L.N. 525 of 2010

PESTICIDES CONTROL ACT
(CAP. 430)

Biocides Regulations, 2010

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

1. The title of these regulations is the Biocides Regulations, 2010, and they shall come into force as follows: Citation.

2. (1) These regulations concern: Scope.

(a) the authorisation and the placing on the market for use of biocidal products;

(b) the mutual recognition of authorisations;

(c) the establishment of a positive list of active substances which may be used in biocidal products.

(2) These regulations apply to biocidal products as defined in regulation 3(1)(a) but shall exclude products that are defined or within the scope of the following instruments for the purposes of these regulations:

(a) the Medicinal Products (Labelling and Packaging) Regulations, 2005; L.N. 393 of 2005.

(b) the Herbal Medicinal Products Regulations, 2005; L.N. 379 of 2005.

(c) the Veterinary Medicinal Products Regulations, 2004; L.N. 469 of 2004.

(d) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

(e) the Active Implantable Medical Devices Regulations, 2008; L.N. 211 of 2008.

L.N. 210 of 2008.

(f) the Medical Devices Regulations, 2008;

L.N. 89 of 1994.

(g) the Additives in Food Regulations, 1994;

L.N. 257 of 1998.

(h) the Flavourings for Use in Foodstuffs and Source Materials for their Production Regulations, 1998;

L.N. 54 of 2005.

(i) the Permitted Food Additives Regulations, 2005;

(j) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC,

L.N. 83 of 2006.

(k) the Food Hygiene and Health Conditions for the Production and Placing on the Market of Certain Products of Animal Origin intended for Human Consumption (Amendments and Repeals) Rules, 2006;

L.N. 225 of 2005.

(l) the Conditions governing the preparation, placing on the market and use of medicated feedingstuffs Rules, 2005;

(m) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition;

L.N. 89 of 2005.

(n) the Products Used in Animal Nutrition Rules, 2005;

L.N. 374 of 2005.

(o) the Circulation and Use of Feed Materials Rules, 2005;

L.N. 424 of 2004.

(p) the Cosmetic Regulations, 2004;

(q) Council Directive 95/5/EC of 27 February 1995 amending Directive 92/120/EEC on the conditions for granting temporary and limited derogations from specific Community health rules on the production and marketing of certain products of animal origin,

L.N. 358 of 2009.

(r) the Plant Protection Products Regulations, 2009 with the exception of substances listed in Schedule VII thereto;

(s) the In Vitro Diagnostic Medical Devices, 2002; L.N. 61 of 2002.

(3) These regulations transpose the provisions of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

(4) These regulations shall apply, without prejudice to relevant Community provisions or measures taken in accordance with them, in particular, to:

(a) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;

(b) Schedule VII to the Plant Protection Products Regulations, 2009; L.N. 358 of 2009.

(c) Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals;

(d) the Protection of the Health and Safety of Workers from the Risks related to Chemical Agents at Work Regulations, 2003, and the General Provisions for Health and Safety at work Places Regulations, 2003; L.N. 227 of 2003. L.N. 36 of 2003.

(e) article 32 of the Commercial Code concerning misleading and comparative advertising. Cap. 13.

(5) Regulation 21 of these regulations shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

3. For the purposes of these regulations the following definitions shall apply: Definitions.

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

"authorisation" means an administrative act by which the Director authorises, following an application submitted by an applicant, the placing on the market of a biocidal product in its territory or in a part thereof;

"basic substance" means a substance which is listed in Schedule I – Part C, whose major use is non-pesticidal but which has some minor use as a biocide either directly or in a product consisting of the substance and a simple diluent which itself is not a substance of concern and which is not directly marketed for this biocidal use; the substances, which could potentially enter Schedule I – Part C in accordance with the procedure laid down in regulations 11 and 12, are inter alia the following:

(i) carbon dioxide,

(ii) nitrogen,

(iii) ethanol,

(iv) 2-propanol,

(v) acetic acid,

(vi) kieselguhr;

"biocidal products" means active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means; an exhaustive list of 23 product types with an indicative set of descriptions within each type is given in Schedule V hereto;

"director" means the head of the Regulatory Affairs Directorate established under the Malta Standards Authority Act or such other head of any Directorate as the Minister may by Order designate in his stead and includes, to the extent of the authority given, any officer authorised by him, in writing, to act in that behalf for any of the purposes of the Pesticides Control Act;

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

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

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

"low-risk biocidal product" means a biocidal product which contains as active substance only one or more of those listed in Schedule I – Part B and which does not contain any substance of concern; under the conditions of use, the biocidal product shall pose only a low risk to humans, animals and the environment;

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

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

"product and process orientated research and development" means any scientific development related

to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance.

"registration" means an administrative act by which the Director, following an application submitted by an applicant, after verification that the dossier meets the relevant requirements of these regulations, allows the placing on the market of a low-risk biocidal product in its territory or in a part thereof;

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

"scientific research and development" means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year;

"substance" means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability 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 the active substance, which 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 effect; such a substance, unless there are other grounds for concern, would be normally a substance classified as dangerous according to the Dangerous Substances (Notifications) Regulations, 2008 and present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of regulation 6 and 7 of the Dangerous Substances and Preparations Regulations, 2007.

L.N. 306 of 2008.

L.N. 10 of 2007.

Authorisation for placing on the market of biocidal products.

4. (1) A biocidal product shall not be placed on the market and used in Malta unless it has been authorised in accordance with these regulations.

(2) By way of derogation from sub-regulation (1):

(a) subject to registration, the placing on the market and use of a low-risk biocidal product shall be allowed, provided that a dossier in accordance with regulation 9(3) has been submitted and verified by the Director; unless otherwise specified, all provisions relating to authorisation under these regulations shall also apply to registration; and

(b) placing on the market and use of commodity substances for biocidal purposes shall be allowed once they have been entered in Schedule I – Part C.

(3) (a) Every application for authorisation shall be decided on without undue delay; and

(b) for applications for biocidal products that require registration, the Director shall take a decision within a period of 60 days.

(4) The Director shall, on his own account or where requested, establish a frame-formulation and communicate it to the applicant when issuing an authorisation for a particular biocidal product:

Provided that without prejudice to regulations 9 and 13 and providing that the applicant has a right of access to the frame-formulation in the form of a letter of access, when a subsequent application for authorisation for a new biocidal product is based on this frame-formulation, the Director shall take a decision with regard to this application within a period of 60 days.

(5) Biocidal products are to be classified, packaged and labelled in accordance with the provisions of these regulations.

(6) Without prejudice to regulation 8(1), authorisations shall be granted for a maximum period of 10 years from the date of first or renewed inclusion of the active substance in Schedule I – Part A or Part B for the product type, without exceeding the deadline specified for the active substance in Schedule I – Part A or Part B; they may be renewed after verification that the conditions

imposed in regulation 6(1) and (2) are still satisfied. Renewal may, where necessary, be granted only for the period necessary to allow the Director to make such verification, where an application for renewal has been made.

(7) Biocidal products are to be properly used. Proper use shall include compliance with conditions established pursuant to regulation 6 and specified under the labelling provisions of these regulations. Proper use shall also involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary. Where biocidal products are used at work, use shall also be in accordance with the requirements of regulations for the protection of workers.

Mutual recognition of authorisations.

5. (1) (a) Without prejudice to regulation 13 hereof, a biocidal product that has already been authorised or registered in one Member State shall be authorised or registered in Malta within 120 days, or 60 days respectively, of an application being received by the Director, provided that the active substance of the biocidal product is included in Schedule I – Part A or Part B and it conforms to the requirements thereof. For the mutual recognition of authorisations, the application shall include a summary of the dossier as required in regulation 9(2)(a) and Schedule II - Part B, Section X and a certified copy of the first authorisation granted. For mutual recognition of registration of low-risk biocidal products, the application shall include the data requirements of regulation 9(3), except for the efficacy data for which a summary shall suffice.

(b) The authorisation may be subject to provisions resulting from the implementation of other measures in accordance with Community law, relating to the conditions for distribution and use of biocidal products intended to protect the health of the distributors, users and workers concerned.

(2) If, in accordance with regulation 6, it is established that:

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

(b) unacceptable tolerance or resistance of the target organism to the biocidal product is demonstrated, or

(c) the relevant circumstances of use, such as climate

or breeding period of the target species, differ significantly from those in the Member State where the biocidal product was first authorised, and an unchanged authorisation may therefore present unacceptable risks to humans or the environment, certain conditions referred to in regulation 21(3)(e), (f), (h), (j) and (l) may be requested to be adjusted to the different circumstances, so that conditions for issue of an authorisation laid down in regulation 6 are satisfied.

(3) (a) Where a low-risk biocidal product has been registered by another Member State does not comply with the definition provided for in the definition "low-risk biocidal product" in regulation 3, the Director may provisionally refuse registration thereof and shall immediately communicate his concerns to the competent authority responsible for the verification of the dossier.

(b) If, within a maximum period of 90 days, an agreement is not reached between the authorities concerned, the matter will be forwarded to the Commission for a decision in accordance with the procedure laid down in regulation 5(4).

(4) Notwithstanding regulations 5(2) and 5(3), where it is believed that a biocidal product authorised by another Member State cannot meet the conditions set out pursuant to regulation 6(1) and consequently proposes to refuse the authorisation or the registration or to restrict the authorisation under certain conditions, the Director shall notify the Commission, other Member States and the applicant and shall provide them with an explanatory document containing the name of the product and its specification and setting out the grounds on which it proposes to refuse or to restrict the authorisation.

(5) (a) If the procedure laid down in regulation 5(4) leads to the confirmation of a refusal of a second or subsequent registration, the Member State that had previously registered the low-risk biocidal product shall, where deemed appropriate by the Standing Committee, take this refusal into consideration and review its registration according to regulation 7.

(b) If this procedure confirms the initial registration, the Member State having introduced the procedure shall register the low-risk biocidal product concerned.

(6) By way of derogation from sub-regulation 5(1), Director may refuse, subject to the Treaty, mutual recognition of authorisations granted for product types 15, 17 and 23 of Schedule V provided that such a limitation can be justified and does not jeopardise the purpose of these regulations.

Conditions for issue of an authorisation.

6. (1) A biocidal product is authorised only if -

(a) the active substance(s) included therein are listed in Schedule I – Part A or Part B and any requirements laid down in the Schedules hereto are fulfilled;

(b) it is established, in the light of current scientific and technical knowledge, and is shown from appraisal of the dossier provided for in regulation 9, according to the common principles for the evaluation of dossiers as laid down in Schedule VI, that, when used as authorised and having regard to:

(1) all normal conditions under which the biocidal product may be used,

(2) how the material treated with it may be used,

(3) 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, such as through 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:

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

(2) its impact on non-target organisms;

(c) the nature and quantity of its active substances 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 Schedule II – Part A or Part B, III – Part A or Part B, IV – Part A or Part B;

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

(2) A biocidal product classified according to regulation 21(1) 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 to, or use by the general public.

(3) Authorisation may be conditional on, and must stipulate the conditions relating to marketing and use necessary to ensure compliance with the provisions of sub-regulation 6(1).

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

Review of an authorisation.

7. During the period for which an authorisation has been granted, it may be reviewed at any time, such as following information received according to regulation 15 if there are indications that any of the conditions referred to in regulation 6 are no longer satisfied. In such instances, the authorisation holder, or the applicant to whom a modification of the authorisation has been granted in accordance with regulation 8, may be required to

submit further information necessary for the review. If need be, the authorisation may be prolonged only for the period necessary to complete the review, but shall be prolonged for the period necessary to provide for further information.

Cancellation or modification of an authorisation.

8. (1) An authorisation shall be cancelled if:

(a) the active substance is no longer included in Schedule I – Part A or Part B as required by regulation 6(1)(a);

(b) the conditions within the meaning of regulation 6(1) for obtaining the authorisation are no longer satisfied;

(c) it is discovered that false or misleading particulars were supplied concerning the facts on the basis of which the authorisation was granted.

(2) An authorisation may also be cancelled if the authorisation holder so requests and states the reasons for the cancellation.

(3) When the Director intends to cancel an authorisation, he shall inform and hear the authorization holder. When cancelling the authorisation, a period of grace may be granted for the disposal or for the storage, marketing and use of existing stocks, of a length in accordance with the reason for the cancellation without prejudice to any period provided for by decision taken pursuant Regulation (EC) No 1907/2006 or in connection with sub-regulation 8(1)(a).

