L.N. 294 of 2004

PESTICIDES CONTROL ACT
(CAP. 430)

Biocides Regulations, 2004

IN exercise of the powers conferred by articles 4 and 5 of the Pesticides Control Act, the Minister of Rural Affairs and the Environment, has made the following regulations:

Title and commencement.

1. The title of these regulations is the Biocides Regulations, 2004, and they shall come into force as follows:

(a) the provisions under Part Two

(i) on the expiry of thirty days following the publication of these regulations in the Gazette in relation to biocidal products not listed under Schedule Two to these regulations;

(ii) on the 15th May, 2004 in relation to biocidal products listed in Schedule Two to these regulations; and

(b) on the expiry of thirty days following the publication of these regulations in the Gazette in relation to all other provisions of these regulations.

Scope and applicability.

2. (1) The scope of these regulations is to provide for the authorisation and control in relation to dealing, advertising and use of any biocidal product or any other active substances intended for use in any biocidal product as specified in the Act.

(2) These regulations shall not apply to those products which are regulated within the scope of any other provision made by or under the Act or any other act, in particular :

(a) provisions relating to proprietary medicinal products;

(b) provisions relating to veterinary medicinal products;

(c) provisions relating to veterinary medicinal products and establishing additional provisions for immunological medicinal products;

(d) provisions relating to medicinal products and establishing additional provisions on homeopathic medicinal products;

(e) provisions relating to veterinary medicinal products and establishing additional provisions on homeopathic veterinary medicinal products;

(f) provisions relating to authorisation and supervision of medicinal products for human and veterinary use;

(g) provisions relating to active implantable medical devices;

(h) the provisions concerning medical devices;

(i) provisions concerning food additives authorised for use in foodstuffs intended for human consumption, relating to flavourings for use in foodstuffs and to source material for their production and on food additives other than colours and sweeteners;

(j) provisions relating to material and articles intended to come into contact with foodstuffs;

(k) provisions laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk based products;

(l) provisions relating to hygiene and health products affecting the production and the placing on the market of egg products;

(m) provisions establishing the health conditions for the production and the placing on the market of fishery products;

(n) provisions establishing the conditions governing the preparation, placing on the market and use of medicated feedingstuffs;

(o) provisions concerning additives in feedingstuffs, on certain products used in animal nutrition and on the marketing of straight feedingstuffs;

(p) provisions relating to cosmetic products;

(q) provisions on certain conditions for granting temporary and limited derogations from specific health rules on the production and the marketing of certain products of animal origin; and

(r) provisions concerning the placing of plant protection products on the market.

(3) These regulations shall apply, without prejudice to any of the following provisions made by or under any other Act or in relation to measures taken in accordance with the said provisions:

(a) provisions relating to restriction on the marketing and use of certain dangerous substances and preparations;

(b) provisions prohibiting the placing on the market and use of biocidal products containing certain active substances;

(c) provisions concerning the export and import of certain dangerous chemicals;

(d) provisions concerning the protection of workers from the risks related to exposure to chemical, physical and biological agents at work and on the introduction of measures to encourage improvements in the safety and health of workers at work; and

(e) provisions concerning misleading advertising.

(4) The provisions of regulation 35 of these regulations shall not apply to the carriage of biocidal products by road, sea or air.

(5) The provisions of Part 2 of these regulations shall not apply in relation to an application for the registration of an active substance listed in Schedule 3 to these regulations or biocidal products listed in Schedule 2 to these regulations as the case may be, which were on the market in Malta on publication of these regulations in the Government Gazette:

Provided that an ad hoc application for the registration of such active substances or authorisation of a biocidal product as the case may require, be made to the director in writing as he may establish in the Gazette:

Provided further that any such registration of an active substance or authorisation of a biocidal product shall be issued by the Director subject to such terms and conditions as he may deem acceptable and on condition that the provisions under Part 2 of these regulations shall be complied within such time as may be stipulated in the registration or authorisation.

PART ONE

GENERAL PROVISIONS

Interpretation.

3. (1) In these regulations, unless the context otherwise requires:

"Act" means the Pesticides Control Act;

"advertising" in relation to biocidal products includes any form of door-to-door information, canvassing activity or inducement designed to promote the supply, sale or use of biocidal products and without prejudice to the generality of the foregoing in particular includes:

(a) the advertising of biocidal products to the general public or to persons who may be expected to use or supply these products;

(b) the provision of inducements to prescribe or supply of biocidal products, by way of a gift, offer or promise of any benefit or bonus, whether in money or in kind, except when the intrinsic value of such an inducement is minimal; and

(c) sponsorship of any meeting attended by persons authorised to deal or who generally use these products:

But shall exclude:

(i) the labelling and the accompanying package leaflets, which are subject to the provisions of Part Four of these regulations;

(ii) correspondence, even if accompanied by material of a non-promotional nature, which is in reply to a specific question about a particular biocidal product; and

(iii) factual, informative, announcement or reference material relating to pack changes, adverse-effect warnings as part of general precautions, trade catalogues, price lists and other material of a similar nature provided that such material does not include any product claim;

"animal" means an animal belonging to species normally fed and kept or consumed by man or otherwise considered as beneficial;

"authorised representative" means any person duly authorised by the Director to act on his behalf for any of the purposes referred to in these regulations;

"basic substance" also referred to as commodity substance means a substance which is listed in Part IB of the Register of active substances, 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 diluents which itself is not a substance of concern and which is not directly marketed for this biocidal use. Such substances shall inter alia include the following:

(a) carbon dioxide;

(b) nitrogen;

(c) ethanol;

(d) 2-propanol;

(e) acetic acid;

(f) kieselguhr;

"dealing" means any activity in the manufacture, import, export, transport, storage, distribution, presenting for sale or sale of any biocidal product;

"The Department" means the Department responsible for plant health;

"frame formulations" means the specifications for a group of biocidal products having the same use and user type, which group of products must convey the same active substances of the same specifications, and their compositions must present only variations from a previously authorised biocidal products which do not affect the level of risk associated with them and their efficacy and for such purpose 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, perfumes by others presenting the same or a lower risk, and which do not decrease its efficacy;

"letter of access" means a document, signed by the owner or owners of relevant data protected under the provisions of these regulations, which states that this data may be used by the Director for the purpose of granting an authorisation or for the registration of a biocidal product in accordance with these regulations;

"low-risk biocidal product" means a biocidal product which does not contain as active substance any substance of concern, under the conditions of use, the biocidal product shall pose only a low risk to humans, animals and the environment;

"manufacturer" means the holder of a manufacturing process for the manufacturing of a biocidal product;

"manufacturing" shall have the same meaning as is assigned to it in the Act;

"preparation" means mixtures or solutions composed of two or more substances;

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

"recognised country" means any Member State of the European Community;

"relevant regulations" means -

The Dangerous Substances (Notification) Regulations, 2001, Legal Notice 318 of 2001,

The Dangerous Substances (Risk Assesment) Regulations 2002, Legal Notice 40 of 2002,

The Dangerous Substances and Preparation (Restrictions) Regulations 2002, Legal Notice 142 of 2002,

The Dangerous Substances and Preparations Regulations, 2002, Legal Notice 221 of 2002, and other regulations as the case may be;

"scientific research and development" means scientific experimentation, analysis or chemical research carried out under controlled conditions; it includes the determination of intrinsic

properties, performance and efficacy as well as scientific investigation related to product development;

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

"substance of concern" means any substance, other than 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 sufficient concentration to create such an adverse effect. Such a substance, unless there are other grounds for concern would be normally a substance classified as dangerous according to the relevant provisions of (Legal Notice 318 of 2001) relating to the classification, packaging and labelling of dangerous substances and present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of the relevant provisions of (Legal Notice 221 of 2002) relating to the classification, packaging and labelling of dangerous preparations.

PART TWO

AUTHORISATION OF BIOCIDAL PRODUCTS

Registration and inclusion of an active substance in The Register of active substances

4. (1) Without prejudice to the provisions of sub-regulation (8) of this regulation and regulation 5 of these regulations, the Director shall register any active substance for an initial period not exceeding ten years:

(a) if he has received an application for the registration of that active substance in such form and such manner and within such a time as he may from time to time, require by notice in the Gazette;

(b) if he has received a dossier for the active substance satisfying the requirements of Annex IVA or the requirements of Annex IIA and, where specified, the relevant parts of Annex IIIA to Council Directive 98/8/EEC of 16 February 1998 concerning the placing of biocidal products on the market (Official Journal of the European Communities, L 123) and as may from time to time be amended;

(c) if he has received a dossier for at least one biocidal product containing the active substance in accordance with the provisions of regulation 17 of these regulations, other than sub-regulation (2) thereof; and

(d) if he has verified the dossiers and finds them to be in compliance with the requirements of Annex IVA and Annex IVB or the requirements of Annex IIA and Annex IIB and, where relevant, Annexes IIIA and IIIB to Council Directive 98/8/EEC of 16 February 1998 concerning the placing of biocidal products on the market (Official Journal of the European Communities, L 123) and as may from time to time be amended.

(2) Notwithstanding the provisions of sub-regulation (4) of this regulation, the Director shall carry out an evaluation of the above mentioned dossiers and take a decision whether to include or otherwise the active substance under the relevant parts of the Register of active substances, within twelve months of accepting the dossiers:

Provided that if, when the dossiers are evaluated, it appears that further information is necessary for full evaluation to be made, the receiving Director shall ask that the applicant to submit such information. The twelve month period shall be suspended from the date of issue of the Director's request until the date the information is received.

(3) An active substance shall, in the light of current scientific and technical knowledge, be included in parts 1, 1A or 1B of the Register of active substances to these regulations if it may be expected that:

(a) biocidal products containing the active substance;

(b) low-risk biocidal products complying with the definition in regulation 3 of these regulations;

(c) basic substances complying with the definition in regulation 3 of these regulations;

will fulfil the conditions laid down in paragraphs (b), (c) and (d) of sub-regulation (2) of regulation 9 of these regulations, taking into account, where relevant, cumulative effects from the use of biocidal products containing the same active substances.

4. (a) The Director shall refuse or remove an entry of an active substance from parts I and, where relevant from parts IA or IB of the Register of active substances to these regulations:

(i) if the evaluation of the active substance in accordance with sub-regulation (2) of regulation 4 of these regulations shows that, under normal conditions of use in any authorised biocidal product, risks to human beings, animals or the environment still give rise to concern, and

(ii) if there is another active substance in part I of the Register of active substances to these regulations for the same product type which, in the light of scientific or technical knowledge, presents significantly less risk to health or to the environment.

When such a refusal or removal is considered, an assessment of an alternative active substance or substances shall take place to demonstrate that it can be used with similar effect on the target organism without significant economic and practical disadvantages for the user and without an increased risk for health or for the environment.

(b) The Director shall carry out the refusal or removal of an active substance from part I and, where from parts IA or IB of the Register of active substances to these regulations under the following conditions:

(i) the chemical diversity of the active substances should be adequate to minimise occurrence of resistance in the target organism;

(ii) it should be applied only to active substances which, when used under normal conditions in authorised biocidal products, present a significantly different level of risk;

(iii) it should be applied only to active substances used in products of the same product type; and

(iv) it should be applied only after allowing the possibility, where necessary, of acquiring experience from use in practice, if it is not already available.

