorise or register a biocidal product if under the proposed conditions of use the foreseeable concentration of the active substan or of a substance of concern or of relevant metabolites or breakdown or reaction products in water (or its sediments) has an unacceptable impact on non-target species in the aquatic, marine or estuarine environment unless it is scientifically demonstrated that under relevant field conditions there is no such unacceptable effec

82 The competent authority shall not authorise or register a biocidal product if under the proposed conditions of use the foreseeable concentration of the active substan or of a substance of concern or of relevant metabolites or breakdown or reaction products in groundwater exceeds the lower of the following concentrations:

- the maximum permissible concentration laid down in accordance with Directive 80/778/EEC[11] , or

- the maximum concentration laid down on inclusion of the active substance in Annex I, IA or IB on the basis of appropriate data, in particular toxicological data,

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

83 The competent authority shall not authorise or register a biocidal product if under the proposed conditions of use the foreseeable concentration of the active substan or of a substance of concern or of relevant metabolites, breakdown or reaction products to be expected in surface water or in its sediments after use of the biocidal product:

(a) exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values established in accordance with:

- Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States[15] ,

- Directive 80/778/EEC[11] or

(b) has an impact deemed unacceptable on non-target species,

unless it is scientifically demonstrated that under relevant field conditions these concentrations are not exceeded.

84 The proposed instructions for use of each biocidal product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of water or its sediments is minimised.

Soil

85 Where unacceptable contamination of soil is likely to occur, the competent authority shall not authorise or register a biocidal product if the active substance or substance of concern contained in it, following use of the biocidal product:

- during tests in the field, persist in soil for more than one year, or

- during laboratory tests, form non-extractable residues in amounts exceeding 70 % of the initial dose after 100 days with a mineralisation rate of less than 5 % in 100 days,

- have unacceptable consequences or effects on non-target organisms,

unless it is scientifically demonstrated that under field conditions there is no unacceptable accumulation in soil.

Air

86 The competent authority shall not authorise or register a biocidal product where there is a foreseeable possibility of unacceptable effects on the air compartment unl it is scientifically demonstrated that under relevant field conditions there is no such unacceptable effect.

Effects on non-target organisms

87 The competent authority shall not authorise or register a biocidal product where there is a reasonably foreseeable possibility of non-target organisms being exposed t the biocidal product to the extent that for any active substance or substance of concern contained in the biocidal product:

- the PEC / PNEC ratio is greater than 1 unless it is clearly established by means of a risk assessment that under field conditions no unacceptable effects occur following use of the biocidal product in accordance with the proposed conditions of use, or

- the bio-concentration factor (BCF) related to fat tissues in non-target vertebrates is greater than 1 unless it is clearly established by means of a risk assessment t under field conditions no unacceptable effects occur, either directly or indirectly, following use of the product in accordance with the proposed conditions of us

88 The competent authority shall not authorise or register a biocidal product where there is a reasonably foreseeable possibility of aquatic organisms including marine a estuarine organisms being exposed to the biocidal product to the extent that for any active substance or substance of concern contained in the biocidal product:

- the PEC / PNEC ratio is greater than 1 unless it is clearly established by means of a risk assessment that under field conditions the viability of aquatic organisms including marine and estuarine organisms is not threatened following use of the biocidal product in accordance with the proposed conditions of use, or

- the bio-concentration factor (BCF) is greater than 1,000 for substances that are readily biodegradable or greater than 100 for those that are not readily biodegradable, unless it is clearly established by means of a risk assessment that under field conditions no unacceptable impact, directly or indirectly, occurs on t viability of exposed organisms including marine and estuarine organisms following use of the biocidal product in accordance with the proposed conditions of use

By way of derogation from the criteria specified in this paragraph, the competent authority may however authorise or register anti-fouling products for use on commercial, public service and naval seagoing vessels for a period of up to 10 years from the 14 May 1998, if fouling control cannot be achieved by other practicab means. On availing of this provision, the competent authority shall, where appropriate, take into account relevant International Maritime Organisation (IMO) resolutic and recommendations.