(4) The conditions of use of an authorisation and, in particular, the manner of use or the amounts used shall be modified by the Director if necessary, on the basis of developments in scientific and technical knowledge and to protect health and the environment.

(5) An authorisation may also be modified if the authorisation holder requests it and states the reasons for the modification.

(6) Where a proposed modification concerns an extension of uses, the Director shall extend the authorisation subject to the particular conditions placed on the active substance listed in Schedule I – Part A or Part B.

(7) Where a proposed modification of an authorisation involves changes to the particular conditions placed on the active substance listed in Schedule I – Part A or Part B, 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 12.

(8) Modifications shall be granted only if it is established that the conditions within the meaning of regulation 6 remain satisfied.

Requirements for authorisation.

9. (1) Application for an authorisation shall be made by, or on behalf of, the person who will be responsible for the first placing on the market of the biocidal product in Malta and shall be to the competent authority of Malta. Every applicant shall be required to have a permanent office within the Community.

(2) An applicant for authorisation of a biocidal product shall submit to the Director:

(a) 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 Schedule II – Part B and, where specified, the relevant parts of Schedule III – Part B, and

(b) for each active substance in the biocidal product, a dossier or a letter of access satisfying, in the light of current scientific and technical knowledge, the requirements set out in Schedule II – Part A and, where specified, the relevant parts of Schedule III – Part A.

(3) By way of derogating from sub-regulation 9(2)(a), a dossier comprising the following data for a low-risk biocidal product is required:

(i) applicant:

(1) name and address,

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

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

(ii) identity of the biocidal product:

(1) trade name,

(2) full composition of the biocidal product,

(3) physical and chemical properties as referred to in regulation 6(1)(d);

(iii) intended uses:

(1) product type (Schedule V) and field of use,

(2) category of users,

(3) method of use;

(iv) efficacy data;

(v) analytical methods;

(vi) classification, packaging and labelling, including a draft label, according to regulation 21 of these regulations;

(vii) safety data sheet prepared in accordance with regulation 17 of the Dangerous Substances and Preparations Regulations, 2007 or Article 31 of Regulation (EC)1907/2006.

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(4) Dossiers shall include a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to those methods. The information in the dossiers supplied in accordance with regulation 9(2) shall be sufficient for an evaluation to be made of the effects and properties referred to in regulation 6(1)(b), (c) and (d). It shall be submitted to the Director in the form of technical dossiers, containing the information and results of the studies referred to in Schedules II – Part A and Part B and, where specified, the relevant parts of Schedules III – Part A and Part B.

(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 each such case, a justification, acceptable to the Director must be submitted. Such

a justification may be existence of a frame-formulation which 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 start only after the dossier is complete.

(7) The name of an active substance must be given as registered in the list contained in Schedule I to the Dangerous Substances Regulations, 2008 or, if the name is not included therein, as given in the European Inventory of Existing Chemical Substances (Einecs), 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. L.N. 306 of 2008.

(8) As a general principle, tests must be conducted according to the methods described in Commission Regulation (EC) 465/2008 and Commission Regulation (EC) 466/2008. In the event of a method being inappropriate or not described, other methods used should, whenever possible, be internationally recognised and must be justified. Where appropriate, tests must be conducted in accordance with the provisions laid down in the Animal Experimentation Regulations, 2003 and in the Good Laboratory Practice Regulations, 2004. L.N. 371 of 2004.

(9) Where test data exist that have been generated before the adoption of these regulations by methods other than those laid down in Commission Regulation (EC) 465/2008 and Commission Regulation (EC) 466/2008, the adequacy of such data for the purposes of these regulations and the need to conduct new tests according to Schedule V must be decided on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrate animals.

(10) The Director shall ensure that a file is compiled on each application. Each file shall contain at least a copy of the application, a record of the administrative decisions taken by the Member State concerning the application and concerning the dossiers submitted in accordance with sub-regulation 9(2), together

with a summary of the latter. On request, the Director shall make available to the other competent authorities and to the Commission the files provided for in this sub-regulation; he shall supply to them, on request, all information necessary for full comprehension of applications and shall, where requested, ensure that applicants provide a copy of the technical documentation laid down in sub-regulation 9(2).

(11) Samples of the preparation and of its ingredients may be required to be provided.

(12) Applications for authorisation may be submitted either in English or in Maltese.

Placing on the market of active substances.

10. (1) Where a substance is an active substance for use in biocidal products, it may not be placed on the market for such use unless:

(a) where the active substance was not on the market before the 8th of March 2000, a dossier has been forwarded to a Member State, which satisfies the requirements of regulation 12(1) and is accompanied by the declaration that the active substance is intended for inclusion in a biocidal product. This shall not apply to substances for use pursuant to regulation 18;

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(b) it is classified, packaged and labelled in accordance with the provisions of the Dangerous Substances Regulations, 2008.

11. (1) In view of current scientific and technical knowledge, an active substance shall be included in Schedule I for an initial period not exceeding 10 years if it may be expected that -

(a) biocidal products containing the active substance,

(b) low-risk biocidal products complying with the definition “low-risk bicidal product” in regulation 3,

(c) commodity substances complying with the definition “basic substance” in regulation 3, will fulfil the conditions laid down in regulation 6(1)(b), (c) and (d), taking into account, where relevant, cumulation effects from the use of biocidal products containing the same active substances:

Provided that an active substance cannot be included in Schedule I – Part B if it is classified according to the Dangerous Substances Regulations, 2008 as:

(i) carcinogenic,

(ii) mutagenic,

(iii) toxic for reproduction,

(iv) sensitising, or

(v) is bioaccumulative and does not readily degrade:

Provided further that, where appropriate, the entry of an active substance in Schedule I – Part A shall refer to the concentration ranges between which the substance can be used.

(2) Inclusion of an active substance in Schedule I shall, where appropriate, be subject to the following:

(a) requirements on:

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

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

(iii) product type in which it may be used,

(iv) manner and area of use,

(v) designation of categories of users, such as industrial, professional or non-professional,

(vi) 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), if necessary,

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

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

(3) The inclusion in Schedule I of an active substance shall be restricted to those product types in Schedule V for which relevant data have been submitted in accordance with regulation 9.

(4) The inclusion of an active substance in Schedule I may be renewed on one or more occasions for periods not exceeding 10 years. The initial inclusion, as well as any renewed inclusion, may be reviewed at any time if there are indications that any of the requirements referred to in regulation 11(1) are not longer satisfied. Renewal may, where necessary, be granted only for the minimum period necessary to complete a review, where an application has been made for such renewal, and shall be granted for the period necessary to provide further information requested in accordance with regulation 12(2).

(5) (a) An entry of an active substance in Schedule I – Part A and, where relevant, Part B or part C may be refused or removed,

(i) if the evaluation of the active substance in accordance with regulation 12(2) shows that, under normal conditions under which it may be used in authorised biocidal products, risks to health or the environment still give rise to concern, and

(ii) if there is another active substance on Schedule I – Part A for the same product type which, in the light of scientific or technical knowledge, presents significantly less risk to health or to the environment:

Provided that 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.

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(b) The refusal or removal of a Schedule I – Part A and, where relevant, Part B or Part C entry shall be carried out 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;

(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;

(v) the complete data dossiers of the evaluation serving or having served for entry in Schedule I shall be put at the disposal of the committee referred to in Article 28(1) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

(c) A decision to remove a Schedule I – Part A entry shall not have immediate effect but shall be delayed for a period of up to a maximum of four years from the date of that decision.

Inclusion of an active substance in Schedule I.

12. (1) Inclusion, or subsequent changes to the inclusion, of an active substance in Schedule I shall be considered when:

(a) an applicant has forwarded to the Director:

(i) a dossier for the active substance satisfying the requirements of Schedule IV – Part A or the requirements of Schedule II – Part A and, where specified, the relevant parts of Schedule III – Part A;

(ii) a dossier for at least one biocidal product containing the active substance satisfying the requirements of regulation 9, with the exception of sub-regulation 12(3) thereof;

(b) the receiving Director has verified the dossiers and is of the opinion that they satisfy the requirements of Schedule IV – Part A and Schedule IV – Part B or the requirements of Schedule II – Part A and Schedules II – Part B and, where relevant, Schedules III – Part A and III – Part B, accepts them and agrees to the applicant forwarding a summary of the dossiers to the Commission and the other Member States.

(2) The receiving Director shall, within 12 months of accepting the dossiers, carry out an evaluation thereof. A copy of the evaluation shall be sent by the Director to the Commission, the other Member States and to the applicant, together with a recommendation for the inclusion, or otherwise, of the active substance in Schedule I:

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 submit such information. The 12-month period shall be suspended from the date of issue of the Director's request until the date the information is received. The Director shall inform the other Member States and the Commission of its action when it informs the applicant.

Procedure for inclusion of an active substance in Schedule I.

13. (1) The Director shall not make use of the information referred to in regulation 9 for the benefit of a second or subsequent applicant:

Use of data held by competent authorities for other applicants.

(a) unless the second of 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 an active substance not on the market on the 8th of March 2000, for a period of 15 years from the date of first inclusion in Schedule I – Part A or Part B, or

(c) in the case of an active substance already on the market on the 8th of March 2000:

(i) until 14 May 2014 for any information submitted for the purposes of these Regulations, except where such information is already protected under existing national rules relating to biocidal products. In such cases, the information shall continue to be protected nationally until the expiry of any remaining period of data protection provided for under national

rules, but not beyond 14 May 2014 or, if applicable, not beyond the date to which the transitional period referred to in regulation 17(1) is extended in accordance with regulation 17(2);

(ii) for a period of 10 years from the date of entry of an active substance onto Schedule I – Part A or Part B for information submitted for the first time in support of the first inclusion in Schedule I – Part A or Part B 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 Schedule I – Part A or Part B;

(ii) maintenance of the entry of Schedule I – Part A or Part B

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 sub-regulation 13(1)(b) and (c), in which case the period of five years shall be extended so as to expire on the same date as those periods.

(2) The Director shall not make use of the information referred to in regulation 9, 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 the 8th of March 2000 for a period of 10 years from the date of first authorisation in any Member State, or:

(c) in the case of a biocidal product containing an active substance already on the market on the 8th of March 2000;

(i) until 14 May 2014 for any information submitted for the purposes of these regulations, except in the case where data are already protected according to existing national rules relating to biocidal products, in which case such data shall be protected nationally until the expiry of any remaining period of data protection provided for under those national rules, but not beyond 14 May 2014 or, if applicable, not beyond the date to which the transitional period referred to in regulation 17(1) is extended in accordance with regulation 17(2);

(ii) for a period of 10 years form the date of entry of an active substance onto Schedule I – Part A or Part B, for information which is submitted for the first time in support of the inclusion in Schedule I – Part A or Part B 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 authorization of a biocidal product;

(ii) submission of data necessary to maintain entry of an active substance onto Schedule I – Part A or Part B 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 sub-regulations 13(2) (b) and (c), in which case the period of five years shall be extended so as to expire on the same date as those periods.

(3) For decisions to be taken in accordance with regulation 11(5), the information referred to in sub-regulations 13(1) and (2) can be used by the Commission, the Scientific Committees as referred to in Article 27 of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market and the Member States.

Cooperation in the use of data for second and subsequent applications for authorisation.

14. (1) In the case of a biocidal product which has already been authorised in accordance with regulations 4 and 6, and without prejudice to the obligations imposed pursuant to regulation 13, the Director may agree that a second or subsequent applicant

for authorization may refer to data provided by the first applicant in so far as the second or subsequent applicant can provide evidence that the biocidal product is similar and its active substances are the same as the one formerly authorised, including degree of purity and nature of impurities.

(2) Notwithstanding regulation 9(2):

(a) an applicant for authorisation of biocidal products shall, before carrying out experiments involving vertebrate animals, enquire of the Director:

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

(ii) as to the name and address of the holder or holders of the authorisation or authorisations.

Provided that the enquiry shall be supported by evidence that the prospective applicant intends to apply for authorisation on his own behalf and that the other information specified in regulation 9(2) is available;

(b) the Director, if satisfied that the applicant intends to apply, shall provide the name and address of the holder or holders of former relevant authorisations and shall at the time inform the holders of the authorisations of the name and address of the applicant.