(5) An active substance shall not be included in part 1A of the Register of active substances to these regulations if it is classified according to relevant regulations as:

(a) carcinogenic,

(b) mutagenic,

(c) toxic for reproduction,

(d) sensitising, or

(e) is bioaccumulative and does not readily degrade.

(6) Where appropriate, the active substance shall be registered under part 1A of the Register of active substances to the concentration ranges between which the substance can be used.

(7) Inclusion of an active substance in parts 1, 1A or 1B of the Register of active substances, shall where appropriate, be subject to;

(a) the requirements on:

(i) the minimum degree of purity of the active substance;

(ii) the nature and maximum content of certain impurities;

(iii) the product type in which it may be used, manner and area of use;

(iv) the designation of categories of users (e.g. industrial, commercial or domestic);

(v) other particular conditions from the evaluation of the information which has been made available in the context of these regulations;

(b) the establishment of the following:

(i) acceptable operator exposure level (AOEL), as the case may be required;

(ii) where relevant, an acceptable daily intake for human beings (ADI) and a maximum residue limit (MRL);

(iii) fate and behaviour in the environment and impact on non-target organisms.

(8) The inclusion of an active substance the Register of active substances to these regulations of an active substance shall be restricted to those product types listed in Schedule One to these regulations.

(9) Following the decision by the competent authority of a recognised country to include or not to include an active substance in Annex I, IA or IB to Council Directive 98/8/EEC of 16 February 1998 concerning the placing of biocidal products on the market (Official Journal of the European Communities, L 123) as may from time to time be amended, the Director shall amend the relevant parts of the Register of active substances whereby Annex 1 shall correspond to Part1 , Annex 1A shall correspond to Part 1A and Annex 1B shall correspond to Part 1B to these regulations to reflect such decisions:

Renewal of registration of an active substance.

5. (1) The Director shall renew the registration of an active substance in parts I, IA or IB of the Register of active substances to these regulations for periods not exceeding ten years if:

(a) he has received an application for renewal in such form and such manner and within such time as the Director may, from time to time require by Notice in the Gazette; and

(b) he is satisfied that the conditions detailed in regulation 4 of these regulations are still being complied with:

Provided that the Director may request the applicant to provide any additional information as he may deem necessary prior to the renewal or otherwise of the authorisation:

Provided further that any renewal of any registration may be subject to any condition as the Director may deem appropriate.

(2) Where an application for renewal in accordance with sub-regulation (1) of this regulation has been submitted to the Director, the validity of the registration granted in accordance with regulation 4 of these regulations shall be deemed to continue to have effect until such time as the Director has determined the application for renewal.

Review of registration of an active substance.

6. (1) Where the Director suspects that any of the conditions established by regulation 4 of these regulations for the inclusion or renewal of inclusion of an active substance in part I, IA or IB of the Register of active substances to these regulations is no longer satisfied, he:

(a) shall require the applicant to submit any further information necessary to establish compliance with the provisions of regulation 4 of these regulations;

(b) may carry out any review or test that he deems necessary;

(c) may remove an active substance from parts I, IA or IB of the Register of active substances to these regulations in accordance with regulation 4 of these regulations.

(2) The Director shall, where necessary, grant renewal of inclusion of an active substance from parts I, IA or IB of the Register of active substances to these regulations in accordance with regulation 4 of these regulations for the minimum period necessary to complete a review.

Refusal or revocation of registration of an active substance.

7. Where in the consideration of an application for renewal in terms of regulation 5 of these regulations or in a review carried out during the currency of a registration in terms of Regulation 6 of these regulations. It is decided that an active substance shall be removed from Part1 and where relevant from Part 1A or 1B because of any of the conditions described in sub-regulation 4 are no longer being complied with. Such a decision shall be notified to the applicant or the Registration holder as the case may be and the removal shall take effect immediately after six months from the date of such notification.

Granting of an authorisation to place an active substance on the market.

8. (1) Subject to the provisions of Regulation 4 of these regulations the Director shall authorise the placing on the market in Malta of any active substance that is intended for use in biocidal products if:

(a) he has received an application submitted in such form and such manner and within such a time as he may from time to time, require by notice in the Gazette:

Provided that the applicant shall have a permanent office in Malta or a recognised country,

(b) in the case where the active substance is listed in Schedule 3 or was not on the market locally or a recognised country before 14 May 2000, a dossier has been submitted, which is in accordance with the requirements of sub-regulation (1) of regulation 4 of these regulations or in accordance with similar requirements in a recognised country and is accompanied by the declaration that the active substance is intended for inclusion in a biocidal product:

Provided that the requirement of this sub-regulation shall not apply to substances for use in accordance with the provisions of regulation 37 of these regulations, and

(c) he has established that the active substance complies with the provisions of relevant regulations regarding the classification, packaging and labelling of dangerous substances.

(2) Provisions of regulation 4 of these regulations mutatis mutandis shall apply to an authorisation under this regulation.

Granting of an authorisation to place a biocidal product on the market.

9. (1) The Director shall authorise the placing on the market of any biocidal product if he has:

(a) received an application for the issue of an authorisation in accordance with regulation 17 of these regulations;

(b) received a product dossier in accordance with regulation 17 of these regulations; and

(c) established that the provisions of sub-regulation (2) hereof are complied with.

(2) Prior to the issue of an authorisation in accordance with sub-regulation (1) hereof, the Director shall, on the basis of information supplied to him by the applicant, be satisfied that:

(a) the active substance is included in Part I or IA of the Register of active substances:

Provided that if the active substance is still pending its registration, the Director may issue an authorisation pending a final decision on the registration of the active substance;

(b) it is established, in the light of current scientific and technical knowledge, and is shown from appraisal of the biocidal product dossier, according to the common principles for the evaluation of dossiers as laid down in Annex VI to Council Directive 98/8/EEC of 16 February 1998 concerning the placing of biocidal products on the market (Official Journal of the European Communities, L 123) as may from time to time be amended that, when used as authorised and having regard to:

- all normal conditions under which the biocidal product may be used,

- how the material treated with it may be used,

- the consequences from use and disposal, the biocidal product:

(i) is sufficiently effective;

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

(iii) has no unacceptable effects itself or as a result of its residues, on human or animal health, directly or indirectly (e.g. thorough drinking water, food or feed, indoor air or consequences in the place of work) or on surface water and groundwater;

(iv) has no unacceptable effect itself, or as a result of its residues, on the environment having particular regard to the following considerations:

- its fate and distribution in the environment; particularly contamination of surface water (including estuarian and seawater), ground water and drinking water,

- its impact on non-target organisms;

(c) the nature and quantity of its active substance and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants, and its residues of toxicological or environmental significance, which result from authorised uses, can be determined according to the relevant requirements in Annexes IIA, IIB, IIIA, IIIB, IVA, or IVB to Council Directive /EEC of 16 February 1998 concerning the placing of biocidal products on the market (Official Journal of the European Communities, L 123) and as may from time to time be amended;

(d) its physical and chemical properties have been determined and deemed acceptable for purposes of the appropriate use, storage and transport of the product; and

(e) the packaging and labelling requirements detailed in Part Four of these regulations are complied with:

Provided that biocidal product may have different specifications and characteristics for the labelling and packaging of different pack sizes.

(3) A biocidal product classified under the relevant regulations as toxic, very toxic or as a category 1 or 2 carcinogen, or as a category 1 or 2 mutagen or classified as toxic for reproduction category 1 or 2 shall not be authorised for marketing, or use by the general public.

(4) Authorisations under these regulations may be subject to such terms and conditions as the director may deem necessary, in relation to

(i) marketing and use of the biocidal product and,

(ii) other requirement under any other legislation.

(5) The applicant shall, as soon as practicable, notify the Director in writing of any change in the information supplied to the Director in the application or dossier and shall provide him with all the evidence that may be deemed necessary to support any identified change.

(6) The Director shall, upon request by the applicant, or on his own initiative, and where relevant, establish a frame-formulation and communicate it to the applicant when issuing an authorisation for a particular biocidal product.

(7) Where a frame formulation has been established, an application for the Authorisation of a biocidal product to which the frame formulation refers, a second subsequent application shall be subject to the provisions of Regulation 17 and 46.

(8) Any application received by the director under this regulation shall be determined by him within a reasonable time not exceeding 60 working days from the date of receipt of an application:

Provided that such time may be suspended until the relevant information is received.

(9) The Director may authorise temporarily, for a period not exceeding 120 days, the placing on the market of biocidal products that are not authorised in accordance with these regulations, for a limited and controlled use if such a measure appears necessary because of unforeseen danger which cannot be contained by other means.

10. (1) Any authorisation for a biocidal product issued in accordance with regulation 9 of these regulations shall, as a minimum, specify: Information found in an authorisation.

(a) the biocidal product trade name;

(b) the chemical name and Chemical Abstracts Service registry number of any active substance contained in the product formulation;

(c) the approved product formulation;

(d) the classification of the biocidal product as a low risk biocidal product or otherwise;

(e) the application rates and instructions for use for the biocidal product being authorised;

(f) the approved labelling and packaging including any advisory phrases or directions that may be related to the storage or use of the product;

(g) any conditions that may be attached to the granting of the authorisation;

(h) the name and contact details of the holder of the authorisation;

(i) the authorisation number;

(j) the term of validity of the authorisation; and

(k) any other specification that the Director may deem necessary.

Duration of validity of an authorisation.

11. Any authorisation issued by the Director in accordance with regulation 9 of these regulations shall be valid for a period not exceeding a period of ten years from the date of first or renewed inclusion of its active substance in Part I or IA of the Register of active substances for the product type.

Provided that the Director may extend the validity of any such authorisation upon the submission of an application for the renewal of the authorisation submitted to him in accordance with regulation 14 of these regulations and the Director is satisfied that the conditions established by regulation 9 of these regulations are being complied with.

Review of authorisation.

12. Where the Director suspects that any of the conditions established by regulation 9 of these regulations is no longer satisfied, he:

(a) shall require the applicant for authorisation or the holder of the authorisation granted in accordance with regulation 9 of

these regulations to submit any further information necessary to establish compliance with the provisions of regulation 9 of these regulations;

(b) may carry out any review or test that he deems necessary;

(c) may suspend or revoke the authorisation in accordance with regulation 13 of these regulations; and

(d) if, after having suspended the authorisation and after carrying out the necessary verifications he establishes that the conditions of regulation 9 of these regulations are being complied with, he may extend the validity of an authorisation for the period equivalent to the time needed for the Director to complete its verification.

Suspension or revocation of an authorisation.

13. (1) Any authorisation issued in accordance with regulation 9 of these regulations may be suspended or revoked by the Director if it is established that:

(a) any information or particular supporting the application for an authorisation was incorrect, false or misleading; or

(b) any requirement as detailed in sub-regulation (2) of regulation 9 of these regulations is no longer satisfied; or

(c) the applicant for authorisation requests that the Director revokes the authorisation to place on the market, deal or use a biocidal product in Malta; or

(d) the biocidal product is no longer satisfactory in the performance of the function or functions for which it was originally intended as detailed in the biocidal product dossier; or

(e) new scientific information or data indicates that the introduction into Malta, the marketing or the use of a biocidal product presents a previously unknown risk or unknown risks which are considered to be unacceptable; or

the active substance is no longer included in Parts 1 or 1A of the Register of active substances as required by paragraph (a) of sub-regulation (2) of regulation 9 of these regulations.