89 The competent authority shall not authorise or register a biocidal product where there is a reasonably foreseeable possibility of micro-organisms in sewage treatment plants being exposed to the biocidal product to the extent that for any active substance, substance of concern, relevant metabolite, breakdown or reaction product th PEC / PNEC ratio is greater than 1, unless it is clearly established by means of a risk assessment that under field conditions no unacceptable impact, either directly o indirectly, occurs on the viability of such micro-organisms.

Unacceptable effects

90 If the development of resistance to the active substance in the biocidal product is likely the competent authority shall take steps to minimise the consequences arising Steps taken may include modification of the conditions associated with an authorisation or registration or refusal to grant an authorisation or registration.

91 An authorisation for a biocidal product intended to control vertebrates shall not be given unless:

- death is synchronous with the extinction of consciousness, or
- death occurs immediately, or
- vital functions are reduced gradually without signs of obvious suffering

For repellent products, the intended effect shall be obtained without unnecessary suffering and pain for the target vertebrate.

Efficacy

92 The competent authority shall not authorise or register a biocidal product that does not possess acceptable efficacy when used in accordance with the conditions specified on the proposed label or with other conditions of authorisation.

93 The level, consistency and duration of protection, control or other intended effects must, as a minimum, be similar to those resulting from suitable reference produc where such products exist, or to other means of control. Where no reference products exist, the biocidal product must give a defined level of protection or control i the areas of proposed use.

Conclusions in relation to the performance of a biocidal product must be valid for all areas of proposed use and for all areas in the territory of the State except where the proposed label prescribes that the biocidal product is intended for use in specific circumstances. The competent authority shall evaluate dose response data generated in trials (which must include an untreated control) involving dose rates lower than the recommended rate, in order to determine whether, or not, the recommended dose is the minimum necessary to achieve the desired effect.

Summary

94 The competent authority shall combine the conclusions arrived at for the active substance and the substances of concern, to produce an overall risk assessment and conclusion for the biocidal product in each of the areas for which risk assessments were carried out *i.e.* effects on humans, animals and the environment. A summa should also be made of the efficacy assessment and of the assessment of unacceptable effects.

The combined summary thus prepared shall include:

- a summary of the effects of the biocidal product on humans,
- a summary of the effects of the biocidal product on animals,
- a summary of the effects of the biocidal product on the environment,
- a summary of the efficacy assessment,
- a summary of the unacceptable effects.

OVERALL INTEGRATION OF CONCLUSIONS

95 The competent authority shall combine the individual conclusions arrived at with regard to effects of the biocidal product on the three main sectors namely, humans health, animal health and the environment to arrive at an overall conclusion for the global effect of the biocidal product.

96 The competent authority shall give due consideration to any relevant unacceptable effects associated with use of the biocidal product, to its efficacy and to the bene associated with its use before making a decision to authorise or not, or to register or not a biocidal product.

97 The competent authority shall ultimately decide whether or not a biocidal product can be authorised or registered and whether any such authorisation or registration shall be subject to any restrictions or conditions, in accordance with the provisions of these Regulations.

SECOND SCHEDULE

Regulation 14

Part 1

INFORMATION AND DOCUMENTATION TO SUPPORT A NOTIFICATION FOR A BIOCIDE PRODUCT IN ACCORDANCE PARAGRAPH (2) OF REGULATION 14

List of information/documentation

	required	Explanation of requirement
1	Applicant	name of company, address, contact person, telephone, facsimile numbers, e-mail address and www site
2	Product name (trade name)	
3	Biocide product type	select from categories listed in Annex V (Part 10 of the First Schedule)
4	Brief description of intended use(s)	*e.g.* disinfectant for use on surfaces and equipment in the meat industry
5	User Type	professional or amateur user
6	Formulation type	use GCPF code *e.g.* EC, wax bloc, paint *etc.* (see Annex XIV set out in the Fourth Schedule of the Regulations of 2001)
7	Packaging	packaging type (material, type of closure), size(s)
8	Wholesale distributor(s)	name of company, address, contact person, telephone, facsimile numbers, e-mail address and www site
9	Detailed specification of the preparation	minimum content of each technical active substance(s) 1 g/kg or g/L; minimum content of each pure active substance(s) in g/kg or g/L; content of other formulants in g/kg or g/L
10	Material Safety Data Sheet for the preparation	
11	Current label (in compliance with these Regulations) for the preparation	
12	Manufacturer of the preparation	name of company, name and address of plant, contact person, telephone, facsimile numbers, e-mail address and www site
13	Manufacturer of each active substance in the preparation	name of company, name and address of plant, contact person, telephone, facsimile numbers, e-mail address and www site
14	Detailed specification of each active substance in the preparation	minimum content in g/kg of pure active substance; maximum content in g/kg of inactive isomers; the ratio of the content of isomers / diastereo-isomers; maximum content in g/kg of each further component, including by-products and impurities; content in g/kg of additives,
15	Details of the manufacturing process (synthesis pathway) for each active substance,	identity of the starting materials, the chemical pathways involved, the identity of by-products and impurities present in the final product
16	Material Safety Data Sheet for each active substance	
17	Material Safety Data Sheet for each formulant	