Provided that -

(i) the holder or holders of former authorisations and the applicant shall take all reasonable steps to reach agreement on the sharing of information, so as to avoid, if possible, the duplication of testing on vertebrate animals;

(ii) the Director shall encourage data-holders to cooperate in the provision of the requested data, with a view to limiting the duplication of testing on vertebrate animals; and

(iii) if it is still not possible for the applicant and holders of former authorizations of the same

product to reach an agreement on the sharing of data, national measures may be introduced, obliging the applicant and holders of former authorisations located within their territory to share the data with a view to avoiding duplicative testing on vertebrate animals and determine both the procedure for utilizing information, and the reasonable balance of the interests of the parties concerned.

New information and obligations of the holder of an authorisation.

15. (1) The holder of an authorization for a biocidal product shall immediately notify the Director of information of which he or she is aware or of which he or she may reasonably be expected to be aware concerning an active substance or a biocidal product containing it and which may affect continuing authorisation. In particular, the following shall be notified:

(a) new knowledge or information on the effects of the active substance or biocidal product for humans or the environment,

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

(c) changes in composition of a biocidal product,

(d) development of resistance,

(e) changes of an administrative nature or other aspects, such as the nature of the packaging.

(2) The Director shall immediately notify other Member States and the Commission of any such information they receive concerning potentially harmful effects for humans or the environment of the new composition of a biocidal product, its active substances, impurities, co-formulants or residues.

Derogation from requirements.

16. (1) By way of derogating from regulations 4 and 6, the placing on the market of biocidal products not complying with the provisions of these regulations may be authorised temporarily for a period not exceeding 120 days for a limited and controlled use if such a measure appears necessary because of an unforseen danger which cannot be contained by other means. In this case, the Director concerned shall immediately inform the other Member States and the Commission of its action and justification for it.

(2) By way of derogation from regulation 6(1)(a) and until an active substance is listed in Schedule I – Part A or Part B, the placing on the market of a biocidal product containing an active substance not listed in Schedule I – Part A or Part B and not yet available on the market on the 8th of March 2000 for purposes other than those defined in regulation 3(2)(c) and (d) may be authorised provisionally for a period not exceeding three years. Such an authorisation may be issued only if, after dossiers have been evaluated in accordance with regulation 12, it is believed that:

(a) the active substance satisfies the requirements of regulation 11, and,

(b) the biocidal product may be expected to satisfy the conditions of regulations 6(1)(b), (c) and (d),

and no other Member State, on the basis of the summary it receives, makes legitimate objection, in accordance with regulation 19(2), to the completeness of the dossiers. Where an objection is made, a decision on the completeness of dossiers shall be taken in accordance with the procedure laid down in Article 28(2) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market without undue delay:

Provided that -

(a) if, following the procedures laid down in Articles 27 and 28(2) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, it is decided that the active substance does not satisfy the requirements specified in regulation 11, the Director shall ensure that the provisional authorisation is cancelled;

(b) in cases where evaluation of dossiers for the purposes of inclusion of an active substance in Schedule I – Part A or Part B is not completed when the period of three years expires, the Director may further provisionally authorise the product for a period not exceeding one year, providing there are good reasons to believe the active substance will satisfy the requirements of regulation 11.

Transitional measures.

17. (1) By way of further derogating from regulations 4(1), 6(1), 9(2) and 9(4), and without prejudice to sub-regulations 17(3), the Director may, until 14 May 2014, continue to apply its current system or practice of placing biocidal products on the market. If a decision to include an active substance in Schedule I or I – Part A sets a later date for compliance with regulation 17(3) than 14 May 2014, this derogation shall continue to apply for products including that active substance until the date set in that decision. The Director may, authorise the placing on the market in its territory of a biocidal products containing active substances not listed in Schedule I – Part A or Part B for that product type. Such active substances must be on the market on the 8th of March 2000 as active substances of a biocidal product for purposes other than those defined in regulation 3(2)(c) and (d).

(2) Following such a decision to include or not to include an active substance in Schedule I, the Director shall ensure that authorisations or, where relevant, registrations for biocidal products containing the active substances and complying with the provisions of these Regulations are granted, modified or cancelled as appropriate.

Research and development.

18. (1) By way of derogation from regulation 4, any experiment or test for the purposes of research or development involving the placing on the market of an unauthorised biocidal product or an active substance intended exclusively for use in a biocidal product shall not take place unless:

(a) 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 dossier 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;

(b) in the case of process-oriented research and development, the information required in regulation 18(1)(a) is notified to the Director before placing on the market occurs and where the experiment or test is to be conducted.

(2) Unauthorised biocidal products 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 into the environment unless the Director has assessed the available data and issued an authorisation for this purpose which limits the quantities to be used and the areas to be treated and may impose further conditions.

(3) Where any experiment or test takes place in a Member State other than in Malta, the applicant shall obtain experiments or tests authorisation from the competent authority of the Member State in the territory of which the experiments or tests are to be conducted:

Provided that if the proposed experiments or tests referred to in regulation 18(1) and (2) are liable to have harmful effects on human or animal health or to have an unacceptable adverse influence on the environment, the Director may either prohibit them or only allow them subject to such conditions as it considers necessary to prevent those consequences.

(4) Regulation 18(2) shall not apply if the Director has granted the person concerned the right to undertake certain experiments and tests and has determined the conditions under which the experiments and tests have to be undertaken.

(5) Common conditions for the application of regulation 18, in particular the maximum quantities of active substances or biocidal products that may be released during experiments and the minimum data to be submitted in order to permit an assessment in accordance with regulation 18(2), shall be adopted. Those measures, designed to amend non-essential elements of these Regulations by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

Information exchange.

19. (1) Within a period of one month from the end of each quarter, the Director shall inform other Member States and the Commission of any biocidal products which have been authorised or registered within their territory or for which an authorization or registration has been refused, modified, renewed or cancelled, indicating at least:

(a) the name or business name of the applicant for, or the holder of, the authorization or registration;

(b) the trade name of the biocidal product;

(c) the name and amount of each active substance which it contains, as well as the name and amount of each dangerous substance in the meaning of regulation 3(2) of the Dangerous Substances Regulations, 2008 and their classification;

L.N. 306 of 2008.

(d) the product-type and the use or uses for which it is authorised;

(e) the type of formulation;

(f) any proposed limits on residues which have been established;

(g) conditions of the authorisation and where relevant, the reasons for the modification or cancellation of an authorisation;

(h) an indication of whether the product is of a special type, such as within a frame-formulation, low risk biocidal product.

(2) Where a Director receives a summary of the dossiers in accordance with regulations 12(1)(b) and 16(2) and has legitimate reason to believe the dossiers are incomplete, it shall immediately communicate its concerns to the competent authority responsible for the evaluation of the dossiers and shall without undue delay inform the Commission and other Member States of its concerns.

(3) The Director shall draw up an annual list of the biocidal products authorised or registered in its territory and shall communicate that list to the other Member States and the Commission.

(4) In accordance with the procedure laid down in Article 28(2) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, a standardised information system shall be set up to facilitate the application of regulations 19(1) and (2).

Confidentiality.

20. (1) Without prejudice to the Freedom of Access to Information on the Environment Regulations, 2005, an applicant may indicate to the Director the information which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially and which he therefore wishes to be kept confidential from all persons other than the competent authorities and the Commission. Full justification will be required in each case. Without prejudice to the information referred to in regulation 20(3) and the provisions of the Dangerous Substances Regulations, 2008 and the Dangerous Substances and Preparations Regulations, 2007 the Director shall take the necessary steps to ensure the confidentiality of the full composition of product formulations if requested by the applicant.

L.N. 116 of 2005.

L.N. 306 of 2008.

L.N. 10 of 2007.

(2) The Director shall decide, on the basis of documentary evidence produced by the applicant, which information shall be confidential within the terms of regulation 20 (1):

Provided that information accepted as being confidential by the Director shall be treated as being confidential by the other competent authorities, Member States and the Commission.

(3) After the authorisation has been granted, confidentiality shall not in any case apply to:

(a) the name and address of the applicant;

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

(c) the name and 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 Dangerous Substances Preparations, 2008 and contribute to the classification of the product;

L.N. 306 of 2008.

(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 9 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 regulation 6(1)(c);

(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;

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

Provided that the Director shall be informed if the applicant or manufacturer or importer of the biocidal product or active substance should later disclose previously confidential information.

(4) The detailed provisions and format for making information publicly available and for implementing regulation 20 shall be decided in accordance with the procedures set out in Article 28(2) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

Classification, packaging and labelling of biocidal products.

L.N. 10 of 2007.

21. (1) Biocidal products shall be classified in accordance with the provisions relating to classification in the Dangerous Substances and Preparations Regulations, 2007.

L.N. 10 of 2007.

(2) Biocidal products shall be packaged in accordance with regulation 12 of the Dangerous Substances and Preparations Regulations, 2007. In addition:

(a) products which may be mistaken for food, drink or feedingstuff shall be packaged to minimize the likelihood of such a mistake being made;

(b) products available to the general public which may be mistaken for food, drink or feedingstuff shall contain components to discourage their consumption.

(3) Biocidal products shall be labelled in accordance with the provisions relating to labelling in the Dangerous Substances and Preparations Regulations, 2007. Labels shall not be misleading or give an exaggerated impression of the product and, in any case, not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless' or similar indications. In addition, the label must show clearly and indelibly the following: L.N. 10 of 2007.

(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, such as liquid concentrates, granules, powders, solids;

(d) the uses for which the biocidal product is authorised, such as wood preservation, disinfection, surface biocide, anti-fouling;

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

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

(m) for microbiological biocidal products, labelling requirements according to the Protection of Workers from Risks related to Exposure to Biological Agents at Work Regulations, 2003:

L.N. 228 of 2003.

Provided that the definition terms:-

(a) items of sub-regulation 3(a), (b), (d) and where applicable (g) and (k) shall always be required to be carried on the label of the product;

(b) the Director shall permit the definition terms of items of sub-regulation 3(c), (e), (f), (h), (i), (j) and (l) to be carried elsewhere on the packaging or on an accompanying leaflet integral to the packaging. These items of information shall be regarded as label information for the purposes of these regulations.

(4) Where a biocidal product identified as insecticide, acaricide, rodenticide, avicide or molluscicide is authorised pursuant to this regulation and is also subject to classification, packaging and labeling according to the Dangerous Substances

and Preparations Regulations, 2007 by virtue of other Community provisions, changes shall be permitted to the packaging and labelling of that product which may be required as a consequence of those provisions in so far as they do not conflict with the conditions of an authorisation issued under these regulations. L.N. 10 of 2007.

(5) Provision of samples, models or drafts of the packaging, labelling and leaflets may be required and shall be submitted upon request from the Director.

(6) Labelling of the biocidal products on the market shall be in English and Maltese. Giving justifiable reasons and depending on the product type, the Director may give permission in writing for the labelling to be in only one language, either in English or Maltese.

(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.

22. (1) The Director shall take the necessary measures to ensure that a system of specific information is established to enable professional and industrial users and, as appropriate, other users of biocidal products to take the necessary measures for the protection of the environment and health as well as helath and safety at the workplace. This shall be done in the form of a safety-data sheet provided by those responsible for the placing on the market of the product. Safety-data sheets.

Provided that the safety-data-sheets shall be prepared:

(a) for biocidal products classified as dangerous and in accordance with regulation 17 of the the Dangerous Substances and Preparations Regulations, 2007, and L.N. 10 of 2007.

(b) for active substancess used exclusively in biocidal products in accordance with the requirements of Article 31 of Regulation (EC)1907/2006.

23. (1) Every advertisement for a biocidal product shall be accompanied by the sentences ‘Use biocides safely. Always read the label and product information before use’. Advertising.

(2) The sentences shall be clearly distinguishable in relation to the whole advertisement. The word 'Biocides' in the prescribed sentences may be replaced with an accurate description of the product-type being advertised, for example wood preservatives, disinfectants, surface biocides, and anti-fouling products.

(3) Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to man or the environment. Under no circumstances may the advertising of a biocidal product mention 'low-risk biocidal product', 'non-toxic', 'harmless' or any similar indications.

Poison Control.

24. (1) (a) The Malta Standards Authority shall be responsible for receiving information on biocidal products which have been placed on the market, including information on the chemical composition of such products, and for making such information available in cases where suspected poisoning arises from biocidal products. Such information may only be used to meet any medical demand by formulating preventive and curative measures, in particular in emergencies. The Director shall ensure that the information is not used for other purposes.