(2) (a) Where the Director suspends or revokes an authorisation, he shall notify the holder of the authorisation in writing of such a decision also providing the holder of the authorisation with detailed reasons on which such a decision was based and shall publish a notice in the Gazette announcing such suspension or revocation.

(b) In the case of a revocation the Director may specify that the commencement of any such revocation shall take effect within a reasonable time for the disposal or for the storage, marketing and use of existing stocks, and this period shall be of a length that reflects the reason for the revocation.

Renewal of an authorisation.

14. (1) On the expiry of an authorisation, the Director shall renew the authorisation if:

(a) he has received an application for renewal in such form and such manner and with such a time as the Director may, from time to time require by Notice in the Gazette; and

(b) he is satisfied that the conditions detailed in regulation 9 of these regulations are still being complied with:

Provided that the Director may request the applicant to provide any additional information he may deem necessary prior to the renewal or otherwise of the authorisation:

Provided further that any renewal of any authorisation may be subject to any condition as the Director may deem appropriate.

(2) Where an application for renewal in accordance with sub-regulation (1) of this regulation has been submitted to the Director, the validity of the authorisation granted in accordance with regulation 9 of these regulations shall be deemed to continue to have effect until such time as the Director has determined the application for renewal.

Modification of an authorisation.

15. (1) Without prejudice to the provisions of regulation 12 of these regulations, the Director may, upon the written request from the holder of the authorisation, modify an authorisation to place a biocidal product on the market in Malta:

Provided that the Director is satisfied that such modification is justified, and appropriate, and where relevant, reflects current scientific opinion.

(2) Without prejudice to regulation 13 of these regulations, the Director may modify the original authorisation if he considers that any condition on which the authorisation was based in accordance with regulation 9 of these regulations has been substantially changed.

(3) Any request for a modification to the authorisation in accordance with sub-regulation (1) of this regulation shall be made by the holder of the authorisation on such form and such manner and within

such time as the Director may, from time to time require by notice in the Gazette.

(4) Where a proposed modification of an authorisation:

(a) concerns an extension of uses, the Director shall extend the authorisation subject to the particular conditions placed on the active substance listed in Parts I or IA of the Register of active substances to these regulations;

(b) involves changes to the particular conditions placed on the active substance listed in Parts I or IA of the Register of active substances, such changes can be made only after evaluation of the active substance, with regard to the proposed changes, in accordance with the procedures laid down in regulation 17 of these regulations.

Obligations of the holder of an authorisation.

16. Without prejudice to any provision made by or under the Act, it shall be the duty of any other person holding an authorisation granted to him in accordance with regulation 9 of these regulations to:

(a) keep such records and for such time as the Director may from time to time require by notice in the Gazette;

(b) inform the Director in writing, as soon as practicable, of any change to any information supplied to the Director for the granting of the authorisation, in particular:

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

(ii) changes in composition of a biocidal product;

(iii) development of resistance of the target harmful organisms;

(iv) changes of an administrative nature or other aspects, such as the nature of the packaging;

(c) inform the Director in writing, as soon as practicable, of any adverse effect on the user through the use or exposure to the product that may have been brought to his attention;

(d) inform the Director, as soon as practicable, of any unexpected adverse effect on the environment or the ecosystem as a result of the use, dispersal, dumping, disposal or otherwise of the biocidal product;

(e) allow the Director or his authorised representative with access to the land or premises at any reasonable time; and

(f) comply with any provision made by or under the Act.

Application for an authorisation of a Biocidal product

17. (1) An application for the granting of an authorisation for the placing on the market in Malta of a biocidal product shall be submitted to the Director in Maltese or English together with a dossier or a letter of access for the biocidal product satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex IIB and, where specified, the relevant parts of Annex IIIB to Council Directive 98/8/EEC of 16 February 1998 concerning the placing of biocidal products on the market (Official Journal of the European Communities, L 123) and as may from time to time be amended, and

Provided that, the Director may from time to time by Notice in the Gazette establish the organisation and content of the application form that is to be submitted by an applicant.

(2) By way of derogation from sub-regulation (1) above, a dossier submitted to the Director in relation to the granting of an authorisation of a low-risk biocidal product shall comprise the following data:

(a) applicant:

(i) name and address,

(ii) manufacturers of the biocidal product and the active substances, (names and addresses including location of manufacturer of the active substances)

(iii) where appropriate, a letter of access to any relevant data needed;

(b) identity of the biocidal product:

(i) trade name,

(ii) full composition of the biocidal product,

(iii) physical and chemical properties as referred to in paragraph (d) of sub-regulation (2) of regulation 9 of these regulations;

(c) intended uses:

(i) product type (as listed in Schedule one to these regulations) and field of use,

(ii) category of users,

(iii) method of use;

(d) efficacy data;

(e) analytical methods;

(f) classification, packaging and labelling, including a draft label, according to Part Four of these regulations;

(g) safety data sheet prepared in accordance with the national provisions relating to the classification, packaging and labelling of dangerous substances.

(3) Only applications submitted by a person having a permanent office in Malta or a recognised country shall be considered for authorisation.

(4) The dossiers under this regulation shall include a detailed and full description of the studies conducted and of the methods used or a literature reference to those methods. The information in the dossiers shall be sufficient for an evaluation to be made of the effects and properties referred to in sub-regulation (2) of regulation 9 of these regulations. It shall be submitted to the Director in the form of technical dossiers, containing the information and results of the studies referred to in Annexes IIB and, where specified, the relevant parts of Annexes IIIB to Council Directive 98/8/EEC of 16 February 1998 concerning the placing of biocidal products on the market (Official Journal of the European Communities, L 123) and as may from time to time be amended.

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

(6) If the evaluation of the dossier shows that further information, including data and results from further testing, is necessary to evaluate the risks of the biocidal product, the Director shall ask the applicant to submit such information. The time period for the evaluation of the dossier shall commence from the provision of such information.

(7) The name of an active substance must be given as registered in the list contained and provided in the relevant regulations relating to the classification, packaging and labelling of dangerous substances or, if the name is not included therein, the active substance must be given its International Standards Organisation (ISO) common name. If the latter is not available, the substance must be designated by its chemical designation according to International Union of Pure and Applied Chemistry (IUPAC) rules.

(8) Tests must be conducted according to the methods described in the relevant regulations relating to the classification, packaging and labelling of dangerous substances. When a method is inappropriate or not described, other methods used should be justified, whenever possible, be internationally recognised. Such tests where appropriate must be conducted in accordance with the relevant provisions of the Animal Welfare Act (Cap 439) regarding the protection of animals used for experimental and other scientific purposes and in any case texts shall comply with the relevant provisions relating to the principles of Good Laboratory Practice (GLP).

(9) Without prejudice to the provisions of sub-regulation 8 of this regulation the need to conduct any test shall be decided by the Director on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrate animals.

(10) The Director may require that samples of the preparation and of its ingredients shall be provided. In addition to the application for the granting of an authorisation to this regulation an applicant shall submit such samples of the biocidal product, of its ingredients and models or drafts of the packaging, labelling and leaflets as the Director may require

Biocidal product record.

18. (1) The Director shall draw up, keep and maintain a separate product record for each biocidal product for which an application for the granting of an authorisation has been submitted in accordance with these regulations.

(2) Each record shall as a minimum contain:

(a) a copy of the application submitted to the Director by the applicant;

(b) a record of the administrative decisions taken by the Director concerning the application and concerning the dossiers submitted in accordance of sub-regulation (1) of regulation 17 of these regulations, with a summary of the latter; and

(c) any other document or information submitted, considered or used during the course of evaluating the application and the dossier.

Registers to be kept and maintained.

19. (1) The Director shall keep and maintain, subject to the provisions of sub-regulation 7 of regulation 4 of these regulations, a register of active and basic substances referred to as 'The register of active substances' for biocidal products which shall be divided into 3 parts Part1, Part 1A and Part 1B. Part 1 shall contain a list of active substances which may be contained in biocidal products; Part 1A shall contain a list of active substances which may be contained in low risk biocidal products; Part 1B shall contain a list basic substances.

(2) Such register shall, as a minimum, contain the following information:

(a) a reference number for the entry in the register;

(b) the date of registration;

(c) the common name of the active substance/s;

(d) the Chemical Abstracts Service (CAS) registry number of each active substance;

(e) the classification of the active substance in accordance with the provisions of sub-regulation (1) of regulation 4 of these regulations or whether such classification is still pending;

(f) the date on which a decision on the classification was made and a track record of any subsequent change in the classification of the active substance; and

(g) any other information the Director may, from time to time, require by Notice in the Gazette.

(3) The Director shall also keep a register of biocidal products which shall, as a minimum, contain the following information:

(a) the authorisation number of the biocidal product;

(b) the date of issue of the current authorisation and a track record of any subsequent issue or otherwise of an authorisation;

(c) the date on which the current term of authorisation will expire;

(d) the name by which the biocidal product is to be placed on the market in Malta;

(e) the name, Chemical Abstracts Service registry number and percentage of all active substances contained within the formulation;

(f) whether the product is a low risk biocidal product or otherwise;

(g) the name and contact details of the authorisation holder; and

(h) any other information the Director may, from time to time, establish.

Publication of registered active substances.

20. (1) The Director shall publish in the Gazette a list of all the active and basic substances contained in the register established under regulation 19 of these regulations and such publication shall:

(a) be issued at least once annually and prior to the 1st day of February;

(b) contain, as a minimum, the following information:

(i) the common name and Chemical Abstracts Service registry number of the active or basic substance;

(ii) the classification of the active or basic substance or an indication that the classification of the active substance is still pending.

(2) Whenever a new active substance has been entered in the register of active substances or the classification of the active or basic substance has changed, the Director shall, by Notice in the Gazette, publish in relation to such active substance, the information specified in paragraph (b) of the foregoing sub-regulation and such publication shall be deemed to amend the list issued under sub-regulation (1) of this regulation.

Publication of authorised biocidal products.

21. (1) The Director shall publish in the Gazette a list of all biocidal products authorised for marketing or use in Malta and such publication shall:

(a) be issued at least once annually and prior to the 1st day of February;

(b) contain, as a minimum, the following information:

(i) the name by which the product is to be placed on the market in Malta;

(ii) the active substance and concentration;

(iii) the name and postal address of the holder of the authorisation;

(iv) whether the product is a low risk biocidal product or otherwise;

(v) the authorisation number of the product.

(2) Whenever an authorisation has been issued in relation to a biocidal product the Director shall, by notice in the Gazette publish in relation to such biocidal product, the information specified in paragraph (b) of the foregoing sub-regulation and such publication shall be deemed to amend the list of biocidal products issued under subregulation (1) of this regulation.

(3) The Director shall by Notice in the Gazette, as soon as practicable, specify the biocidal product for which the authorisation has been suspended or revoked and such publication shall be deemed to amend the list of biocidal products issued under sub-regulation (1) of this regulation.

Recognition of equivalent standards.

22. (1) For the purposes of these regulations, and without prejudice to the provisions of regulation 46 of these regulations the Director may deem that a biocidal product or an active substance that is intended for inclusion in a biocidal product satisfies the conditions of these regulations, if in relation to such product, an authorisation has been issued by a recognised country.