PART 2

NOTIFICATION FORM FOR BIOCIDAL PRODUCTS

Information and documentation to support a notification for a biocide product in accordance paragraph (2) of regulation 14

Product (brand name): .....

Biocidal product type: (select from list in Annex V - enter product type number(s)) .....

Formulation Type (GCPF Code): (*e.g.* EC, SC, wax block, paint *etc.*) .....

Brief description of intended use(s): .....

.....

Name and address of the formulator (manufacturer) of the biocidal product: .....

.....

Applicant: .....

.....

Primary wholesale distributor (s): .....

.....

Pack sizes	Packaging type (materials and construction)

For Amateur Use:	Yes	No	For Professional Use:	Yes	No
Material Safety Data Sheet (MSDS) for the biocidal product enclosed:				Yes	No
Current/proposed product label (in compliance with the Regulations) enclosed:				Yes	No

For Official Use

PCS No: .....

Category: .....

Reference product: .....

Associated products: .....

Initials: .....

Detailed specification of the preparation:

	Identity of each substance in the preparation*	**CAS number**	**Manufacturer of the active substance**	**minimum content of technical material (g/kg)**	**minimum content of pure technical material (g/kg)**	**MSDS enclosed (indicate yes or no)**	**Letter of access enclos (if required yes or no)**
1							
2							
3							
4							
5							
6							
7							

	Identity of each formulant (other than active substance) in the preparation*	**Trade name (if applicable)**	**CAS number**	**Manufacturer of the formulant**	**function of the formulant**	**minimum content of formulant (g/kg)**	**MSDS enclosed (indicate yes or no)**	**Letter of access enclos (if required yes or no)**
1								
2								
3								
4								
5								
6								
8								
9								

10

Detailed specification of each active substance in the biocidal product (to be completed for each such active substance)

Active substance: (specify*)	**minimum content of pure material:**	**g/k**

Identity of each by-product or impurity*	maximum content in g/kg
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	

Identity of each inactive isomer*	maximum content in g/kg
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	

Ratio of the content of isomers/diastereoisomers: (specify)

Identity of each additive*	maximum content in g/kg
1	
2	
3	

4

5

Details of the manufacturing process (synthesis pathway) for each active substance in the biocide product (to be completed for each such active substance):

Active substance: (specify*)

Identity of each starting material*

1

2

3

4

5

6

7

8

9

10

Brief description of the chemicals pathways involved

Identity of by-products and impurities present in the final product*

1

2

3

4

5

6

7

8

9

10

11

12

THIRD SCHEDULE

Regulation 3

1 S.I. No. 142 of 1998 : Medicinal Products (Licensing and Sale) Regulations, 1998

transposing: Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to

proprietary medicinal products[16]

2 S.I. No. 179 of 1996 : Animal Remedies Regulations, 1996

transposing: Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States on veterinary medicinal products [17]

3 S.I. No. 179 of 1996 : Animal Remedies Regulations, 1996

transposing: Council Directive 90/677/EEC of 13 December 1990 extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological medicinal products[18]

4 S.I. No. 142 of 1998 : Medicinal Products (Licensing and Sale) Regulations, 1998

transposing: Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products[19]

5 S.I. No. 179 of 1996 : Animal Remedies Regulations, 1996

transposing: Council Directive 92/74/EEC of 22 September 1992 widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products [20]