(b) The Director shall take the necessary steps to ensure that the appointed bodies provide all the requisite guarantees for maintaining the confidentiality of the information received. The Director shall ensure that the appointed bodies have at their disposal all the information required to carry out the tasks for which they are responsible form the manufacturers or persons responsible for marketing.

(c) For biocidal products already on the market on the 8th of March 2000, the Director shall take measures to comply with regulation 24 within three years of the 8th of March 2000.

Compliance with requirements.

25. (1) (a) The Director shall take the necessary arrangements for biocidal products which have been placed on the market to be monitored to establish whether they comply with the requirements of these regulations.

(b) Every three years after the 8th of March 2000, the Director shall forward to the Commission by 30 November of the third year a report on their action in these matters together with information on any poisonings involving biocidal products.

Charges.

26. (1) The Director shall establish systems obliging those having placed or seeking to place biocidal products on the market and those supporting entries for active substances on Schedule I to pay charges, corresponding as far as possible to their costs in carrying out all the different procedures associated with the provisions of these regulations.

Competent authorities.

27. (1) The Malta Standards Authority shall be the competent authority within the meaning of these regulations.

Civil and criminal liability.

28. (1) Measures necessary to adapt Schedules II – Part A, II – Part B, III – Part A, III – Part B, IV – Part A or IV – Part B or the descriptions of product types in Schedule V to technical progress or to specify data requirements for each of these product types shall be adopted. Those measures, designed to amend non-essential elements of these Regulations, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

Adaptation to technical progress.

29. (1) The granting of authorisation and all other measures in conformity with these Regulations shall be without prejudice to general civil and criminal liability in the Member States of the manufacturer and, where applicable, of the person responsible for placing the biocidal product on the market or using it. The sanctions applicable for infringement of the provision of these regulations shall be those provided for in Part 9 of the Pesticides Control Act.

Cap. 430.

Safeguard clause.

30. (1) Where the Director has valid reasons to consider that a biocidal product which was authorised, registered or is bound to authorise or register pursuant to regulations 4 or 5, constitutes an unacceptable risk to human or animal health or the environment, it may provisionally restrict or prohibit the use or sale of that product on its territory. The director shall immediately inform the Commission and the other Member States of such action and give reasons for its decision. A decision shall then be taken on the matter within 90 days in accordance with the procedure laid down in Article 28(3) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

Dealing in Biocidal products.

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

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

(b) biocidal product unless this is authorized 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 32 of these regulations.

Application for an authorisation to deal.

32. (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, 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:

Provided that this time limit can be suspended until all relevant information is submitted.

(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 regulation 32(5) 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.

33. (1) Any authorisation issued by the Director in accordance with regulation 32 of these regulations shall be valid for such a period not exceeding three 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 36 of these regulations and if he is satisfied that the conditions established by regulation 32 of these regulations are still being complied with.

Review of authorisation.

34. (1) Without prejudice to regulation 35 of these regulations, and if the Director suspects that any of the conditions established by regulation 31 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 32 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 35 of these regulations.

Suspension or revocation of an authorisation.

35. (1) Any authorisation issued in accordance with regulation 31 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 31 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.

36. 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;

(b) he is satisfied that the conditions detailed in regulation 32 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.

37. (1) Without prejudice to the provisions of regulation 34 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 35 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 31 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.

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Obligations of the holder of an authorization.

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

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

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 authorized 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 31 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.

Notification of entry into Malta.

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

(2) 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.

(3) The Import Licence shall be submitted to the Director for approval at least one week before importation of biocidal products together with other documents that deem necessary.

40. The Biocides Regulations, 2004 are hereby revoked. Revokes L.N 294 of 2004.

SCHEDULE I

PART A

List of Active Substances with Requirements Agreed At Community Level for Inclusion in Biocidal Products

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
1	sulfuryl fluoride	sulfuryl difluoride EC No: 220-281-5 CAS No: 2699-79-8	> 994 g/kg	1 January 2009	31 December 2010	31 December 2018	8	Member States shall ensure that authorizations are subject to the following conditions: (1) the product may only be sold to and used by professionals trained to use it; (2) appropriate risk mitigation measures are included for operators and bystanders; (3) concentrations of sulfuryl fluoride in remote tropospheric air are monitored. Member States shall also ensure that reports of the monitoring referred to in point (3) are

								transmitted by authorisation holders directly to the Commission every fifth year starting from 1 January 2009.
			994 g/kg	1 July 2011	30 June 2013	30 June 2021	18	Member States shall ensure that authorizations are subject to the following conditions: (1) Products shall only be sold to and used by professionals trained to use them. (2) Appropriate measures to protect fumigators and bystanders during fumigation and venting of treated buildings or other enclosures must be taken. (3) Labels and/or safety-data sheets of products shall indicate that, prior to fumigation of any enclosure, all food items must be removed. (4) Concentrations of sulfuryl fluoride in remote tropospheric air are monitored. (5) Member States shall also ensure that reports of the monitoring referred to in point (4) are transmitted by authorization holders directly to the Commission every fifth year, starting at the latest five years after the authorisation. The limit of detection for the analysis shall be at least 0,5 ppt (equivalent to 2,1 ng sulfuryl fluoride/m3 of tropospheric air).
2	dichlofluanid	N-(Dichlorofluoromethylthio)-N′,N′-dimethyl-N-phenylsulfamide	> 96 % w/w	1 March 2009	28 February 2011	28 February 2019	8	Member States shall ensure that authorizations are subject to the following conditions: (1) Products authorised for

		EC No: 214-118-7 CAS No: 1085-98-9						industrial and/or professional use must be used with appropriate personal protective equipment. (2) In view of the risks identified for the soil compartment appropriate risk mitigation measures must be taken to protect that compartment. (3) Labels and/or safety-data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for re-use or disposal.
3	clothianidin	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-Nitroguanidine EC No: 433-460-1 CAS No: 210880-92-5	950 g/kg	1 February 2010	31 January 2012	31 January 2020	8	When assessing, in accordance with Article 5 and Annex VI, the application for authorization of a product, Member States shall assess those use/exposure scenarios and/or populations that have not been representatively addressed in the Community level risk assessment and that may be exposed to the product. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to

								acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: In view of the risk identified for the soil, surface water and groundwater compartments, products cannot be authorised for the treatment of wood that will be used outdoors unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for reuse or disposal.
4	Difethialone	3-[3-(4′-bromo[1,1′ biphenyl]-4-yl)-1,2,3,4-tetrahydronaphth-1-yl]-4-hydroxy-2H-1-benzothiopyran-2-one EC No: n/a CAS No: 104653-34-1	976 g/kg	1 November 2009	31 October 2011	31 October 2014	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed.

								Member States shall ensure that authorizations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 0,0025 % w/w and only ready-for-use baits shall be authorised. (2) Products shall contain an aversive agent and, where appropriate, a dye. (3) Products shall not be used as tracking powder. (4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
5	etofenprox	3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether EC No: 407-980-2 CAS No: 80844-07-1	970 g/kg	1 February 2010	31 January 2012	31 January 2020	8	When assessing, in accordance with Article 5 and Annex VI, the application for authorisation of a product, Member States shall access those use and/or exposure scenarios and/or populations that have not been representatively addressed in the Community level risk

								assessment and that may be exposed to the product. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: In view of the risk identified for workers, products cannot be used year round unless dermal absorption data is provided to demonstrate that there are no unacceptable risks from chronic exposure. In addition, products intended for industrial use must be used with appropriate personal protective equipment.
6	tebuconazole	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol EC No: 403-640-2 CAS No: 107534-96-3	950 g/kg	1 April 2010	31 March 2012	31 March 2020	8	Member States shall ensure that authorizations are subject to the following conditions: In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products

								authorised for industrial use indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. In addition, products cannot be authorised for the *in situ* treatment of wood outdoors or for wood that will be in continuous contact with water unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.
7	carbon dioxide	carbon dioxide EC No: 204-696-9 CAS No: 124-38-9	990 ml/l	1 November 2009	31 October 2011	31 October 2019	14	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in

								order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.
8	propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole EC No: 262-104-4 CAS No: 60207-90-1	930 g/kg	1 April 2010	31 March 2012	31 March 2020	8	Member States shall ensure that authorizations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorized for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

								In addition, products cannot be authorised for the *in situ* treatment of wood outdoors or for wood that will be exposed to weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.
9	Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin EC No: 259-978-4 CAS No: 56073-07-5	960 g/kg	1 April 2010	31 March 2012	31 March 2015	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 75 mg/kg and only ready-for-use products shall be authorised. (2) Products shall contain an aversive agent and, where appropriate, a dye. (3) Products shall not be used as tracking powder.

								(4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
10	K-HDO	Cyclohexylhydroxydiazene 1-oxide, potassium salt EC No: n/a CAS No: 66603-10-9 (This entry also covers the hydrated forms of K-HDO)	977 g/kg	1 July 2010	30 June 2012	30 June 2020	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. Member States shall ensure that authorizations are subject to the following conditions: (1) in view of the possible risks for the environment and workers, products shall not be used in other systems than industrial, fully automated and closed ones unless the application for product authorisation demonstrates that risks can be reduced to acceptable levels in

								accordance with Article 5 and Annex VI; (2) in view of the assumptions made during the risk assessment, products must be used with appropriate personal protective equipment, unless the application for product authorisation demonstrates that risks to users can be reduced to acceptable levels by other means; (3) in view of the risk identified for infants, products shall not be used for the treatment of wood that may enter in direct contact with infants.
11	IPBC	3-iodo-2-propynyl butylcarbamate EC No: 259-627-5 CAS No: 55406-53-6	980 g/kg	1 July 2010	2010 30 June 2012	30 June 2020	8	Member States shall ensure that authorisations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to

								protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hardstanding to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
12	Chlorophacinone	Chlorophacinone EC No: 223-003-0	978 g/kg	1 July 2011	30 June 2013	30 June 2016	14	In view of the identified risks for non-target animals, the active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in products other than tracking powder shall not exceed 50 mg/kg and only ready-for use products shall be authorised. 2. Products to be used as tracking powder shall only be placed on the market for use by trained professionals. 3. Products shall contain an aversive agent and, where appropriate, a dye. 4. Primary as well as secondary exposure of humans, non-target

								animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
13	Thiabendazole	2-thiazol-4-yl-1H-benzoimidazole EC No: 205-725-8 CAS No: 148-79-8	985 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Member States shall ensure that authorizations are subject to the following conditions: in view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, with respect to the double-vacuum and dipping application tasks, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorization that risks to industrial and/or professional users can be reduced to an acceptable level by others means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorized for industrial use shall indicate that freshly treated timber must be

								stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. Products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.
14	thiamethoxam	thiamethoxam EC No: 428-650-4 CAS No: 153719-23-4	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Member States shall ensure that authorizations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels

								and/or safety data sheets of products authorized for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. Products shall not be authorised for the *in situ* treatment of wood outdoors or for wood that will be exposed to weathering, unless data have been submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.
15	alphachloralose	(R)-1,2-O-(2.2,2-Trichloroethylidene)-*α*-D-glucofuranose	825 g/kg	1 July 2011	30 June 2013	30 June 2021	14	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate

								measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. In particular, products cannot be authorised for outdoor use unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 40 g/kg. 2. Products shall contain an aversive agent and a dye. 3. Only products for use in tamper resistant and securely closed bait boxes shall be authorised.
16	brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-napthyl]-4-hydroxycoumarin EC No: 259-980-5	950 g/kg	1 February 2012	31 January 2014	31 January 2017	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a

		CAS No: 56073-10-0						comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
17	bromadiolone	3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one	969 g/kg	1 July 2011	30 June 2013	30 June 2016	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to

		EC No: 249-205-9 CAS No: 28772-56-7						bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
18	Thiacloprid	(Z)-3-(6-chloro-3-pyridylmethyl)-	975 g/kg	1 January 2010	n/a	31 December 2019	8	When assessing the application for authorization of a product in

		1,3-thiazolidin-2-ylidenecyanamide EC No: n/a CAS No: 111988-49-9						accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorization that risks to industrial and/or professional users can be reduced to an acceptable level by other means.