(2) For the purposes of the issue of an authorisation in accordance with regulation 9 of these regulations the Director shall not require that tests and analysis already carried out by a recognised country be repeated for the purposes of issuing an authorisation provided that:

(a) the applicant makes a request for the application to be treated in accordance with this sub-regulation;

(b) the applicant provides suitable evidence as to the authenticity of the authorisation issued by a recognised country to the satisfaction of the Director;

(c) tests and analysis were carried out under circumstances of use, such as climate or breeding period of the target species, relevant to the use of the biocidal product that are comparable to those existent in Malta.

(3) Where any test or analysis required for authorisation under these regulations has not been carried out under conditions as are referred to in paragraph (c) of sub-regulation (2) of this regulation, the Director may require that:

(a) the applicant carries out such tests or analyses in accordance with conditions existing in Malta;

(b) if the applicant so requests, the authorisation shall be issued subject to such conditions that may be required in order to render any non-comparable circumstances of use, such as climate or breeding period of the target species in the regions concerned, irrelevant for the purposes of comparability.

Where following any test or analysis carried out as referred in sub-regulation (3) of this regulation, it is established that such tests or analyses establish that the product does not satisfy the conditions established in these regulations in all respects, the Director shall issue the authorisation subject to:

(i) adjustment of conditions referred to in paragraphs (e), (f), (h), (j) and (l) of sub-regulation (3) of regulation 35 of these regulations to render irrelevant any non-comparable circumstances for the purposes of comparability; and

(ii) any other such restriction as he may deem appropriate.

Abridged authorisation process and requirements for biocidal products already authorised in Malta and in a recognised country.

23. (1) Subject to the provisions relating to the conditions for distribution and use of biocidal products under this or any other legislation, the Director may authorise the use of an abridged authorisation process in relation to a biocidal product that is identical to another product already authorised for placing on the market in Malta or in relation to a biocidal product which is placed on the market in a recognised country:

(2) For the purposes of sub-regulation 1 of this regulation, "identical biocidal products" means that the product is manufactured by the same or an associated company or under license of such company and, that the formulation of the product and its active substances are the same.

(3) An application for an authorisation for the placing on the market of a biocidal product in accordance with the provisions of this regulation shall contain, as a minimum, the following information:

(a) a summary of the dossier as required sub-regulation (1) of regulation 17 of these regulations and Section X of Annex IIB to Council Directive 98/8/EEC of 16 February 1998 concerning the placing of biocidal products on the market (Official Journal of the European Communities, L 123) and as may from time to time be amended, and a certified copy of the first authorisation granted; and in the case of low-risk biocidal products, the data requirements of sub-regulation (2) of regulation 17 of these regulations, except for the efficacy data for which a summary shall suffice;

(b) the trade name of the product to be imported;

(c) the authorisation number of the imported product;

(d) the original label of the imported product and an official translation of it in the Maltese and English languages;

(e) the trade name of the reference product;

(f) the authorisation number of the reference product;

(g) the trade name with which the product will be marketed in Malta;

(h) the proposed draft label of the product to be marketed in Malta;

(i) a sample of the product as it will be marketed in Malta;

(j) a sample of the package as it will be marketed in Malta; and

(k) any other additional information as the Director may deem necessary for establishing that the conditions specified in this regulation are satisfied:

Provided that the active substance of the biocidal product is included in Parts I or IA of the Register of active substances and conforms to the requirements thereof.

(4) In establishing whether the conditions of sub-regulation (1) of this regulation are satisfied, the Director may consult with the

competent authority of the recognised country in which the biocidal product has been authorised to be placed on the market.

(5) If the Director is not fully satisfied that the product is identical, he may carry out such chemical or other analysis of the product with the aim of establishing its identicality.

(6) Any authorisation issued in accordance with this regulation shall be valid for a maximum period of three (3) years from the date of issue and shall, unless previously revoked, be renewable on application by the holder made at least three (3) months before expiry of the validity period.

(7) The Director shall determine the application within a reasonable time not exceeding 45 working days from the date of receipt of an application:

Provided that such time may be suspended until all the relevant information is received:

Provided further that the Director may refuse the granting of an authorisation according to this regulation in the following circumstances:

(a) for product types 15, 17 and 23 listed in Schedule One to these regulations if such limitation can be justified and does not jeopardise the purposes of these regulations;

(b) in accordance with the provisions of regulation 4 of these regulations, the Director establishes that the target species is not present in harmful quantities;

(c) in accordance with the provisions of regulation 4 of these regulations, the Director establishes that there is unacceptable tolerance or resistance of the target organism to the biocidal product.

Placing of a basic substance on the market

24. Notwithstanding any of the provisions under this part, the Director shall on application thereof authorise the placing on the market of a basic substance for biocidal purposes provided that such substance is listed under Part 1B in the register of active substances

PART THREE

DEALING IN BIOCIDAL PRODUCTS

Authorisation to deal in biocidal products and their active substances.

25. (1) No person shall deal in any:

(a) active substance unless this is authorised in accordance with these regulations;

(b) biocidal product unless this is authorised for placing on the market in Malta in accordance with these regulations;

(2) No person shall deal in any active substance or biocidal product unless he is in possession of an authorisation to deal in active substances or biocidal products granted to him in accordance with regulation 26 of these regulations.

Application for an authorisation to deal.

26. (1) Any application for the granting of an authorisation to deal in biocidal products or active substances shall be made in writing to the Director and shall contain such information, and accompanied by such documents, samples and other material as the director may require.

(2) Any application shall contain as a minimum the following requirements:

(a) the nature of any activity related to the dealing of active substances and biocidal products the applicant wishes to undertake;

(b) the place where such activity is to take place, and suitable information, documentation and evidence as may be required in order to show that such place is suitable and sufficient for that purpose;

(c) evidence to show that the place where such activity is to take place has the necessary equipment and control facilities as may be required by the director;

(d) evidence to show that the health and safety of staff shall be protected and ensured at all times;

(e) the name and postal address and any other contact details of the applicant;

(f) the name of the person who will be effectively responsible for carrying out the activity;

(g) in the case of an application for the manufacture of a biocidal product, the name of the biocidal product and any formulation which is to be, or intended to be manufactured, assembled or in any way modified including details of the type and concentration of any active substance to be found within the formulation.

(3) The Director shall determine the application within a reasonable period of time; not exceeding 45 working days from the date of receipt of an application:

(4) Where an application has been made to the Director for the granting of an authorisation to deal in accordance with this regulation, the Director may, before determining the application, request the applicant to submit such further information relating to the application as he may consider requisite and where any such request has been made, the provision of sub-regulation (3) of this regulation shall be suspended until the additional information, has been submitted.

(5) Any authorisation issued in accordance with this regulation shall be made in writing and be subject to any such condition the Director may deem necessary so that the business of dealing shall be carried out in accordance with the provisions made by or under the Act.

Duration of validity of an authorisation.

27. Any authorisation issued by the Director in accordance with regulation 26 of these regulations shall be valid for such a period not exceeding three (3) years as may be specified in the authorisation:

Provided that the Director may extend the validity of any such authorisation upon the submission of an application for its renewal of the authorisation submitted to him in accordance with regulation 30 of these regulations and if he is satisfied that the conditions established by regulation 26 of these regulations are still being complied with.

Review of authorisation.

28. Without prejudice to regulation 29 of these regulations, and if the Director suspects that any of the conditions established by regulation 25 of these regulations is no longer satisfied, the Director:

(a) shall require the applicant for authorisation or the holder of the authorisation to submit further information necessary to establish compliance with the provisions of regulation 26 of these regulations or such other information as may be reasonably required;

(b) may carry out any inspection, review or test that he deems necessary;

(c) may suspend the authorisation in accordance with regulation 29 of these regulations.

Suspension or revocation of an authorisation.

29. (1) Any authorisation issued in accordance with regulation 26 of these regulations may be suspended or revoked by the Director if it is established that:

(a) any information or particular supporting the application for an authorisation was incorrect, false or misleading; or

(b) any requirement as detailed in regulation 25 of these regulations is no longer satisfied; or

(c) the applicant for authorisation requests that the Director revokes the authorisation to deal in biocidal products or active substances; or

(d) if the activity is being carried out in contravention to any provision made by or under the Act.

(2) Where the Director suspends or revokes an authorisation, he shall notify the holder of the authorisation in writing of such suspension or revocation also providing reasons on which such a decision was based.

Renewal of an authorisation.

30. On the expiry of an authorisation, the Director shall renew the authorisation if:

(a) he has received an application for renewal in such form and in such manner and within such time as the Director may, from time to time require by notice in the Gazette;

(b) he is satisfied that the conditions detailed in regulation 26 of these regulations are still being complied with:

Provided that the Director may request the applicant for any additional information he may deem necessary prior to the renewal or otherwise of the authorisation:

Provided further that any renewal of any authorisation may be subject to any such as the director may deem appropriate:

Modification of an authorisation.

31. (1) Without prejudice to the provisions of regulation 28 of these regulations, the Director may, upon the written request of the holder of the authorisation, modify an authorisation to carry out a dealing activity if the Director is satisfied that such modification is justified and appropriate, and where relevant, reflects current scientific opinion.

(2) Without prejudice to regulation 29 of these regulations, the Director may modify the original authorisation if he considers that any condition on which the authorisation was based in accordance with regulation 25 of these regulations has been substantially altered.

(3) Any request for a modification to the authorisation in accordance with sub-regulation (1) of this regulation shall be made by the holder of the authorisation in such form and in such manner and within such a time as the Director may, from time to time require by Notice in the Gazette.

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Obligations of the holder of an authorisation.

32. (1) Without prejudice to any other provision made by or under the Act, it shall be the duty of any person holding an authorisation granted to him in accordance with regulation 26 of these regulations to:

(a) keep such records in such manner as the Director may from time to time establish by notice in the Gazette:

Provided that the Director may establish different records to be kept for different types of dealing activities;

(b) inform the Director, as soon as practicable and in writing, of any change in any information provided to the Director for the granting of the authorisation;

(c) allow the Director or his authorised representative access to the land or premises where dealing is carried out at any reasonable time;

(d) make available to the Director or his authorised representative such records that he may require; and

(e) comply with the provisions made by or under the Act.

(2) To the extent that may be applicable a person holding an authorisation under regulation 25 of these regulations shall exercise general supervision over his employees and shall, before requiring or permitting any of such employees to handle or to apply any biocidal product:

(a) provide such employees with proper training in the safe handling and application of biocides;

(b) ensure that any safety precaution set out in the label, or otherwise prescribed, is understood and complied with; and

(c) ensure that such workers wear suitable protective clothing provided by him.

(3) Where a person holding an authorisation of biocidal products has even the slightest suspicion that any biocidal product has caused any poisoning, he shall immediately notify the appropriate health authority.

Publication of list of authorised dealers

33. (1) The Director shall publish annually in the Gazette a list of all persons authorised to act as dealers in accordance with the provisions of these regulations.

(2) Such list shall contain the following information:

(a) the name, surname and postal address of the authorised dealer;

(b) the postal address of any premises used by the dealer for the purposes of carrying out his business;

(c) the date and validity of the authorisation.

Notification of entry into Malta.

34. (1) Any person authorised to deal in biocidal products shall notify the Director of any consignment of any authorised biocidal product or active substance he brings into Malta.

(2) Such notice shall be submitted in such form and in such manner and within such time as the Director may from time to time require by notice in the Gazette.

(3) The information supplied in relation to a biocidal product or active substance shall as a minimum include the following information:

(a) the name of the product and the batch number;

(b) the authorisation number;

(c) the country of origin;

(d) the quantity of the consignment; and

(e) the date and place of bringing into Malta.