6 Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human a veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[21]

7 S.I. No. 253 of 1994 European Communities (Active Implantable Medical Devices) Regulations, 1994

transposing: Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[2

7 S.I. No. 252 of 1994 : European Communities (Medical Devices) Regulations, 1994

transposing: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[23]

8 S.I. No. 252 of 23 of 1992: European Communities (Labelling of Additives for use in Foodstuffs) Regulations, 1992

transposing: Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption[24]

9 S.I. No. 252 of 22 of 1992: European Communities (Flavourings for Use in Foodstuffs) Regulations, 1992

transposing: Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs an to source materials for their production[25]

10 S.I. No. of 128 of 1997: European Communities Detailed provisions on the Control of Additives, other than Colours and Sweeteners for Use in Foodstuffs) Regulations, 1997

transposing: European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners[26]

11 S.I. No. 307 of 1991 : European Communities (Materials and Articles Intended to Come into Contact with Foodstuffs) Regulations, 1991, as amended by S.I. No. 2 of 1998 : European Communities (Materials and Articles Intended to Come into Contact with Foodstuffs) (Amendment) Regulations, 1998

transposing: Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended come into contact with foodstuffs[27]

12 S.I. No. 9 of 1996 : European Communities (Hygienic Production and Placing on the Market of Raw, Milk, Heat-Treated Milk and Milk-based Products) Regulation 1996

transposing: Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk based products[28]

13 S.I. No. 293 of 1991 : European Communities (Egg Products) Regulations, 1991 as amended by S.I. No. 419 of 1992 : European Communities (Egg Products) Regulations, 1992

transposing: Council Directive 89/437/EEC of 20 June 1989 on hygiene and health problems affecting the production and the placing on the market of egg products[29]

14 S.I. No. 170 of 1996 : European Communities (Fishery Products) (Health Conditions and Hygiene Rules for Production and Placing on the Market) Regulations, 19

transposing: Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products

15 S.I. No. 176 of 1994 : European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations, 1994

transposing: Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[31]

16 S.I. No. 49 of 1989 : European Communities (Additives in Feedingstuffs) Regulations, 1989 as last amended S.I. No. 186 of 2000 : European Communities (Additiv in Feedingstuffs) (Amendment) Regulations, 2000

transposing: European Communities Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[32]

17 S.I. No. 433 of 1986 : European Communities (Protein Feedingstuffs) Regulations, 1986 as last amended by S.I. No. 190 of 2000 : European Communities (Protein Feedingstuffs) (Amendment) Regulations, 2000

transposing: Council Directive 82/471/EEC of 30 June 1982 on certain products used in animal nutrition[33]

18 S.I. No. 200 of 1984 : European Communities (Marketing of Feedingstuffs) Regulations, 1984 as last amended by S.I. No. 161 of 1998 : European Communities (Marketing of Feedingstuffs) (Amendment) Regulations, 1998

transposing: Council Directive 77/101/EEC of 23 November 1976 on the marketing of straight feedingstuffs[34]

19 S.I. No. 87 of 1997 : European Communities (Cosmetic Products) Regulations, 1997 as last amended S.I. No. 203 of 2000 : European Communities (Cosmetic Products) (Amendment) Regulations, 1998

transposing: Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[35]

20 S.I. No. 126 of 1995 : European Communities (Meat Products and Other Products of Animal Origin) Regulations, 1997

transposing: Council Directive 95/5/EC of 27 February 1995 amending Directive 92/120/EEC on the conditions for granting temporary and limited derogations from specific Community health rules on the production and marketing of certain products of animal origin[36]

21 S.I. No. 139 of 1994 : European Communities (Authorisation, Placing on the Market and Control of Plant Protection Products), Regulations 1994 as last amended by S.I. No. 359 of 2001 : European Communities Authorisation, Placing on the Market and Control of Plant Protection Products) (Amendment) (No. 3) Regulations, 20

transposing: Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[37]

FOURTH SCHEDULE

Regulation 37

CERTIFICATE OF RESULT OF ANALYSIS CARRIED OUT BY A DESIGNATED ANALYST

Laboratory Reference Number .....