								2. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. 3. Products shall not be authorised for the *in situ* treatment of wooden structures near water, where direct losses to the aquatic compartment cannot be prevented, or for wood that will be in contact with surface water, unless data have been submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.
19	Indoxacarb (enantiomeric reaction mass S:R 75:25)	Reaction mass of methyl (S)- and methyl(R)-7-chloro-2.3,4a,5-tetrahydro-2-[methoxycarbonyl-(4-trifluoromethoxyphenyl) carbamoyl]indeno[1,2-e] [1.3,4]oxadiazine-4acarboxylate (This entry	796 g/kg	1 January 2010	n/a	31 December 2019	18	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or

		covers the 75:25 reaction mass of the S and R enantiomers) EC No: n/a						exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: Appropriate risk mitigation measures must be taken to minimise the potential exposure of humans, of non-target species and of the aquatic environment. In particular, labels and/or safety-data sheets of products authorized shall indicate that: 1. Products shall not be placed in areas accessible to infants, children and companion animals. 2. Products shall be positioned away from external drains. 3. Unused products shall be disposed of properly and not washed down the drain.

								For amateur uses, only ready-to-use products shall be authorised.
20	aluminium phosphide releasing phosphine	aluminium phosphide EC No: 244-088-0 CAS No: 20859-73-8	830 g/kg	1 September 2011	31 August 2013	31 August 2021	14	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. In particular, products cannot be authorised for indoor use unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Member States shall ensure that authorizations are subject to the

								following conditions: 1. Products shall only be sold to and used by specifically trained professionals. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. These include, amongst others, the use of appropriate personal protective equipment, the use of applicators and the presentation of the product in a form designed to reduce operator exposure to an acceptable level. 3. In view of the risks identified for terrestrial non-target species, appropriate risk reduction measures must be applied. These include, amongst others, the non-treatment of areas where other burrowing mammals than the target species are present.
			830 g/kg	1 February 2012	31 January 2014	31 January 2022	18	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the Union level risk assessment. In particular, where relevant, Member States shall assess outdoor use. When granting product

								authorisation, Member States shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Member States shall ensure that authorizations are subject to the following conditions: 1. Products shall only be supplied to and used by specifically trained professionals in the form of ready-for-use products. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas. 3. For products containing aluminium phosphide that may lead to residues in food or feed,

								labels and/or safety data sheets for authorized products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).
21	fenpropimorph	(+/-)-cis-4-[3-(p-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine EC No: 266-719-9 CAS No: 67564-91-4	930 g/kg	1 July 2011	30 June 2013	30 June 2021	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the

								following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
22	boric acid	boric acid EC No: 233-139-2 CAS No: 10043-35-3	990 g/kg	1 September 2011	31 August 2013	31 August 2021	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, he populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment.

						When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: 1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation

								measures. In particular, labels and/or safety-data sheets of products authorized for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
23	boric oxide	Diboron trioxide EC No: 215-125-8 CAS No: 1303-86-2	975 g/kg	1 September 2011	31 August 2013	31 August 2021	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions:

								1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
24	disodium tetraborate	disodium tetraborate EC No: 215-540-4 CAS No (anhydrous): 1330-43-4 CAS No (pentahydrate):	990 g/kg	1 September 2011	31 August 2013	31 August 2021	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the

		12267-73-1 CAS No (decahydrate): 1303-96-4						product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorisations are subject to the following conditions: 1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that

								the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
25	disodium octaborate tetrahydrate	disodium octaborate tetrahydrate EC No: 234-541-0 CAS No: 12280-03-4	975 g/kg	1 September 2011	31 August 2013	31 August 2021	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.

								Member States shall ensure that authorizations are subject to the following conditions: 1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorized for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
26	Magnesium phosphide releasing	Trimagnesium diphosphide EC No: 235-023-7	880 g/kg	1 February 2012	31 January 2014	31 January 2022	18	When assessing the application for authorization of a product in accordance with Article 5 and

	phosphine	CAS No: 12057-74-8						Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the Union level risk assessment. In particular, where relevant, Member States shall assess outdoor use. When granting product authorisation, Member States shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Member States shall ensure that authorizations are subject to the following conditions: 1. Products shall only be supplied to and used by specifically trained professionals in the form of ready-for-use products. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level.

								For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas. 3. For products containing magnesium phosphide that may lead to residues in food or feed, labels and/or safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).
27	Nitrogen	Nitrogen EC No: 231-783-9 CAS No: 7727-37-9	999 g/kg	1 September 2011	31 August 2013	31 August 2021	18	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the

								following conditions: 1. Products may only be sold to and used by professionals trained to use them. 2. Safe working practices and safe systems of work must be in place to ensure minimum risk, including the availability of personal protective equipment if necessary.
28	Coumatetralyl	Coumatetralyl EC No: 227-424-0 CAS No: 5836-29-3	980 g/kg	1 July 2011	30 June 2013	30 June 2016	14	In view of the identified risks for non-target animals, the active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in products other than tracking powder shall not exceed 375 mg/kg and only ready-for use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation

								measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
29	tolylfluanid	Dichloro-N-[(dimethylamino) sulphonyl]fluoro-N-(p-tolyl)methanesulphenamide EC No: 211-986-9 CAS No: 731-27-1	960 g/kg	1 October 2011	30 September 2013	30 September 2021	8	Products shall not be authorised for the *in situ* treatment of wood outdoors or for wood that will be exposed to weathering. Member States shall ensure that authorizations are subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial or professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorization that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial or professional use shall indicate that freshly treated timber must be stored after treatment under

								shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
30	Acrolein	Acrylaldehyde EC No: 203-453-4 CAS No: 107-02-8	913 g/kg	1 September 2010	Not applicable	31 August 2020	12	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: 1. Waste waters containing acrolein shall be monitored prior to discharge, unless it can be demonstrated that risks for the environment can be reduced by other means. Where necessary in view of the risks to marine environment, waste waters shall be held in suitable tanks or reservoirs or appropriately treated before discharge. 2. Products authorised for industrial and/or professional use shall be used with appropriate personal protective equipment, and safe operational procedures shall be established, unless it can be demonstrated in the application for product

								authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by others means.
31	Flocoumafen	4-hydroxy-3-[(1*RS*,3*RS*;1*RS*,3*RS*)-1,2,3,4-tetrahydro-3-[4-(4-trifluoromethylbenzyloxy) phenyl]-1-naphthyl] coumarin EC No 421-960-0 CAS No 90035-08-8	955 g/kg	1 October 2011	30 September 2013	30 September 2016	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation

								measures. Those include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
32	Warfarin	(RS)-4-hydroxy-3-(3-oxo-1-phenylbutyl)coumarin EC No: 201-377-6 CAS No: 81-81-2	990 g/kg	1 February 2012	31 January 2014	31 January 2017	14	The active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: 1. the nominal concentration of the active substance shall not exceed 790 mg/kg and only ready-for-use products shall be authorised; 2. products shall contain an aversive agent and, where appropriate, a dye; 3. primary and secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the possibility of restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper

								resistant and secured bait boxes.
33	Warfarin sodium	Sodium 2-oxo-3-(3-oxo-1-phenylbutyl)chromen-4-olate EC No: 204-929-4 CAS No: 129-06-6	910 g/kg	1 February 2012	31 January 2014	31 January 2017	14	The active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. the nominal concentration of the active substance shall not exceed 790 mg/kg and only ready-for-use products shall be authorised; 2. products shall contain an aversive agent and, where appropriate, a dye; 3. primary and secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the possibility of restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
34	Dazomet	Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione EC No: 208-576-7	960 g/kg	1 August 2012	31 July 2014	31 July 2022	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the

		CAS No: 533-74-4						particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the EU level risk assessment. In particular, where relevant, Member States shall assess any other use than professional use outdoors for the remedial treatment of wooden poles by insertion of granules. Member States shall ensure that authorisations are subject to the following condition: Products authorised for industrial and/or professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by others means.
35	N,N-diethyl-meta-toluamide	N,N-diethyl-m- toluamide EC No: 205-149-7 CAS No: 134-62-3	970 g/kg	1 August 2012	31 July 2014	31 July 2022	19	Member States shall ensure that authorisations are subject to the following conditions: 1. primary exposure of humans shall be minimized by considering and applying appropriate risk mitigation measures, including, where applicable, instructions for the amount and frequency of application of the product on human skin; 2. labels on products intended for application on human skin, hair or clothing shall indicate that the product is intended only for restricted use on children between two and twelve years old, and that

								it is not intended for use on children less than two years old, unless it can be demonstrated in the application for product authorisation that the product will meet the requirements of Article 5 and Annex VI without such measures; 3. products must contain deterrents for ingestion.
For the implementation of the common principles of Schedule VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm								

PART B

List of Active Substances with Requirements agreed at Community Level for Inclusion in Low-Risk Biocidal Products

No	Common name	IUPAC name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions
1	Carbon dioxide	Carbon dioxide EC No: 204-696-9 CAS No: 124-38-9	990 ml/l	1 November 2009	31 October 2011	31 October 2019	14	Only for use in ready-for-use gas canisters functioning together with a trapping device.
Note: For the implementation of the common principles of Schedule VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm								

PART C

List of Basic Substances with Requirements agreed at Community Level

SCHEDULE II

PART A

COMMON CORE DATA SET FOR ACTIVE SUBSTANCES

CHEMICAL SUBSTANCES

1. Dossiers on active substances are required to address at least all the points listed under `Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. 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 competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

Dossier requirements

I. Applicant

II. Identity of the active substance

III. Physical and chemical properties of the active substance

IV. Methods of detection and identification

V. Effectiveness against target organisms and intended uses

VI. Toxicological profile for man and animals including metabolism

VII. Ecotoxicological profile including environmental fate and behaviour

VIII. Measures necessary to protect man, animals and the environment

IX. Classification and labelling

X. Summary and evaluation of Sections II to IX

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

I. APPLICANT

1.1. Name and address, etc.

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

II. IDENTITY

2.1. Common name proposed or accepted by ISO and synonyms

2.2. Chemical name (IUPAC nomenclature)

2.3. Manufacturer's development code number(s)

2.4. CAS and EC numbers (if available)

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

2.6. Method of manufacture (syntheses pathway in brief terms) of active substance

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

2.8. Identity of impurities and additives (e.g. stabilisers), together with the structural formula and the possible range expressed as g/kg or g/l, as appropriate

2.9. The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower

2.10. Exposure data in conformity with Annex VI of Regulation (EC) No. 1907/2006.

III. PHYSICAL AND CHEMICAL PROPERTIES

3.1. Melting point, boiling point, relative density[1]

3.2. Vapour pressure (in Pa)[1]above

[1] These data must be submitted for the purified active substance of stated specification

3.3. Appearance (physical state, colour)[2]

3.4. Absorption spectra (UV/VIS, IR, NMR), and a mass spectrum, molar extinction at relevant wavelengths, where relevant [1]

3.5. Solubility in water including effect of pH (5 to 9) and temperature on solubility, where relevant[1]

3.6. Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature[1]

3.7. Thermal stability, identity of relevant breakdown products

3.8. Flammability including auto-flammability and identity of combustion products

3.9. Flash-point

3.10. Surface tension

3.11. Explosive properties

3.12. Oxidising properties

3.13. Reactivity towards container material

IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

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

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

(a) Soil

(b) Air

(c) Water: the applicant should confirm that the substance itself and any of its degradation products which fall within the definition of pesticides given for "pesticides" and "pesticides – total" under Part B of Annex I Parameters and Parametric Values Of Legal Notice 17 of 2009 Water Intended for Human

[2] These data must be submitted for the active substance of stated specification

Consumption Regulations can be estimated with adequate reliability at the MAC specified in those Regulations for individual pesticides

(d) Animal and human body fluids and tissues

V. EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES

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

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

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

5.4. Mode of action (including time delay)

5.5. Field of use envisaged

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

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

5.8. Likely tonnage to be placed on the market per year

VI. TOXICOLOGICAL AND METABOLIC STUDIES

6.1. Acute toxicity

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

6.1.1. Oral

6.1.2. Dermal

6.1.3. Inhalation

6.1.4. Skin and eye irritation[3]

6.1.5. Skin sensitisation

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

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

6.3. Short-term repeated dose toxicity (28 days)

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

6.4. Subchronic toxicity 90-day study, two species, one rodent and one non-rodent

6.5. Chronic toxicity([4])

One rodent and one other mammalian species

6.6. Mutagenicity studies

6.6.1. *In-vitro* gene mutation study in bacteria

6.6.2. *In-vitro* cytogenicity study in mammalian cells

6.6.3. *In-vitro* gene mutation assay in mammalian cells

6.6.4. If positive in 6.6.1, 6.6.2 or 6.6.3, then an *in-vivo* mutagenicity study will be required (bone marrow assay for chromosomal damage or a micronucleus test)

6.6.5. If negative in 6.6.4 but positive *in-vitro* tests then undertake a second *in-vivo* study to examine whether mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow

6.6.6. If positive in 6.6.4 then a test to assess possible germ cell effects may be required

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[3] Eye irritation test shall not be necessary where the active substance has been shown to have potential corrosive properties.