Advertising of biocidal products.

35. (1) No person shall advertise or cause to be advertised any biocidal product in any manner whatsoever unless such advertising has been authorised by the Director.

(2) The Director shall from time to time by Notice in the Gazette, establish, the form, content, manner and time for the submission of an application for the issue of an authorisation for the advertising of a biocidal product.

(3) The Director shall authorise the advertising of a biocidal product if:

(a) he has received an application in accordance with sub-regulation (2) of this regulation;

(b) he is satisfied that the advertising sufficiently represents the content and conditions of the authorisation;

(c) the advertising does not make use of any statement which cannot be technically proven;

(d) the advertising does not include any statement that is false or otherwise misleading;

(e) the advertising does not encourage the use of the biocidal product for any purpose or circumstance or instruction other than those specified by the authorisation for the biocidal product issued in accordance with regulation 9 of these regulations;

(f) the advertising does not contain any wording or statement that claims or implies the absolute safety of the biocidal product and in particular shall not include any of the statements ‘low-risk biocidal product’ or ‘non-toxic’ or ‘harmless’ or any similar statement.

(g) the advertising contains the statement ‘Use biocides safely. Always read the label and product information before use’:

(4) In any authorised advertising the word biocide may be replaced by an accurate description of the product type referred to in Schedule 1 to these regulations.

PART FOUR

LABELLING AND PACKAGING OF BIOCIDAL PRODUCTS

Labelling of a biocidal product.

36. (1) Biocidal products shall be classified and packaged in accordance with the provisions relating to classification and packaging of relevant regulations.

(2) Biocidal products shall be classified labelled and packaged in accordance with the provisions relating to packaging and labelling of relevant regulations. Labels shall not be misleading or give an exaggerated impression of the product. Subject to the provisions of these regulations, the label must show clearly and indelibly the following:

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

(b) the authorisation number allocated to the biocidal product by the Director;

(c) the type of preparation contained within the product (e.g. liquid concentrates, granules, powders, solids, etc.);

(d) the uses for which the biocidal product is authorised (e.g. wood preservation, disinfection, surface biocide, anti-fouling, etc.);

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

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

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

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

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

(j) the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next 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; particulars for adequate cleaning of equipment; 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 feedingstuff and directions to prevent animals from being exposed);

and where applicable:

(k) restricitions to the use of biocidal products;

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

(3) Information detailed in paragraphs (a), (b), (d) and where applicable (g) and (k) of this sub-regulation shall always be carried on the label of the product. Information detailed in paragraphs (c), (e), (f), (h), (i), (j) and (l) of this sub-regulation may be carried elsewhere on the packaging or on an accompanying leaflet integral to the packaging. Such information shall be regarded as label information for the purposes of these regulations.

(4) In the case of microbiological biocidal products, labelling shall also comply with the provisions made by or under the Occupational Health and Safety Act relating to the protection of workers from risks related to exposure to biological agents at work.

(5) It is prohibited for a label of a biocidal product to contain the statement ‘low-risk biocidal product’ or ‘non-toxic’ or ‘harmless’ or any similar phrase.

(6) Where a biocidal product identified as an insecticide, acaricide, rodenticide, avicide or molluscicide is authorised under these regulations is subject to the provisions of relevant regulations, the Director may permit changes to the packaging and labelling of that product in so far as these do not conflict with the conditions of the authorisation issued under these regulations.

(7) The label shall be resistant to exposure to normal conditions of storage, handling and use and shall ensure that its contents shall remain clear and legible throughout the expected product shelf-life.

Packaging of a biocidal product.

37. The packaging, including any material constituting the immediate container, any outer packaging or any fastening device of any biocidal product, shall as a minimum, satisfy the following requirements:

(a) be designed and constructed so that its contents cannot disperse or leak in the environment during storage, transport, handling or otherwise of the container other than for the purpose of use or safe disposal;

(b) packaging shall be designed in a manner to minimise the likelihood for food, drink or feeding stuff;

(c) not be susceptible to degradation through its contact or exposure to its contents and shall be stable under normal conditions of storage, handling or use;

(d) shall not be liable to form harmful or dangerous compounds through the chemical interaction with any of its contents; and

(e) be sealed in such a way that such a seal is irreparably damaged when the packaging is opened for the first time.

(f) In the case of biocidal products which may be mistaken for food, drink or feeding stuff shall contain components to discourage their consumption.

PART FIVE

RESEARCH AND DEVELOPMENT

Authorisation for experimentation, research or testing.

38. (1) Without prejudice to the provisions made by or under the Act, the Director may, upon receiving a written request for the issue of an authorisation for a biocidal product or active substance for the purpose of research and development in accordance with this regulation, authorise in writing, for a specific period of time, to keep, use, manipulate, study or otherwise experiment upon any biocidal product or any active substance intended exclusively for use in a biocidal product.

(2) An unauthorised biocidal product or an active substance for exclusive use in a biocidal product may not be placed on the market for the purpose of any experiment or test which may involve or result in release to the environment unless the Director has assessed the complete record and issued an authorisation. Such authorisation shall limit the quantities to be used and areas to be treated as the director may deem fit to impose. Provided that such an authorisation shall not be required if the director has granted the pertson concerned the right to undertake such experiments and tests under the conditions of the authorisation issued for such research and development.

(3) Such request shall be submitted in such form and in such manner and within such time as the Director may, from time to time require by Notice in the Gazette and shall, as a minimum contain all the necessary information that may be deemed necessary to establish and define:

(a) the biocidal product or active substance and the maximum quantities that are to be used or released during the course of such experimentation, research or testing;

(b) the chemical, physical and biological properties of the biocidal product or active substance as determined by scientifically acceptable and validated laboratory testing including a dossier containing all the available data to permit an assessment to be made on the possible effects on human or animal health or the possible impact on the environment;

(c) the premises, equipment, conditions and procedures to be used for purposes of experimentation, research or testing using the biocidal product or active substance and that these are suitable for use in such purpose;

(d) any procedure, precaution and any matter that the Director may consider necessary to be undertaken during such test, research or experiment;

(e) the procedures and precautions to be taken when any human being, animal, plant or the environment or any other object is, or may come in contact with or exposed to any biocidal product or active substance;

(f) the details of all contingency plans in case of any possible contamination, release or spread of the biocidal product or active substance;

(g) the minimum records that are to be kept, maintained and made available upon request to any authorised representative and the minimum period for which these records are to be kept;

(h) the name and related qualifications or expertise of the applicant, the person responsible for undertaking the test, research or experiment, and where relevant any person which may be engaged in such undertaking;

(i) the contact details of the applicant;

(j) the details on how the biocidal product or active substance or any other test material is to be disposed or destroyed after use;

(k) any other conditions or additional information as the Director may reasonably require from the applicant in writing.

(4) In granting an authorisation in accordance with this regulation the Director shall:

(a) take into consideration the result of any inspection or any test carried out by an authorised representative in order to verify or establish any of the information outlined in sub-regulation (2) of this regulation;

(b) be satisfied that, in the case of scientific research and development, the persons concerned draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance and compile a complete record containing all available data on possible effects on human or animal health or impact on the environment. This information shall, if requested, be made available to the Director;

(c) be satisfied that, in the case of process-oriented research and development, the complete record referred to in paragraph (b) of this sub-regulation is submitted to him and where the process oriented research & development is carried out in a recognised country such complete record shall also be submitted to the Competent Authority of such recognised country;

(d) be satisfied that the test, research or experimentation is appropriate and safe;

(e) be satisfied that the test, research or experimentation does not involve, or result in, release into the environment unless he has assessed the available data and issued an authorisation for the purpose which limits the quantities to be used and the areas to be treated:

(f) be satisfied that the authorised person has at his disposal the expertise or capability to safely handle the biocidal product or active substance that is being authorised for use in the experimentation, research or testing;

(g) be satisfied that all the necessary precautions shall be taken at all times by the authorised person or, where relevant, his employees or representatives; and

(h) the premises, equipment, procedures and contingency plans are suitable and appropriate.

(5) An application submitted under this regulation shall be in such form and in such manner and within such time as the Director may, from time to time require by Notice in the Gazette.

Provided that the Director may, before determining the application, request the applicant to submit such further information relating to the application as he may consider appropriate.

(6) The authorisation under this regulation may be issued in relation to testing or experimentation for any biocidal product or active substance whether such biocidal product or active substance is authorised or otherwise.

Duration of validity of an authorisation.

39. Any authorisation issued by the Director in accordance with regulation 38 of these regulations shall be valid for such period not exceeding 2 years as may be specified the Director but shall never exceed a maximum validity period of two years:

Provided that the Director may extend the validity of any such authorisation upon the submission of an application for the renewal submitted to him in accordance with regulation 43 of these regulations.

Obligations of the holder of an authorisation.

40. The holder of an authorisation issued by the Director in accordance with regulation 38 of these regulations shall take all the necessary steps and measures to ensure that the conditions of such an authorisation are complied with at all times.

Refusal of an authorisation.

41. The Director shall not issue an authorisation in accordance with regulation 38 of these regulations if he has:

(a) any reasonable doubt to believe that the information contained in the application may be false, inaccurate or of a misleading nature;

(b) reason to believe that the risks to human beings, animals or the environment outweigh the potential benefits that will be derived from the experimentation, research or testing.

Notification of any change in conditions.

42. The holder of an authorisation issued by the Director in accordance with regulation 38 of these regulations shall immediately notify the Director of any change in any information submitted for issue of the authorisation under this Part.

Renewal of an authorisation for research & development.

43. (1) On the expiry of an authorisation, the Director shall renew the authorisation if:

(a) he has received an application for renewal in such form and in such manner and within such time as the Director may from time to time require by Notice in the Gazette;

(b) he is satisfied that the conditions detailed in regulation 38 of these regulations are still being complied with:

Provided that the Director may request the applicant to provide additional information as he may deem necessary prior to the renewal or otherwise of the authorisation:

Provided further that any renewal of any authorisation may be subject to any such condition, as the Director may deem appropriate.

(2) Where an application for renewal in accordance with sub-regulation (1) of this regulation has been submitted to the Director, the validity of the authorisation granted in accordance with regulation 38 of these regulations shall be deemed to continue to have effect until such time as the Director has determined the application for renewal.

Suspension or revocation of an authorisation for experimentation etc.

44. (1) Any authorisation issued in accordance with regulation 38 of these regulations may be suspended or revoked by the Director if it is established that:

(a) any information or particular supporting the application for an authorisation was incorrect, false or misleading; or

(b) any requirement as detailed in regulation 38 of these regulations is no longer satisfied; or

(c) the holder of the authorisation requests that the Director revokes the authorisation.

(2) Where the Director suspends or revokes an authorisation, he shall notify in writing the holder of the authorisation of such suspension or revocation with detailed reasons on which such a decision was based.

Modification of an authorisation for experimentation etc.

45. (1) The Director may, upon the written request of the holder of the authorisation, and if he is satisfied that such modification is justified, modify an authorisation issued in accordance with regulation 38 of these regulations.

(2) Any request for a modification to the authorisation in accordance with sub-regulation (1) of this regulation shall be made by the holder of the authorisation in such form and such manner and within

such time as the Director may, from time to time require by Notice in the Gazette.

PART SIX

MISCELLANEOUS

Confidentiality.