Sample of .....

received by the designated analyst on .....

from ..... an authorised officer for the purposes of the European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) Regulations, 2001

Methods of analysis used .....

.....

.....

This is to certify that the above mentioned sample, which was duly fastened and sealed, has been analyzed under the provisions of the European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) Regulations, 2001 and that the results of the analysis are as follows:-

.....

.....

.....

.....

.....

Cost of analysis: .....

This certificate is issued under the European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) Regulations, 2001

Date .....

Signed .....

Designated Analyst

.....

Designated Analyst

.....

Designated Analyst

FIFTH SCHEDULE

Regulation 37

CERTIFICATE OF RESULT OF ANALYSIS CARRIED OUT BY THE STATE CHEMIST

Laboratory Reference Number .....

Sample of .....

taken at the premises of ..... on .....

temperature and place of storage .....

Date .....

Signed .....

Authorized Officer

received by the State Chemist on .....

from .....

Methods of analysis used .....

.....

.....

This is to certify that the above mentioned sample, which was duly fastened and sealed, has been analyzed under the provisions of the European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) Regulations, 2001 and that the results of the analysis are as follows:-

.....

.....

.....

.....

.....

Cost of analysis: .....

This certificate is issued under the European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) Regulations, 2001

Date .....

Signed .....

State Chemist.

SIXTH SCHEDULE

APPLICATION AND ANNUAL FEES FOR ACTIVE SUBSTANCES OF BIOCIDAL PRODUCTS AND FOR NOTIFICATION, AUTHORISATION AND REGISTRATION OF BIOCIDAL PRODUCTS

Regulation 42 (2)

Part 1

Fees for the consideration of applications for the inclusion of an active substance in Annex I, IA or IB, for the renewal of any such inclusion and for the variation of any such inclusion:

Column (1)	Column (2)*
	€
Receipt, registry and completeness check	
Data and information relating to identity, physical and chemical properties and methods of analysis	
Toxicological and metabolism data and information	
Data and information relating to residues	
Data and information relating to fate and behaviour in the environment	
Ecotoxicological data and information	
Efficacy data and information	
Co-ordination of evaluation and preparation of monograph	

Evaluation of further data and comments provided

Part 2

Regulation 42 (2)

Fees for the consideration of applications for the authorisation or registration of a biocidal product or renewal of an authorisation or registration of a biocidal product:

Column (1)	Column (2)*
	€
Each dossier satisfying the requirements of Annex IIB	
Each dossier satisfying the requirements of Annex IIIB	
Each dossier satisfying the requirements of Annex IVB	
Each dossier satisfying the requirements of paragraph (4) of Regulation 4	

Part 3

Regulation 42 (2)

Fees for the consideration of applications for modification of an authorisation or registration of a biocidal product:

Column (1)	Column (2) *
Category	
	€
I	
II	
III	

"Category I" means a modification in the authorization of a biocidal product involving a major additional use, a major change in the manner of use, or a major formulatio change;

"Category II" means a modification in the registration of a biocidal product involving a major additional use, a major change in the manner of use, or a major formulation change;

"Category III" means a modification in the authorization or registration of a biocidal product involving a minor additional use, a minor change in the manner of use, or a minor formulation change.

Part 4

Regulation 42 (8)

Annual fees and late annual fees:

Column (1)	Column (2)
	€
Annual fee	254
Late annual fees	380

Given under my Official Seal this 18th day of December 2001

L.S.

Joe Walsh

_____

Minister for Agriculture, Food and Rural Development

Explanatory Note

(This note is not part of the instrument and does not purport to be a legal interpretation)

These Regulations specify the requirements and conditions for the authorisation and registration of biocidal products, which must be complied with in relation to their placi on the market and use, in accordance with European Parliament and Council Directive 98/8/EC, as well as introducing relevant enforcement and financial provisions.

In addition, the Regulations specify the transitional arrangements for the placing on the market and use of biocidal products pending their authorisation or registration in accordance with the Regulations.