6.7. Carcinogenicity study[4]

One rodent and one other mammalian species. These studies may be combined with those in 6.5

6.8. Reproductive toxicity[5]

6.8.1. Teratogenicity test — rabbit and one rodent species

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

6.9. Medical data in anonymous form

6.9.1. Medical surveillance data on manufacturing plant personnel if available

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

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

6.9.4. Epidemiological studies on the general population, if available

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

6.9.6. Sensitisation/allergenicity observations, if available

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

6.9.8. Prognosis following poisoning

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

VII. ECOTOXICOLOGICAL STUDIES

7.1. Acute toxicity to fish

[4] The long-term toxicity and carcinogenicity of an active substance may not be required where a full justification demonstrates that these tests are not necessary

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

7.2. Acute toxicity to *Daphnia magna*

7.3. Growth inhibition test on algae

7.4. Inhibition to microbiological activity

7.5. Bioconcentration

Fate and behaviour in the environment

7.6. Degradation

7.6.1. Biotic

7.6.1.1. Ready biodegradability

7.6.1.2. Inherent biodegradability, where appropriate

7.6.2. Abiotic

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

7.6.2.2. Phototransformation in water including identity of the products of transformation[1]

7.7. Adsorption/desorption screening test

Where the results of this test indicate the need to do so, the test described in Schedule III – Part A Section XII.1 paragraph 1.2 shall be required, and/or the test described in Schedule III – Part A Section XII.2 paragraph 2.2

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

VIII. MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

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

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

8.3. Emergency measures in case of an accident

8.4. Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil

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

8.5.1. Possibility of reuse or recycling

8.5.2. Possibility of neutralisation of effects

8.5.3. Conditions for controlled discharge including leachate qualities on disposal

8.5.4. Conditions for controlled incineration

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

IX. CLASSIFICATION AND LABELLING

Proposals including justification for the proposals for the classification and labelling of the active substance according to L.N 306 of 2008.

Hazard symbol(s)

Indications of danger

Risk phrases

Safety phrases

X. SUMMARY AND EVALUATION OF SECTIONS II TO IX

PART B

COMMON CORE DATA SET FOR BIOCIDAL PRODUCTS

CHEMICAL PRODUCTS

1. Dossiers on biocidal products are required to address at least all the points listed under `Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. 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 competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Legal Notice 10 of 2007 should be used wherever possible to minimise animal testing.

Dossier requirements

I. Applicant

II. Identity of the biocidal product

III. Physical and chemical properties of the biocidal product

IV. Methods for identification and analysis of the biocidal product

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

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

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

VIII. Measures necessary to protect man, animals and the environment

IX. Classification, packaging and labelling

X. Summary and evaluation of Sections II to IX

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

I. APPLICANT

1.1. Name and address, etc.

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

II. IDENTITY

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

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

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

III. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES

3.1. Appearance (physical state, colour)

3.2. Explosive properties

3.3. Oxidising properties

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

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

3.6. Relative density

3.7. Storage stability — stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the biocidal product; reactivity towards container material

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

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

IV. METHODS OF IDENTIFICATION AND ANALYSIS

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

4.2. In so far as not covered by Schedule II – Part A, paragraph 4.2, analytical methods including recovery rates and the limits of determination for toxicologically and ecotoxicologically relevant components of the biocidal product and/or residues thereof, where relevant in or on the following:

(a) Soil

(b) Air

(c) Water (including drinking water)

(d) Animal and human body fluids and tissues

(e) Treated food or feedingstuffs

V. INTENDED USES AND EFFICACY

5.1. Product type and field of use envisaged

5.2. Method of application including description of system used

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

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

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

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

5.7. Effects on target organisms

5.8. Mode of action (including time delay) in so far as not covered by Schedule II – Part A, paragraph 5.4

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

Efficacy data

5.10. The proposed label claims for the product and efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate

5.11. Any other known limitations on efficacy including resistance

VI. TOXICOLOGICAL STUDIES

6.1. Acute toxicity

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

6.1.1. Oral

6.1.2. Dermal

6.1.3. Inhalation

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

6.2. Skin and eye irritation([1])

6.3. Skin sensitisation

6.4. Information on dermal absorption

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

6.6. Information related to the exposure of the biocidal product to man and the operator

Where necessary, the test(s) described in Schedule II – Part A, shall be required for the toxicologically relevant non-active substances of the preparation

VII. ECOTOXICOLOGICAL STUDIES

7.1. Foreseeable routes of entry into the environment on the basis of the use envisaged

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

7.3. Available ecotoxicological information relating to exotoxicological relevant non-active substances (i.e. substances of concern), such as information from safety data sheets

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

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

8.2. Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment; in so far as not covered by Schedule II – Part A, paragraph 8.3

8.3. Procedures, if any, for cleaning application equipment

8.4. Identity of relevant combustion products in cases of fire

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

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

(a) Air

(b) Water, including drinking water

(c) Soil

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

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

IX. CLASSIFICATION, PACKAGING AND LABELLING

— Proposals for packaging and labelling

— Proposals for safety-data sheets, where appropriate

— Justification for the classification and labelling according to the principles of regulation 21 of these Regulations

— Hazard symbol(s)

— Indications of danger

— Risk phrases

— Safety phrases

— Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials to be included

X. SUMMARY AND EVALUATION OF SECTIONS II TO IX

Notes

([1]) Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

SCHEDULE III

PART A

ADDITIONAL DATA SET FOR ACTIVE SUBSTANCES

CHEMICAL SUBSTANCES

1. Dossiers on active substances are required to address at least all the points listed under `Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. 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 competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

III. PHYSICAL AND CHEMICAL PROPERTIES

1. Solubility in organic solvents, including effect of temperature on solubility[1]

2. Stability in organic solvents used in biocidal products and identity of relevant breakdown products[2]

IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

1. Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, in/on food or feedstuffs and other products where relevant

VI. TOXICOLOGICAL AND METABOLIC STUDIES

1. Neurotoxicity study

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[1] These data must be submitted for the purified active substance of stated specification.
[2] These data must be submitted for the active substance of stated specification.

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

2. Toxic effects on livestock and pets

3. Studies related to the exposure of the active substance to humans

4. Food and feedingstuffs

   If the active substance is to be used in preparations for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored the tests referred to in Section XI, part 1 shall be required

5. If any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, are considered necessary, then the test(s) referred to in Section XI, part 2 shall be required

6. If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required

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

VII. ECOTOXICOLOGICAL STUDIES

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

2. If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in Sections XII and XIII shall be required

3. If the result of the test in paragraph 7.6.1.2 of Schedule II – Part A is negative and if the likely route of disposal of the active substance is by sewage treatment then the test described in Section XIII, part 4.1 shall be required

4. Any other biodegradability tests that are relevant from the results in paragraphs 7.6.1.1 and 7.6.1.2 of Schedule II – Part A

5. Phototransformation in air (estimation method), including identification of breakdown products[1]

6. If the results from paragraphs 7.6.1.2 in Schedule II – Part A or from paragraph 4, above, indicate the need to do so, or the active substance has an overall low or absent abiotic degradation, then the tests described in Section XII, part 1.1, part 2.1 and, where appropriate, part 3 shall be required

VIII. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

1. Identification of any substances falling within the scope of List I or List II of the Schedule of Legal Notice 203 of 2002 Regulations for the Protection of Groundwater against Pollution caused by Certain Dangerous Substances on the protection of groundwater against pollution caused by certain dangerous substances

XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. Food and feedingstuffs studies

1.1. Identification of degradation and reaction products and of metabolites of the active substance in treated or contaminated foods or feedstuffs

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

1.3. Overall material balance for the active substance. Sufficient residue data from supervised trials to demonstrate that residues likely to arise from the proposed use would not be of concern for human or animal health

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

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

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

1.7. Proposed acceptable residues and the justification of their acceptability

1.8. Any other available information that is relevant

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

2. Other test(s) related to the exposure to humans

Suitable test(s) and a reasoned case will be required

XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1. Fate and behaviour in soil

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

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

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

1.4. Extent and nature of bound residues

2. Fate and behaviour in water

2.1. Rate and route of degradation in aquatic systems (as far as is not covered by Schedule II – Part A, paragraph 7.6) including identification of metabolites and degradation products

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

3. Fate and behaviour in air

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

4. Summary and evaluation of parts 1, 2 and 3

XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. Effects on birds

1.1. Acute oral toxicity — this need not be done if an avian species was selected for study in Section VII, part 1

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

1.3. Effects on reproduction

2. Effects on aquatic organisms

2.1. Prolonged toxicity to an appropriate species of fish

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

2.3. Bioaccumulation in an appropriate species of fish

2.4. *Daphnia magna* reproduction and growth rate

3. Effects on other non-target organisms

3.1. Acute toxicity to honeybees and other beneficial arthropods, e.g. predators. A different test organism shall be chosen from that used in Section VII, part 1

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

3.3. Effects on soil non-target micro-organisms

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

4. Other effects

4.1. Activated sludge respiration inhibition test

5. Summary and evaluation of parts 1, 2, 3 and 4

PART B

ADDITIONAL DATA SET FOR BIOCIDAL PRODUCTS

CHEMICAL PRODUCTS

1. Dossiers on biocidal products are required to address at least all the points listed under `Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. 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 competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Legal Notice 10 of 2007 should be used wherever possible to minimise animal testing.

XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. Food and feedingstuffs studies

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

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

1. Other test(s) related to the exposure to humans

Suitable test(s) and a reasoned case will be required for the biocidal product

XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1. Where relevant all the information required in Schedule III – Part A, Section XII

2. Testing for distribution and dissipation in the following:

(a) Soil

(b) Water

(c) Air

Test requirements 1 and 2 above are applicable only to ecotoxicologically relevant components of the biocidal product

XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. Effects on birds

1.1. Acute oral toxicity, if not already done in accordance with Schedule II – Part B, Section VII

2. Effects on aquatic organisms

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

2.1.1. Particular studies with fish and other aquatic organisms

2.1.2. Residue data in fish concerning the active substance and including toxicologically relevant metabolites

2.1.3. The studies referred to in Schedule III – Part A, Section XIII, parts 2.1, 2.2, 2.3 and 2.4 may be required for relevant components of the biocidal product

2.2. If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms under field conditions

3. Effects on other non-target organisms

3.1. Toxicity to terrestrial vertebrates other than birds

3.2. Acute toxicity to honeybees

3.3. Effects on beneficial arthropods other than bees

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

3.5. Effects on soil non-target micro-organisms

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

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

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

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

4. Summary and evaluation of parts 1, 2, and 3

SCHEDULE IV

PART A

DATA SET FOR ACTIVE SUBSTANCES

MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI

1. For the purposes of these regulations, the term micro-organisms shall be understood as including also viruses and fungi. Dossiers on active micro- organisms shall address at least all the points listed under 'Dossier requirements' below. For all micro-organisms subject to an application for inclusion into Schedule I – Part A or Part B, all available relevant knowledge and information in literature must be provided. The information related to the identification and characterization of a micro-organism including mode of action is particularly important and must be entered in sections I to IV and provides the bases for an assessment of potential impacts on human health and of environmental effects.

2. Where information is not necessary owing to the nature of the micro-organism regulation 9(5) shall apply.

3. A dossier within the meaning of regulation 12(1) shall be prepared on strain level of the micro-organism unless information is submitted that shows that the species is known to be sufficiently homogenous regarding all characteristics, or the applicant provides other arguments in accordance with regulation 9(5).

4. Where the micro-organism has been genetically modified within the meaning of regulation 2(1) of Legal Notice 170 of 2002 concerning the Deliberate Release into the Environment of Genetically Modified Organisms Regulations, a copy of the evaluation of the data concerning the assessment of the risks to the environment as established in regulation 4(2) of that Legal Notice, shall also be submitted.