46. (1) In any case where any information has been submitted to the director in relation to any application under these regulations, the applicant may request the director to treat any information so submitted to him to be treated as confidential being of an industrial or commercial nature. In submitting such a request the applicant shall substantiate his demand.

(2) The director may, if he deems such a request to be justified allow such information to be treated as confidential. In such a case the holder of an authorisation necessary shall inform the Director of any disclosure by himself or his representative of any such confidential information to any other person.

(3) Notwithstanding the provision of sub regulation 1 of these regulations the following information shall after the issue of an authorisation, not be treated as confidential:

(a) the name and postal address of the applicant;

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

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

(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 which are regarded as dangerous within the meaning of the provisions of relevant regulations relating to the classification, packaging and labelling of dangerous substances which contribute to the classification of the product;

(f) physical and chemical data concerning the active substance and biocidal product;

(g) any ways of rendering the active substance or biocidal product harmless;

(h) a summary of the results of the tests required pursuant to regulation 17 of these regulations to establish the substance's or product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;

(i) 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) methods of analysis referred to in paragraph (c) of sub-regulation (2) of regulation 9 of these regulations;

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

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

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

Use of data held by the Director for other applicants.

47. (1) Where an application has been made for the registration of an active substance, which has already been registered by another applicant in terms of regulation 4 of these regulations. Information in relation to the first applicant should not be disclosed for the benefit of the second or subsequent applicant:

(a) unless the second or subsequent applicant has the written agreement in the form of a letter of access of the first applicant that use may be made of such information, or

(b) in the case of any information submitted for a registration of an active substance made under paragraph (b) of subregulation 1 of regulation 8 of these regulations, before the lapse of 15 years from the date of first inclusion in part 1 or 1A in the register of active substances, or

(c) in the case of an active substance already on the market on May 14, 2000 for a period of 10 years from the date of entry of an active substance into Parts I or IA of the Register of active substances to these regulations for information submitted for the first time in support of the first inclusion in Parts I or IA of the

Register of active substances of either the active substance or an additional product type for that active substance,

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

(i) variation of the requirements of the entry on Parts I or IA of the Register of active substances;

(ii) maintenance of the entry of Parts I or IA of the Register of active substances for a period of five years from the date of decision following receipt of further information unless the five-year period expires before the period provided for in paragraphs (b) and (c) of this sub-regulation, in which case the period of five years shall be extended so as to expire on the same date as those periods.

(2) Where an application has been made for the authorisation of a biocidal product, which has already been registered by another applicant in terms of regulation 9 of these regulations. Information in relation to the first applicant should not be disclosed for the benefit of the second or subsequent applicant:

It shall not be made use of the information referred to in regulation 17 of these regulations, for the benefit of a second or subsequent applicant:

(a) unless the second or subsequent applicant has the written agreement in the form of a letter of access of the first applicant that use may be made of such information; or

(b) in the case of a biocidal product containing an active substance not on the market on May 14, 2000 for a period of 10 years from the date of first authorisation or;

(c) in the case of a biocidal product containing an active substance already on the market on May 14, 2000, for a period of 10 years from the date of entry of an active substance onto Parts I or IA of the Register of active substances, for information which is submitted for the first time in support of the inclusion in Parts I or IA of the Register of active substances either of the active substance or of an additional product type for that active substance;

(d) in the case of any data submitted for the first time for either of the following:

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

(ii) submission of data necessary to maintain entry of an active substance onto Parts I or IA of the Register of active substances for a period of five years from the date of first receipt of further information, unless the five-year period expires before the period in paragraphs (b) and (c) of this sub-regulation, in which case the period of five years shall be extended so as to expire on the same date as those periods.

Fees.

48. Where any provision of these regulations provides that the Director may issue or grant any authorisation or may carry out any verification, test, analysis or any other activity in relation to the issue, renewal or maintenance of such authorisation, the Director may request the payment of such fees as may be required to cover the costs and expenses of such services as may be prescribed.

Deletions and Safeguards

49. (1) Every other provision of law made from or under this Act that regulates these regulations in a different manner shall be deleted upon the expiry of thirty days upon the publication of these regulations in the Gazette.

(2) Without prejudice, such deletions shall be made to anything made or omitted under the provisions made before that date.

SCHEDULE ONE

(Regulation 4)

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS

These product-types exclude products where they are covered by the provisions mentioned in sub-regulation (2) of regulation 2 these regulations for the purposes of these provisions and their subsequent modifications.

MAIN GROUP 1: Disinfectants and general biocidal products

These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Product-type 1: Human hygiene biocidal products
Products in this group are biocidal products used for human hygiene purposes.

Product-type 2: Private area and public health area disinfectants and other biocidal products
Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals, as well as products used as algaecides.
Usage areas include, inter alia, 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
Products in this group are 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
Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.

Product-type 5: Drinking water disinfectants
Products used for the disinfection of drinking water (for both humans and animals).

MAIN GROUP 2: Preservatives

Product-type 6: In-can preservatives
Products used for the preservation of manufactured products, other than foodstuffs or feedingstuffs, in containers by the control of microbial deterioration to ensure their shelf life.

Product-type 7: Film preservatives
Products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.

Product-type 8: Wood preservatives
Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms.
This product type includes both preventive and curative products.

Product-type 9: Fibre, leather, rubber and polymerised materials preservatives
Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.

Product-type 10: Masonry preservatives

Products used for preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack.

Product-type 11: Preservatives for liquid-cooling and processing systems
Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.
Products used for the preservation of drinking water are not included in this product type.

Product-type 12: Slimicides
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
Products used for the preservation of metalworking fluids by the control of microbial deterioration.

MAIN GROUP 3: Pest control

Product-type 14: Rodenticides
Products used for the control of mice, rats or other rodents.

Product-type 15: Avicides
Products used for the control of birds.

Product-type 16: Molluscicides
Products used for the control of molluscs.

Product-type 17: Piscicides
Products used for the control of fish; these products exclude products for the treatment of fish diseases.

Product-type 18: Insecticides, acaricides and products to control other arthropods
Products used for the control of arthropods (e.g. insects, arachnids and crustaceans).

Product-type 19: Repellents and attractants
Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.

MAIN GROUP 4: Other biocidal products

Product-type 20: Preservatives for food or feedstocks
Products used for the preservation of food or feedstocks by the control of harmful organisms.

Product-type 21: Antifouling products
Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

Product-type 22: Embalming and taxidermist fluids
Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

Product-type 23: Control of other vertebrates
Products used for the control of vermin.

SCHEDULE TWO

(Regulation 1)

LIST OF BIOCIDAL PRODUCTS

3 in 1 safe & Guard
A/F plum / A/F pink
ABC (Hand Sanitiser)
Abios PM
Absorbin super shield II
Acardust
Acimatic
ACP ultima 1277 blue
ACP ultima 1377 green
ACP ultima 1877 black
Actecide AZ
Actecide EPW
Actecide SB
Acticide AZ
Acticide B20
Acticide BAC 50
Acticide BG
Acticide BX
Acticide BX-H
Acticide CS
Acticide EP
Acticide EP Paste
Acticide EPW
Acticide F
Acticide FS
Acticide LA
Acticide OTW
Acticide SB
Acticide Spx
Acticide SR
Acticide SR 3033
Acticide SR 3056-Acticide of 9
Adesvin
Aevest Naftalina GR 100
Afrotin B.W.
Afrotin LC
Agrisense
Aguanta S1
Air Freshner with Bactericide
Alfacron
Algastop
Algicide plus
Algimous
Algon P Powder
Algon PS Pasta
Alkyd based primer
Alpha Septin
Alpine air freshner moth repellent
Altura 619
Alu - Safe

Amarsperse
Amazzones
Ant & insect killer
Ant Bait
Anti ant duster
Anti insect concentrate
Anti insect spray
Anti mite spray
Anti Muffa Kathon
Anti pest
Antifouling Combic
Antifouling copper bot
Antifouling Economic SP-Sea
Antifouling nautic
Antifouling Nautic Space 79031/79052
Antifouling seaguardian
Antifouling seaquantum classic
Antifouling seaquantum F8
Antifouling seaquantum plus
Antifouling seaquantum ultra
Antifouling seaqueen
Antiseptic concentrate
Antivegetattiva 56
Antivegetattiva Gommoni
Api life Var
Apistan
Aqualine Black
Aqualine spray
Aqualine white-volvo grey
Aquasafe
Armitage Flea spray for dogs
Armitage Pet Bedding and house hold flea spray
Arquad
Arvyrat
Autan
Autan active aerosol
Autan active lotion
Autan active pump spray
Autan active stick
Autan Akut
Autan family milk
Autovap
Bacteria X
Bactericide NB
Ban Mite
Bansect flea & tick collars for cats
Bansect squeeze-on/dogs
Baracaf
Bartoline Woodworm killer
Basic care shampoo
Bath powder
Baygon EC / Blattanex
Baygon Genius
Baygon Genius
Baygon Masterfly
Baygon spray
Baygon Spray Blue/Yellow/Premix

Baygon Spray Green Premix
Bayvarol strips
Beaphar 404 Feather lice spray
Beaphar cat flea collars
Beaphar dog flea collars
Beaphar flea repellent foam
Beaphar Household wash & Clean
Beaphar Nature Herbal Collars cats - dogs
Bengal 45 notti
Bengal coils
Bengal mats
Bengal Mosquito coils
Betapal Concentrate
Big red flea spray
Bio cat -a- pult
Bio Fly Down
Bio Kill Liquid
Bio long last
Bio Multirose
Bioallethrin
Biocaf 1320
Biocidial wash
Bird Batch Spray Disinfectants
Bird protector
Bird protector large & small
Birdspray
Black disinfectant
Black friar
Blitz
Blue crystal Alpha
Blue Crystal omega
Blue Steak
Bob Insecticide
Bob Insecticide
Bob Insetticida Conc
Bob Martin antiseptic oitment
Bob Martin flea powder cats
Bob Martin flea powder dogs
Bob Martin insecticidal shampoo
Bob Martin natural flea soap
Bogena dog flea collar
Bogena insecticidal flea collar
Bolfo Flea & Tick Collars
Bolfo Powder
Bop Martin Anti flea collars
Bop Martin Pestroy Powder
Bounodor pastiglia
Briban 40 EC
Brichlor chlorine tablets
Briller
Brimpex
Brimpex
Briswin Algicide
Brody Fresh Bait
Bromatol concentrate
Bromatrol ready to use bait
BTC 1010

Bucciato
Budenat G 446
Budenat G 447
Buonodor Airfreshner
Buzz
Canitex Flea collar dogs & cats
Canitex flea powder
Canitex Flea shampoo
Canitex flea solution spray
Canovel Flea collars
Canovel Insect spray
Canovel Insecticidal Flea collars
Capital 70
Caput Polvere
Caput Spray
Carbakol 5
Carbaryl Dust
Carbolene
Cat & dog flea collars (Otella & Harmony)
Cat flea powder
Cat flea spray
Catch anti mosquito coils
Catch intelligent electric diffuser
Catch perfumed anti mosquito coils
Catch perfumed vaporiser
CB Attrax roach Bait
CBM 8 Intermitox Powder
CBS 20 Super powder
CBS 20 Super Spray Cons.
Chestnut compound
Chlorifix
Chlorikal
Cidex solution/sticks
Citronella Insect Repellent
Citronella repellent stick
Citronella w/insect repellent
Clam-Trol CT - 1
Clamtrol CT-1
Classic wax polish
Clear n Clean longer life algicide
Clinafarm
Cockroach attractant tablet
Cockroach trap
Coconut D Ethanolamide
Collare Antiparassitico
Collare per Cani
Collare per Gatti
Colorado
Combat Ant & Crawling Ins. Killer Spray
Combat Ant & Crawling Insect Killer Powder
Combat Fly & Wasp Killer
Combat insect bite rep. stick/liquid
Combat insect rep. spray
Combi clean
Concentrated Algicide
Conservante K
Conservative G