[1] O.J. No. L 123/1 24/4/1998

[2] O.J. No. L196/1 16/8/1967

[3] O.J. No. L225/1 21/08/2001

[4] O.J. No. L230/1 19/8/1991

[1] O.J. No. L 123/1 24/4/1998

[5] O.J. No. L358/1 18/12/1986

[6] O.J. No L15/29 17/01/1987

[7] O.J. No. L158/40 06/10/1990

[8] O.J. No. L 374/1 31/12/1990 as last amended by Directive 95/30/EC (O.J. No. L 155/3, 6/7/1995)

[9] O.J. No. L 212/24 7/8/2001

[10] O.J. No. L270/26 15/08/1979

[11] O.J. No. L229/11 30/08/1980 as last amended by Directive 91/692/EEC (O.J. No. L 377/48, 31/12/1991).

[12] O.J. No. L20/43 26/01/1980

[13] O.J. No. L374/1 31/12/1990 as last amended by Directive 95/30/EC (O.J. No. L155/5, 06/07/1995)

[14] O.J. No. L227/9 08/09/1993

[11] O.J. No. L229/11 30/08/1980 as last amended by Directive 91/692/EEC (O.J. No. L 377/48, 31/12/1991).

[15] O.J. No. L194/26 25/07/1975 as last amended by Directive 91/692/EEC (O.J. L377/48, 31/12/1991)

[11] O.J. No. L229/11 30/08/1980 as last amended by Directive 91/692/EEC (O.J. No. L 377/48, 31/12/1991).

* ISO common names, where available should be used, in other cases the chemical name of each constituent (EINECS or ELINCS), and the CAS and EC numbers should provided

* ISO common names, where available should be used, in other cases the chemical name of each constituent (EINECS or ELINCS), and the CAS and EC numbers should provided

* ISO common names, where available should be used, in other cases the chemical name of each constituent (EINECS or ELINCS), and the CAS and EC numbers should provided

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* ISO common names, where available should be used, in other cases the chemical name of each constituent (EINECS or ELINCS), and the CAS and EC numbers should provided

[16] O.J. No. 22/369 09/02/1965 as last amended by Directive 93/39/EEC (O.J. No. L214/22, 24/08/1993).

[17] O.J. No. L317/1 06/11/1981 as last amended by Directive 93/40/EEC (O.J. No. L214/31, 24/08.1993)

[18] O.J. No. L373/26 31/12/1990

[19] O.J. No. L297/8 13/10/1992

[20] O.J. No. L297/12 13/10/1992

[21] O.J. No. L214/1 24/08/1993

[22] O.J. No. L189/17 20/07/1990 as last amended by Directive 93/68/EEC (O.J. No. L 220/1, 31/08/1993)

[23] O.J. No. L169/1 12/07/1993

[24] O.J. No. L40/1 11/02/1989 as last amended by Directive 94/34/EC (O.J. No. L237/1, 10/09/1994)

[25] O.J. No. L184/61 15/07/1988 as last amended by Directive 91/71/EEC (O.J. No. L42/25, 15/02/1991).

[26] O.J. No. L 61/1 18/03/1995 as last amended by Directive 96/85/EC (O.J. No. L86/4, 28/03/1997)

[27] O.J. No. L 40/38 11/02/1989

[28] O.J. No. L268/1 14/09/1992 as last amended by Directive 94/71/EC (O.J. No. L368/33, 31/12/1994)

[29] O.J. No. L212/87 22/07/1989

[30] O.J. No. L268/15 24/09/1991 as last amended by Directive 95/71/EC (O.J. No. L332/40, 30/12/1995)

[31] O.J. No. L92/42 07/04/1990

[32] O.J. No. L270/1 14/12/1970 as last amended by Directive 97/6/EC (O.J. No. L35/11, 05/02/1997)

[33] O.J. No. L213/8 21/07/1982 as last amended by Directive 96/25/EC (O.J. No. L125/35, 23/05/1996)

[34] O.J. No. L32/1 03/02/1977

[35] O.J. No. L262/169 27/09/1976 as last amended by Directive 97/18/EC (O.J. No. L114/43, 11/05/1997)

[36] O.J. No. L51/12 08/03/1995

[37] O.J. No. L230/1 19/08/1991 as last amended by Directive 2001/49/EC (O.J. No. L176/61, 29/06/2001)

* amounts as the Minister may by order determine

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