5. If the biocidal product action is known to be partly or entirely due to the effect of a toxin/metabolite, or if significant residues of toxins/metabolites are to be expected not related to the effect of the active micro-organism, a dossier for the toxin/metabolite shall be submitted in accordance with the requirements of Schedules II – Part A and, where specified, the relevant parts of Schedule III – Part A.

Dossier requirements

SECTIONS:

I. Identity of the micro-organism

II. Biological properties of the micro-organism

III. Further information on the micro-organism

IV. Analytical methods

V. Effects on human health

VI. Residues in or on treated materials, food and feed

VII. Fate and behaviour in the environment

VIII. Effects on non-target organisms

IX. Classification and labeling

X. Summary and evaluation of sections I to IX including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

I. IDENTITY OF THE MICRO-ORGANISM

1.1. Applicant

1.2. Manufacturer

1.3. Name and species description, strain characterization

1.3.1. Common name of the micro-organism (including alternative and superseded names)

1.3.2. Taxonomic name and strain indicating whether it is a stock variant, a mutant strain or a genetically modified organism (GMO); for viruses, taxonomic designation of the agent, serotype, strain or mutant

1.3.3. Collection and culture reference number where the culture is deposited

1.3.4. Methods, procedures and criteria used to establish the presence and identity of the micro-organism (e.g. morphology, biochemistry, serology, etc.)

1.4. Specification of the material used for manufacturing of formulated products

1.4.1. Content of the micro-organism

1.4.2. Identity and content of impurities, additives, contaminating microorganisms

1.4.3. Analytical profile of batches

II. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM

2.1. History of the micro-organism and its uses. Natural occurrence and geographical distribution

2.1.1. Historical background

2.1.2. Origin and natural occurrence

2.2. Information on target organism(s)

2.2.1. Description of the target organism(s)

2.2.2. Mode of action

2.3. Host specificity range and effects on species other than the target organism

2.4. Development stages/life cycle of the micro-organism

2.5. Infectiveness, dispersal and colonisation ability

2.6. Relationships to known plant or animal or human pathogens

2.7. Genetic stability and factors affecting it

2.8. Information on the production of metabolites (especially toxins)

2.9. Antibiotics and other anti-microbial agents

2.10. Robustness to environmental factors

2.11. Effects on materials, substances and products

III. FURTHER INFORMATION ON THE MICRO-ORGANISM

3.1. Function

3.2. Field of use envisaged

3.3. Product type(s) and category of users for which the micro-organism should be listed in Schedule I

3.4. Method of production and quality control

3.5. Information on the occurrence or possible occurrence of the development of resistance of the target organism(s)

3.6. Methods to prevent loss of virulence of seed stock of the microorganism

3.7. Recommended methods and precautions concerning handling, storage, transport or fire

3.8. Procedures for destruction or decontamination

3.9. Measures in case of an accident

3.10. Procedures for waste management

3.11. Monitoring plan to be used for the active micro-organism including handling, storage, transport and use

IV. ANALYTICAL METHODS

4.1. Methods for the analysis of the micro-organism as manufactured

4.2. Methods to determine and quantify residues (viable or non-viable)

V. EFFECTS ON HUMAN HEALTH

TIER I

5.1. Basic information

5.1.1. Medical data

5.1.2. Medical surveillance on manufacturing plant personnel

5.1.3. Sensitisation/allergenicity observations

5.1.4. Direct observation, e.g. clinical cases

5.2. Basic studies

5.2.1. Sensitisation

5.2.2. Acute toxicity, pathogenicity, and infectiveness

5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness

5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness

5.2.2.3. Intraperitoneal/subcutaneous single dose

5.2.3. *In vitro* genotoxicity testing

5.2.4. Cell culture study

5.2.5. Information on short-term toxicity and pathogenicity

5.2.5.1. Health effects after repeated inhalatory exposure

5.2.6. Proposed treatment: first aid measures, medical treatment

5.2.7. Any pathogenicity and infectiveness to humans and other mammals under conditions of immunosuppression

END OF TIER I

TIER II

5.3. Specific toxicity, pathogenicity and infectiveness studies

5.4. Genotoxicity — *In vivo* studies in somatic cells

5.5. Genotoxicity — *In vivo* studies in germ cells

END OF TIER II

5.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation

VI. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED

6.1. Persistence and likelihood of multiplication in or on treated materials, feedingstuffs or foodstuffs

8.7. Further studies

8.7.1. Terrestrial plants

8.7.2. Mammals

8.7.3. Other relevant species and processes

8.8. Summary and evaluation of effects on non-target organisms

IX. CLASSIFICATION AND LABELLING

The dossier shall be accompanied by a reasoned proposals for allocating an active substance which is a micro-organism to one of the risk groups specified in regulation 2 of Legal Notice 228 of 2003 on the protection of workers from risks related to exposure to biological agents at work together with indications on the need for products to carry the biohazard sign specified in Schedule II to that Legal Notice.

X. SUMMARY AND EVALUATION OF SECTIONS I TO IX INCLUDING CONCLUSIONS OF THE RISK ASSESSMENT AND RECOMMENDATIONS

PART B

DATA SET FOR BIOCIDAL PRODUCTS

MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI

1. For the purposes of these Regulations, the term micro-organisms shall be understood as including also viruses and fungi. This Schedule provides stat requirements for the authorization of a biocidal product based on preparations of micro-organisms. For all biocidal products based on preparations containing micro-organisms that are subject to application, all available relevant knowledge and information in should be provided. The information related to the identification and characterization of all components in a biocidal product is particularly important and must be entered in sections I to IV and provides the basis for an assessment of possible impacts on human health and environmental.

2. Where information is not necessary owing to the nature of the micro-organism regulation 9(5) shall apply.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Legal Notice 306 of 2008 and Legal Notice 10 of 2007 concerning the Dangerous Substances and Preparations Regulations shall be used wherever possible to minimize animal testing.

4. Where testing is done, a detailed description (specification) of the material used and its impurities, according to the provisions of Section II, must be provided. Where necessary, data as established in Schedules II – Part B, II – Part B shall be required for all the toxicologically/eco-toxicologically relevant chemical components of the biocidal product, in particular if the components are substances of concern as defined in regulation 3(1)(e).

5. In cases where a new preparation is to be dealt with, extrapolation from Schedules IV – Part A, could be acceptable, provided that all the possible effects of the components, especially on pathogenicity and infectiveness, are evaluated.

Dossier requirements

SECTIONS:

I. Identity of the biocidal product

II. Physical, chemical and technical properties of the biocidal product

III. Data on application

IV. Further information on the biocidal product

V. Analytical methods

VI. Efficacy data

VII. Effects on human health

VIII. Residues in or on treated materials, food and feed

IX. Fate and behaviour in the environment

X. Effects on non-target organisms

XI. Classification, packaging and labelling of the biocidal product

XII. Summary and evaluation of sections I to XI including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

I. IDENTITY OF THE BIOCIDAL PRODUCTS

1.1.Applicant

1.2. Manufacturer of the biocidal product and the micro-organism(s)

1.3. Trade name or proposed trade name, and manufacturer's development code number of the biocidal product

1.4. Detailed quantitative and qualitative information on the composition of the biocidal product

1.5. Physical state and nature of the biocidal product

1.6. Function

II. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT

2.1. Appearance (colour and odour)

2.2. Storage stability and shelf-life

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

2.2.2. Other factors affecting stability

2.3. Explosivity and oxidising properties

2.4. Flash point and other indications of flammability or spontaneous ignition

2.5. Acidity, alkalinity and pH value

2.6. Viscosity and surface tension

2.7. Technical characteristics of the biocidal product

2.7.1. Wettability

2.7.2. Persistent foaming

2.7.3. Suspensibility and suspension stability

2.7.4. Dry sieve test and wet sieve test

2.7.5. Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)

2.7.6. Emulsifiability, re-emulsifiability, emulsion stability

2.7.7. Flowability, pourability (rinsability) and dustability

2.8. Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered

2.8.1. Physical compatibility

2.8.2. Chemical compatibility

2.8.3. Biological compatibility

2.9. Summary and evaluation of physical, chemical and technical properties of the biocidal product

III. DATA ON APPLICATION

3.1. Field of use envisaged

3.2. Mode of action

3.3. Details of intended use

3.4. Application rate

3.5. Content of micro-organism in material used (e.g. in the application device or bait)

3.6. Method of application

3.7. Number and timing of applications and duration of protection

3.8. Necessary waiting periods or other precautions to avoid adverse effects to human and animal health and the environment

3.9. Proposed instructions for use

3.10. Category of users

3.11. Information on the possible occurrence of the development of resistance

3.12. Effects on the materials or products treated with the biocidal product

IV. FURTHER INFORMATION ON THE BIOCIDAL PRODUCT

4.1. Packaging and compatibility of the biocidal product with proposed packaging materials

4.2. Procedures for cleaning application equipment

4.3. Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment

4.4. Recommended methods and precautions concerning: handling, storage, transport or fire

4.5. Measures in the case of an accident

4.6. Procedures for destruction or decontamination of the biocidal product and its packaging

4.6.1. Controlled incineration

4.6.2. Others

4.7. Monitoring plan to be used for the active micro-organism and other micro-organism(s) contained in the biocidal product including handling, storage, transport and use

V. ANALYTICAL METHODS

5.1. Methods for the analysis of the biocidal product

5.2. Methods to determine and quantify residues

VI. EFFICACY DATA

VII. EFFECTS ON HUMAN HEALTH

7.1. Basic acute toxicity studies

7.1.1. Acute oral toxicity

7.1.2. Acute inhalation toxicity

7.1.3. Acute percutaneous toxicity

7.2. Additional acute toxicity studies

7.2.1. Skin irritation

7.2.2. Eye irritation

7.2.3. Skin sensitisation

7.3. Data on exposure

7.4. Available toxicological data relating to non-active substances

7.5. Supplementary studies for combinations of biocidal products

7.6. Summary and evaluation of effects on human health

VIII. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED

IX. FATE AND BEHAVIOUR IN THE ENVIRONMENT

X. EFFECTS ON NON-TARGET ORGANISMS

10.1. Effects on birds

10.2. Effects on aquatic organisms

10.3. Effects on bees

10.4. Effects on arthropods other than bees

10.5. Effects on earthworms

10.6. Effects on soil micro-organisms

10.7. Additional studies on additional species or higher tier studies such as studies on selected non-target organisms

10.7.1. Terrestrial plants

10.7.2. Mammals

10.7.3. Other relevant species and processes

10.8. Summary and evaluation of effects on non-target organisms

XI. CLASSIFICATION, PACKAGING AND LABELLING OF THE BIOCIDAL PRODUCT

As established in regulation 21, proposals including justification for the classification and labelling of the biocidal product in accordance with the provisions set in Legal Notice 306 of 2008 and Legal Notice 10 of 2007 must be submitted. The classification comprises of the description of the category/categories of danger and qualifying risk phrases for all dangerous properties. On the basis of the classification, a proposal for labelling including the hazard symbol(s) and indications of danger, risk phrases and safety phrases should be given. The classification and labelling shall be in regard to the chemical substances contained in the biocidal product. If necessary, specimens of proposed packaging shall be submitted to the competent authority of a Member State.

The dossier shall be accompanied by a reasoned proposal for allocation to one of the risk groups specified in regulation 2 of Legal Notice 228 of 2003 together with

indications on the need for products to carry the biohazard sign specified in Schedule II to that Legal Notice.

XII. SUMMARY AND EVALUATION OF SECTIONS I TO XI INCLUDING CONCLUSIONS OF THE RISK ASSESSMENT AND RECOMMENDATIONS

SCHEDULE V

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN REGULATION 3(1)(a) OF THESE REGULATIONS

These product-types exclude products where they are covered by the regulations mentioned in regulation 2(2) of these regulations for the purposes of these regulations 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 VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

CONTENTS

— Summary

Overall integration of conclusions

DEFINITIONS

(a) *Hazard identification*

This is the identification of the adverse effects which a biocidal product has an inherent capacity to cause.

(b) *Dose (concentration) — response (effect) assessment*

This is the estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

(c) *Exposure assessment*

This is the determination of the emissions, pathways and rates of movement of an active substance or a substance of concern in a biocidal product and its transformation or degradation in order to estimate the concentration/doses to which human populations, animals or environmental compartments are or may be exposed.