Contrac Blox
Contrac pellets
Cool Touch
Cooper Pybuthrin 2/16
Coopermatic flykiller
Coopex max smoke generators
Coopex smoke generator
Coopex WP
Copper Ethanolamine complex
Copper paint
Corsa
Corsaire 611
Cosmos
Cosmos coloured
Cosmos white
Couch & grass killer
Crackdown
Crawling insect killer
crawling insects and ant killer
Creolin 2000
Cruiser premium
Cruiser superior
CTX / Astral export concentrated Algicide
Cuprinol cuprotect fungicide spray
Cuprinol cuprotect Int. mould killer
Cuprinol dark oak wood preserver light oak
Cuprinol Green wood preserver
Cuprinol preservative base
Cuprinol teak oil wood treatment
Cuprinol wood preserver 5 star
Cuprinol wood preserver clear
Cuprinol wood preservere golden brown
Cuprinol wood worm killer (low odour)
Curatin sticky dusting powder
Curratin discs
Cutinox cord (Biologically active agent)
Cynamina ultra
Cyperkill 10 WP
Cypermethrin 10 EC
Daffinneutro
Daffiverde
Damelene
Deadline concentarte liquid
Deadline contact dust
Decamethrin
Defencare
Defendog
Degesch plates
Dekur- Roachkiller
Dekur Roachkiller Depot
Deltarocca
Delu Hundefeind
Denkarin Rat Bait
Derasect Dermadectic Mange wash
Derasect Tar & Sulphur Shampoo
Deration
Dermanol

Dermosan
Desalgin
Detia
Detia electro
Detia gas EX-T/P
Detia insect strip
Detia Moth Strips
D-Foam Chlor
Diacap
Diacap 300cs
Dichlor 60
Dichlorvos
Disentyl
Disinfest
Dispelair CF 16
Distlimex
Diversan
Diverside Super
Diversol CX
Divosan
Dog & Cat powder form
Dog flea collars
Dog flea powder
Dog flea Shampoo
Dog flea spray
Dogacron
Dogs/Cats water resistant flea collar
Dolphin
Dowicii 75 Preservative
Drags liquid ator
Drax ant gel
Dry Net spray
Dudu
Duracide
Duracide 15
Duracide 16
Duracide P
Duramitex
Durham B 1730
Dursban Pro
Dustmitex
Dynamite insect spray
Dynamite Insecticide powder
Dynamite Insecticide repellent
Ecolock fly stop-fly papers
Ecolock glue-rodent blu
Ecolock tablets-rodent sticky traps
Ecosane 5000/3000
Ecotech
Electrone Mosquito Killer
Empire 20
Encia K.O. cat flea collars
Encia K.O. dog flea collars
Envirobac ABT
Envirobac BR
Eolia - Prodifa
Epoxy Filler

Epoxy filler comp B
Epoxy H.B. comp B.
Epoxy H.B. comp.A + comp B.
Esalo Mosquito Mats
Esbiothrin EBT 40/60
Eskolin Polvere
Eteroc
Ethylene Generating concentrate
Euro
Eurozolfi (Sofital)
Euxyl 100
Everbuild Lumberjack Universal rot & Woodworm killer
Everbuild Lumberjack Wood preserver
Extra strength insecticide killer
Facorat
Family Bird
Family cat flea collar
Family dog flea collar
Family dog insect spray
Farco rapid kill insecticide
Farco rapid kill pellets wax blocks
Farco rapid kill powder insecticide
Farm spray
Farmec rat grain
Fast Acting Ant Killer
Fendona
Fenitrothion Tech.
Ffly repellent
Ficam D
Ficam Plus
Ficam ulv
Ficam W
Finiluisspray
Flea & Tick collars for cats & dogs
Flea & tick shampoo for cats & dogs
Flea & tick spray for small animals
Flea drops for dogs & cats
Flea powder
Flea powder Herbal
Flea spray for cats & dogs
Flego
Flego spray
Flit crawling insect killer
Flit crawling insect killer powder
Flit Fcik
Flit Flying & Crawling Insect
Flit flying insect killer
Flit mats mosquito repellent
Flit mosquito mats
Fly & wasp killer
Fly Away
Fly banquet
Fly free zone
Fly Killer
Fly Killer Mosche e zanzare
Fly Killer Scarafaggi e formiche
Fly ribbons & fly sticks

Fly select
Fly spray Paral
Flyside 150
Flytex
Foractil
Forte fog P. fumes
Fresh flush toilet blue
Friend dog/cat flea powder
Friends cat flea collars
Friends dog flea drops
Friends dog flea shampoo
Friends dog/cats flea pump spray
Friends flea dog aerosol
Friends odour neutralising shampoo
Friends puppy shampoo
Frigosan
Frontline spot-on chat -chien
Frontline Spray
Fulmine
Funginex
Fungus & Mildew killer
Fural 150
Furat special pellets
Garden House
Gardene
Garotta scoot
Germal
Gibbons rat bait
Giraglia TF bianco
Giraglia TF blu
Giraglia TF Grigio
Goldbend
Golden Marlin
Golden Marlin Mascamone
Goldifloc Cationic liquid
Goliath Bait 12gr
Goliath gel
Goliath gel/zero roach bait
Guylets antimite powder
Hard racing 7648 A
Hard Top
Hard Top and Bucciato
Hard top clear
Hartz dog flea& killer spray
Hartz flea long life collars cats - dogs
Hartz one spot for cats & kittens
Hartz one spot for dogs & puppies
Hartz Rid flea collars Cats-dogs
Hartz rid flea shampoo for dogs 240ml
Hartz rid flea shampoo for dogs 240ml
Hartz two in one tick powder for dogs
Hatacide 17
Hatacide 19
Hawaii
Head to tail cat flea collars
Head to tail insecticidal spray
Hempel Antifouling space

Herbal flea drops
Herbal flea repellent collar
Herbal moth away
High glass urethane enamel
Hit Crawling insect Killer
Hit flying insect killer
Hoof stabilier
Household dust mite control
Hydrophane farmyard louse powder
Iguasu
Inoxibrill
Insect free
Insect repellent patches
Insect repellent spray/lotion
Insectex Fliegenfiel
Insectex Fliegentot
Insecticidal & Cond. shampoo
Insecticidal dog shampoo
Insecticidial dog shampoo for puppy
Insectoplus
Insektbloker power on
Intercleen
Intersleek 386 Light grey base
Intersleek 386 tie coat curing agent
Intersleek 386 tiecoat accelerator
Intersleek 425 finish accelerator
Intersleek 425 finish blue base
Intersleek 425 finish curing agent
Intersmooth 110
Intersmooth 120
Intersmooth 130
Intersmooth 210
Intersmooth 220
Intersmooth 230
Intersmooth 320
Intersmooth 330
Intersmooth 340
Intersmooth 460 / 360 ecoflex
Interspeed 200
Interspeed 2000
Interspeed 2001
Interspeed extra strong
Interspeed super
Interspeed system 2
Interspeed ultra
Intertox
Iodactiv
Iosil M 200
Ivomec
Japan Mat
Jeyes Freshbin
Johnsons tick off
Jungle Formula
Jungle formula asp away
Jungle formula gel
Jungle formula Liquid
Jungle formula lotion

Jungle formula Roll on
K.O. spray antiparasittico per cani
K.O. spray antiparasittico per ucellini
Kadox
Kaputt
Karlie dog & cat flea collars
Keep off repellent
Kelatren 384 FE
Ketzyme flea powder
Ketzyme flea spray
Ketzyme Insect spary
Ketzyme insecticidial powder
Kill Rat
Killgerm cypermethrin
Killgerm Propoxur
Killgerm Propoxur 20 EC
Killgerm Pyrethrum spray
Killgerm rodent deodorant
Killgerm Sakarat concentrate
Killgerm Terminate
Killgerm woodworm killer
Killing tablets
Killing Tarmicida (moth killer)
Klausol
Kleen Pool long life algicide
Kleen pools
Kleen water clarifier
Klerat
Klerat mouse tube
Klerat wax Blocks
Klipper Klean
Komatic
Komatic Aerosol
Konk 1 flying insect killer
Konk flying insect killer
Kordonio (WP/EC)
Koryl 5
Kudox
La Briantina
Langlow Abicide 82
Lanirat
Larvadex
LD 100 red
LD 100 red
Lemon oil shampoo
Leo ear cleaner cat
Leverline med
Levermed gel
Light weight Filler
Light weight Filler component
Limater
Limaval
Liquid ant bait
Liquid floculant
Liquisol
Lurectron Denkamethrin
Lurectron Fly Bait

Lurectron Maggot Stop
Lurectron Spray
Lysol
M.P.X.
Mammosan
Mammosan Fortex
Mammosan fortex blu
Mammosan verde
Manaus
Manosept
Marine primer bianco
Max Antiparasite for cats & dogs
Max Antiparasite powder
Max Antiparasite shampoo for cats & dogs
Max collars
Max force ultra
Maxforce
Medi scrub
Medo
Melsicide S 50
Mergal
Mergal S09
Metatin
Methylparaben
Metiroc 35 WG
Metokill
Metom fly
Micron 55 Superyacht 900 tin replacement - antifouling
Micron CSC Antifouling
Micron CSE
Micron extra
Micron optima
Microtech ant paint
Microtreat 2010
Microtreat 2200
Midabrill
Midamatic
Midge away cream
Mijex cream
Mijex spray
Mijex stick
Mille dynamic
Mini space
Mink oil shampoo
MIP RC LF 250
Miper
Miper
Mistral 621
Mite & lice bird spray
Mitex herbal scrubs
Mnistral Rame
Moon tiger cream
Moon tiger liquid
Moontiger Mosquito Coils
Moontiger Mosquito mats
Morkit PB
Mosi-Band

Mosiguard Gel
Mosiguard Spray
Mosiguard stick
Moskacid refills
Moskiller
Mosquito Milk/Gel
Mosquito repellent stick
Mosquito-Go wipes
Moth cake
Mothanks
Mothballs Tarmil Naphathalene
Motox Insect Spray
Moustidose creme Bebes / Infants
Moustidose evaporateur - Citronella
Moustidose gel apaisant
Moustidose Lotion adults / children
Moustidose lotion bebes / enfants
Moustidose recharge liquid
Moustidose tablets
Moustidose tropical lotion
Moustidose vapourisateur
MPX
Multidis WC
Muratt rat bait
Naba Naphtalene Balls
Naphtalene balls
Naphtalene Moth Balls
Naphtalene refined
Nautical eroding antifouling
Nebocide CP 18 - Preventol D6
Nekatarm Mothballs
Nelson
Neo Carbosan
Neo Royal
Neopybuthrin 15
Neopybuthrin 276
Neopybuthrin 30
Neopybuthrin 341
Neo-Pynamin forte
Neporex 2SG
Neporex SP 50
Netzmittel liquid
Neuron
Nevonal
New Improved Cruiser Premium
Nexis liquid refill
Nexis Zanzare
Niagara
Nipacide 10
Nipacide CFX 2
Nipacide CX 140
Nippon ant & crawling insect killer
Nippon ant killer liquid
Nippon ant killer powder
Non - feed antiseptic spray
Non stop coloured
Non stop white

Nuvan
Nuvan 1000EC / 500 EC
Nuvan 500 EC
Nuvanol
Nylar 4 EW
Off.Pump Spray lotion
Off.repellent cream
Off.repellent spray
Orion Aerosol Hogar y Plantas
Orion Antimites
Orion Antipolilla
Orion Ants Bait
Orion cockroach Bait
Orion Repellent Moscas & Mosquitos
Orion T.F.
Osmoshell
Osmoshell comp.B
Ozonit
P3 Topax 21
Para Plus
Para special Lice
Parapropile
Pasticlor 90
Patriot
Pearl tarme diffuser / bustine
Pellit Gel
Penguin cleaner
Penguin remover
Pentasan
Pentasol
Performance coloured
Performance white
Permanent 50
Permasmoke
Permethrin
Permethrin 25 / 75
Permethrin Cis
Pertex
Pestroy flea & Insect killer powder
Pestroy flea collar for cats
Pestroy flea collar for dogs
Pestroy flea killer spray
Pestroy insecticidal shampoos
Pet Behave
Petitt ACP 50
Petitt ACP 51
Pettit alumacoat
Pettit high build primer
Pettit metal primer
Pettit thinner
Pettit trimidad
PH-G
PH-L
Phostoxin
Pif Paf
Pif Paf cik Aerosol
Pif Paf dusting powder

Pif Paf faster knock down
Pif Paf faster knockdown fik
Pif Paf fik Aerosol
Pif Paf low allergenic FIK
Pif Paf low allergenic odourless
Pif Paf powder cip
Pif Paf powder plus cik
Pif Paf power plus crawling insect
Pigeon insect spray
Pigeon spray
Pilot LL Antifouling
Pine concentrate
Pine Disinfectant
Pine fresh (Concentrate pine disinfectant)
Pine oil
Piperonyl Butoxide
Pir Eco Sol
Pirexyl
Pirov
Pot Pourri Bags
Pot Pourri Disinfectant
Powder in-repellent spray
Predator
Predippo 1000
Presept Granules
Pretect flea & tick shampoo for dogs & puppies
Pretect household flea & tick spray
Prevelon
Prevent
Preventef
Preventef Chat
Preventef chien
Preventic
Preventol
Preventol A4-S
Preventol R50
Prima Tin free
Professional hard antifouling
Professional soft antifouling
Promise
Propeller Bianco
Propeller Grigio
Propeller Nero
Propoxur
Propoxur Tech
Proroc 50
Proticall insecticide for dogs
Proxel G L
Pulvisol
Puppy flea powder
Pussy & Kittens Trainer
Pussy/Fres repellent
Pybuthrin 2 / 16
Pynamin Forte
Pyrenone Aerosols
Qac Disinfectant
QAC Pine Disinfectant

Qamlin
Racumin Cat Bait
Racumin tracking powder
Raffaello 3 Azzurro
Raffaello 3 Blu Prof
Raffaello 3 Grigio Chiaro
Raffaello 3 Nero
Raffaello 3 Rosso
Raffaello Racing Bianco
Raffaello sprint black
Raffaello sprint blue
Raffaello sprint red
Raffaello sprint white
Raid All Pupose Insect Killer
Raid Ant & cockroach killer
Raid ant Bait
Raid ant killer powder
Raid coils
Raid electric liquid & refill
Raid electric mat & refill
Raid flying Insect Killer
Raid Guard fly killer
Raid mothproofer
Raid portable electric & refills
Raid wasp nest destroyer
Raid yard Guard
Rap crawling insect killer-Super Duracide
Rap flying insect killer-Duracide P
Rat Service
Ratona
Red Mite Killer
Regaflon
Rentokil / Sectokil liquid Bait
Rentokil Biotrol Concentrate
Rentokil Muscatrol
Rentokill woodworm treatment
Residex
Residex P
Reudanon
Rid flea shampoo
Rid flea spray for cats & dogs-Dog & Cat spray form
Rid mite
Ridasect
RIDX flea spray
Rio of London Airfreshner
Riviera SP
Riviera TF
Rocima 197
Rocima 392
Rocima 506
Rodasept
Rodent Klerat wax Blocks
Rodenticide Bait oil
Rodexion
Rodine Warfarin RTU bait
Rogar X
Rose Moth Repellent

Rotryn
Roussell Uclas Insect Powder
Roussell Uclas one shot Aerosol
Roussell Uclas Pybuthrin 33 BB
Rug-de-bug
S.C. Johnsons raid fly & wasp killer
Safe
Salvador
Samurai Mat
Samurai Mosquito Des. Tablets
Sanimac
Sansonil Super 25
Saquafen
Sargasso coloured
Sargasso white
Scalibor Collar
Scentinel Air freshner & moth repellent
Scentinel perfumed toilet block
Schiumactivclor
Schrum Elektro
Schrum Strip
Scirocco
Scram crawling insect killer
Scram ready mix bait
Scram warfarin concentrate
Seal to heal
Seargents Vetscription
Secto ant & crawling insect killer
Secto ant bait unit
Secto cat & dog flea powder
Secto cat flea collar
Secto cat flea spray
Secto cat flea spray fingertip dispenser
Secto dog flea spray aerosol
Secto dog odour neutralising spray
Secto dog shampoo
Secto enz stain
Secto flea spray for dogs
Secto hormone rooting powder
Secto insect killer powder extra strength
Secto insecticidal dog flea collars
Secto keep off
Secto medicated shampoo
Secto mini space insect killer unit
Secto moth killer unit
Secto slug and snail killer granules
Sectokil Dubbien
Sectokil wirdien
Self Polish Antifouling
Septanin
Septiclor-Super
Sergeants flea & tick shampoo for dogs W/oat meal
Sergeants flea & tick spray for dogs
Sergeants Pre Tect flea & tick spr. cats & dogs
Sergeants Pre Tect flea & tick spr. For dogs & puppies
Sergeants skip-flea & tick shampoo
Sergeants skip-flea soap for dogs

Sergents flea & tick spray for cats
Sergents flea & tick spray for dogs
Shaws
Shellgard Dogbands
Shelltox concentrate
Show Shimmer
Sicursept
Sicursept PLA
Sigill - Anti wood worm
Sintegrigio
Snip
Snow white Naphtalene
Sodium chlorate
Sodium Dehydroacetate
Sorex Rodenticide
Sorex Warfarin
Sovaq Insecticide
Spam
Speed 51
Speed undercoat
Speed undercoat B
Spira "No Bite" Mosquito Killer
Spira Fly Ribbon
Spira insecticide powder
Spira Mats
Spira Mosquito Coils
Spira of Bengal mats
Spira-Nexis mosquito mats
Spira-Nexis Spirallette coils
Spira-Nexis30/45 Notti
Spirigone Aerosol
Spirigone Aerosol
Spiritex Concentrate E.C.
Sporal D pet scrub
Spring cut flower nourishment
Stay off
Sterminio Liquid
Sterminio tablets Zampirella
Stick
Stomoxinec
Stop Insect
Stop orion
Stucco A Spatola
Sulphur
Sumithrin
Sunspot super Algaecide
Super active antiseptic, disinfectant
Super Cobra Flying-crawling Insect Killer
Super Duracide P
Super Guard
Super yaucht antifouling
Superman Fly Catcher
Swak Natural Insecticide
Sweet itch mange & Eczema Lotion
Swift
Swimming Algicide
Systemic insecticide

Tabercat / Family cat
Taberdog / Family dog
Taberdog collar insecticide
Taberdog polve insecticide
Tabernil Bird spray
Tad ant - insect spray
Tad anti - insect concentrate
Tad anti - insect spray
Tad fly Bait granules
Taktic 12.5
Tapyflo & spray
Tar shampoo
Tarmi Deo
Tarmil
Tarmistop
TBTF/Metatin
TBTO
Teddy
Tego 51
Tenuran
Terrasan Ant Killer
Terrasan Anti cat spray
Terrasan Anti dog spray
Tetramethrin
Tetramethrin Tech
Texas
Thick Pine Disinfectant
Thinner 10
Thinner 7
Thinnner 17
Three star badge naphtalene Balls
Tibs flea powder 55Q
Tigene wipes/sprays
Tiguvon cats
Tiguvon dogs
Timber Pres Wood
Tobby/Fres repellent
Toilet cleaner & descaler
Tokyo Mat
Tomcat Bait
Tomcat Blox
Tomcat sachet
Tonhematic Insecticide
Top coat alkyd based
Top form tray fresh
Topline
Trap-A-fly
Trap-A-Roach
Trawler
Trilux
Trilux 33 Superyacht 800 tin replacement - Antifouling
Trinidad SR 1377 green
Trinidad SR 1877 black
Trixie collars for dogs & cats
Tryplosan
Ultra white shmpoo
V.K. Flea & Tick cat collar

V.K. Flea & Tick dog collar
V.K. Flea & Tick Powder
V.K. Flea shampoo
V.K. Siphotrol Spray
Vape Anti-moth
Vape fly catch ribbon
Vape KO flies and mosquitoes
Vape KO Super cockroaches & Ants
Vape magic
Vape mat
Vape mouse Killer
Vape Spirale coils
Vape Tecno 2 cockroaches & Ants
Vape Tecno 2 Multinsetto
Vape Tecno Mosche e zanzare
Varat rodenticide bait
VC Offshore extra antifouling
Vc offshore with teflon
VC Prop-N-Drev Balck
VC Prop-O-Drev (Black Grey)
Verdesol
Vermikill
Vet K Pet spray
Vetzyme flea powder
Vetzyme flea spray
Vetzyme insecticidal powder
Vetzyme JDS dog Shampoo
Viazan
Vijurrax spray insecticide
Vinil Primer
Visco Block
Vulcano
Vulcano coils
Vulcano coils perfumed
Vulcano elletro machine & mats
Vulcano Piastrine mats
Wallside 250
Warfarin concentrate Liquid
Wasp & Hornet killer
Water based flying insect killer
Water clarifier
Water-resistant collar for dogs
White fly sticky sheets
White guard
Woodpecker fresh floral deodorant Ball
Woodworm treatment
Woodworm treatment spray
Yaucht line bilge cleaner
Yaucht line fender cleaner
Yaucht line gel coat cleaner
Yaucht line general cleaner
Yaucht line liquid rubbing
Yaucht line marine polish
Yaucht line marine wax
Yaucht line polwax
Yaucht line super cleaner
Yaucht line teak brightner

Yaucht line teak cleaner
Yaucht line teak oil
Yaucht line wax shampoo
Yaucht rubbing
Yellow jackets & wasp trap
Zanza - No
Zanzarella
Zanzarella After pen roll
Zanzarella After spray
Zanzarella After stick
Zanzarella Natura crema gel
Zanzarella Natura spray
Zanzarella Natura stick
Zanzarella nature cream gel
Zanzarella nature spray
Zanzarella Salviette 50 pezzi
Zapicid giallo
Zapicida spray
Zebra Brand
Zero roach bait
Zig Zag
Zinc Phosphide
Zineb tech
Zoflora antibacterial cleanser
Zoflora antibacterial room fragrance
Zolfo Giallo 80/99