(d) *Risk characterisation*

This is the estimation of the incidence and severity of the adverse effects likely to occur in a human population, animals or environmental compartments due to actual or predicted exposure to any active substance or substance of concern in a biocidal product. This may include `risk estimation' i.e. the quantification of that likelihood.

(e) *Environment*

Water, including sediment, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms.

INTRODUCTION

1. This Schedule lays down principles to ensure that evaluations made and decisions taken by a Member State concerning the authorisation of a biocidal product providing it is a chemical preparation results in

a harmonised high level of protection for humans, animals and the environment in accordance with regulation 6(1)(b) of these regulations.

2. In order to ensure a high and harmonised level of protection of human and animal health and of the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of any risks identified during the proposed normal use of the biocidal product. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product.

3. A risk assessment on the active substance or substances present in the biocidal product is always required. This will already have been carried out for the purpose of Schedule I. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.

4. Additional risk assessments shall be carried out, in the same manner as described above, on any other substance of concern present in the biocidal product where relevant for the use of the biocidal product.

5. In order to carry out a risk assessment data are required. These data are detailed in Schedules II, III and IV and, recognising that there are a wide variety of product types, are flexible according to the product type and associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. Member States should take due consideration of the requirements of regulations 13 and 14 of these regulations in order to avoid duplication of data submissions. The minimum set of data required for an active substance in any biocidal product type, however, shall be that detailed in Annex VI to Regulation 1907/2006; these data will already have been submitted and assessed as part of the risk assessment required for entry of the active substance into Schedule I to these regulations. Data may also be required on a substance of concern present in a biocidal product.

6. The results of the risk assessments carried out on an active substance and on a substance of concern present in the biocidal product shall be integrated to produce an overall assessment for the biocidal product itself.

7. When making evaluations and taking decisions concerning the authorisation of a biocidal product the Member State shall:

(a) take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues;

(b) evaluate, where relevant, justifications submitted by the applicant for not supplying certain data.

8. The Member State shall comply with the requirements of mutual recognition as stated in regulation 5(1), (2) and (6) of these regulations.

9. It is known that many biocidal products present only minor differences in composition and this should be taken into account when evaluating dossiers. The concept of `frame-formulations' is relevant here.

10. It is known that certain biocidal products are considered as posing only a low risk, these biocidal products, while complying with the requirements of this Schedule, are subject to a simplified procedure as detailed in regulation 4 of these regulations.

11. The application of these common principles shall lead to the Member State deciding whether or not a biocidal product can be authorised, such authorisation may include restrictions on use or other conditions. In certain cases the Member State may conclude that more data are required before an authorisation decision can be made.

12. During the process of evaluation and decision-making, Member States and applicants shall cooperate in order to resolve any questions on the data requirements quickly or to identify at an early stage any additional studies required, or to amend any proposed conditions for the use of the biocidal product or to modify its nature or its composition in order to ensure full compliance with the requirements of this Schedule or of these regulations. The administrative burden, especially for small and medium-sized enterprises (SMEs), shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.

13. The judgments made by the Member State during the evaluation and decision-making process must be based on scientific principles, preferably recognised at international level, and be made with the benefit of expert advice.

EVALUATION

General principles

14. The data submitted in support of an application for authorisation of a biocidal product shall be examined for completeness and overall scientific value by the receiving Member State. After acceptance of these data the Member State shall utilise them by carrying out a risk assessment based on the proposed use of the biocidal product.

15. A risk assessment on the active substance present in the biocidal product shall always be carried out. If there are, in addition, any substances of concern present in the biocidal product then a risk assessment shall be carried out for each of these. The risk assessment shall cover the proposed normal use of the biocidal product together with a realistic worst-case scenario including any relevant production and disposal issue either of the biocidal product itself or any material treated with it.

16. For each active substance and each substance of concern present in the biocidal product, the risk assessment shall entail a hazard identification and the establishment of appropriate no-observed-adverse-effect levels (NOAEL), where possible. It shall also include, as appropriate, a dose (concentration) — response (effect) assessment, together with an exposure assessment and a risk characterisation.

17. The results arrived at from a comparison of the exposure to the no-effect level concentrations for each of the active substances and any substances of concern shall be integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available the results of the qualitative assessments shall be integrated in a similar manner.

18. The risk assessment shall determine:

    (a) the risk to humans and animals,

    (b) the risk to the environment,

    (c) the measures necessary to protect humans, animals and the general environment during both the proposed normal use of the biocidal product and in a realistic worst-case situation.

19. In certain cases it may be concluded that further data are required before a risk assessment can be finalised. Any such additional data requested shall be the minimum necessary to complete such a risk assessment.

Effects on humans

20. The risk assessment shall take account of the following potential effects arising from the use of the biocidal product and the populations liable to exposure.

21. The effects previously mentioned result from the properties of the active substance and any substance of concern present. They are:

— acute and chronic toxicity,

— irritation,

— corrosivity,

— sensitisation,

— repeated dose toxicity,

— mutagenicity,

— carcinogenicity,

— reproduction toxicity,

— neurotoxicity,

— any other special properties of the active substance or substance of concern,

— other effects due to physico-chemical properties.

22. The populations previously mentioned are:

— professional users,

— non-professional users,

— humans exposed indirectly via the environment.

23. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of regulation 21 of these Regulations then dose (concentration) —

response (effect) assessment, exposure assessment and risk characterisation shall be required.

24. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not lead to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern, e.g. adverse environmental effects or unacceptable residues.

25. The Member State shall apply paragraphs 26 to 29 when carrying out a dose (concentration) — response (effect) assessment on an active substance or a substance of concern present in a biocidal product.

26. For repeated dose toxicity and reproductive toxicity the dose response relationship shall be assessed for each active substance or substance of concern and, where possible, the no-observed-adverse-effect level (NOAEL) identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified.

27. For acute toxicity, corrosivity and irritation, it is not usually possible to derive a NOAEL or LOAEL on the basis of tests conducted in accordance with the requirements of these Regulations. For acute toxicity, the LD50 (median lethal dose) or LC50 (median lethal concentration) value or, where the fixed dose procedure has been used, the discriminating dose shall be derived. For the other effects it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the product.

28. For mutagenicity and carcinogenicity it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product. However, if it can be demonstrated that an active substance or a substance of concern identified as a carcinogen is non-genotoxic, it will be appropriate to identify a N(L)OAEL as described in paragraph 26.

29. With respect to skin sensitisation and respiratory sensitisation, in so far as there is no consensus on the possibility of identifying a dose/concentration below which adverse effects are unlikely to occur in a subject already sensitised to a given substance, it shall be sufficient to evaluate whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product.

30. Where toxicity data derived from observations of human exposure, e.g. information gained from manufacture, from poison centres or epidemiology surveys, are available special consideration shall be given to those data when carrying out the risk assessment.

31. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed indirectly via the environment) for which exposure to a biocidal product occurs or can reasonably be foreseen. The objective of the assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of each active substance or substance of concern to which a population is, or may be exposed during use of the biocidal product.

32. The exposure assessment shall be based on the information in the technical dossier provided in conformity with regulation 9 of these regulations and on any other available and relevant information.

Particular account shall be taken, as appropriate, of:

— adequately measured exposure data,

— the form in which the product is marketed,

— the type of biocidal product,

— the application method and application rate,

— the physico-chemical properties of the product,

— the likely routes of exposure and potential for absorption,

— the frequency and duration of exposure,

— the type and size of specific exposed populations where such information is available.

33. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied.

These models shall:

— make a best possible estimation of all relevant processes taking into account realistic parameters and assumptions,

— be subjected to an analysis taking into account possible elements of uncertainty,

— be reliably validated with measurements carried out under circumstances relevant for the use of the model,

— be relevant to the conditions in the area of use.

Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties shall also be considered.

34. Where, for any of the effects set out in paragraph 21 a NOAEL or LOAEL had been identified, the risk characterisation shall entail comparison of the NOAEL or LOAEL with the evaluation of the dose/concentration to which the population will be exposed. Where a NOAEL or LOAEL cannot be established a qualitative comparison shall be made.

Effects on animals

35. Using the same relevant principles as described in the section dealing with effects on humans, the Member State shall consider the risks posed to animals from the biocidal product.

Effects on the environment

36. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments — air, soil and water (including sediment) — and of the biota following the use of the biocidal product.

37. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of these regulations then dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation shall be required.

38. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been

conducted but the results have not led to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern. Such grounds may derive from the properties and effects of any active substance or substance of concern in the biocidal product, in particular:

— any indications of bioaccumulation potential,

— the persistence characteristics,

— the shape of the toxicity/time curve in ecotoxicity testing,

— indications of other adverse effects on the basis of toxicity studies (e.g. classification as a mutagen),

— data on structurally analogous substances,

— endocrine effects.

39. A dose (concentration) — response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as the predicted no-effect concentration (PNEC). However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) — response (effect) then has to be made.

40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of regulation 9 of these regulations. It shall be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g.LD50 (median lethal dose), LC50 (median lethal concentration), EC50 (median effective concentration), IC50 (concentration causing 50% inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)).

41. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor.

The specifications for the assessment factors shall be elaborated in the notes for technical guidance which, to this end, shall be based particularly on the indications given in Subsidiary Legislation 427.15 – Legal Notice 40 of 2002 Dangerous Substances (Risk Assessment) Regulations.

42. For each environmental compartment an exposure assessment shall be carried out in order to predict the concentration likely to be found of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.

43. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions including any relevant contribution from material treated with biocidal products are known or are reasonably foreseeable.

44. The PEC, or qualitative estimation of exposure, shall be determined taking account of, in particular, and if appropriate:

— adequately measured exposure data,

— the form in which the product is marketed,

— the type of biocidal product,

— the application method and application rate,

— the physico-chemical properties,

— breakdown/transformation products,

— likely pathways to environmental compartments and potential for adsorption/desorption and degradation,

— the frequency and duration of exposure.

45. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in paragraph 33. Where appropriate, on a case-by-case basis, relevant

monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.

46. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.

47. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.

Unacceptable effects

48. Data shall be submitted to and evaluated by the Member State to assess whether the biocidal product does not cause unnecessary suffering in its effect on target vertebrates. This shall include an evaluation of the mechanism by which the effect is obtained and the observed effects on the behaviour and health of the target vertebrates; where the intended effect is to kill the target vertebrate the time necessary to obtain the death of the target vertebrate and the conditions under which death occurs shall be evaluated.

49. The Member State shall, where relevant, evaluate the possibility of the development of resistance to an active substance in the biocidal product by the target organism.

50. If there are indications that any other unacceptable effects may occur the Member State shall evaluate the possibility of such effects occurring. An example of such an unacceptable effect would be an adverse reaction to fastenings and fittings used in wood following the application of a wood preservative.

Efficacy

51. Data shall be submitted and evaluated to ascertain if the efficacy claims of the biocidal product can be substantiated. Data submitted by the applicant or held by the Member State must be able to demonstrate the efficacy of the biocidal product against the target organism when used normally in accordance with the conditions of authorisation.

52. Testing should be carried out according to Community guidelines if these are available and applicable. Where appropriate, other methods can

be used as shown in the list below. If relevant acceptable field data exist, these can be used.

— ISO, CEN or other international standard method

— national standard method

— industry standard method (accepted by Member State)

— individual producer standard method (accepted by Member State)

— data from the actual development of the biocidal product (accepted by Member State).

Summary

53. In each of the areas where risk assessments have been carried out, i.e. effects on man, animals, and the environment, the Member State shall combine the results for the active substance together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This should take account of any likely synergistic effects of the active substance(s) and substances of concern in the biocidal product.

54. For biocidal products containing more than one active substance any adverse effects shall also be combined to produce an overall effect for the biocidal product itself.

DECISION MAKING

General principles

55. Subject to paragraph 96, the Member State shall come to a decision regarding the authorisation for use of a biocidal product as a result of the integration of the risks arising from each active substance together with the risks from each substance of concern present in the biocidal product. The risk assessments shall cover normal use of the biocidal product together with a realistic worst-case scenario including any relevant disposal issue either of the biocidal product itself or any material treated with it.

56. In making a decision concerning authorisation, the Member State shall arrive at one of the following conclusions for each product type and for

each area of use of the biocidal product for which application has been made:

1. the biocidal product cannot be authorised;

2. the biocidal product can be authorised subject to specific conditions/restrictions;

3. more data is required before a decision on authorisation can be made.

57. If the conclusion arrived at by the Member State is that additional information or data are required before an authorisation decision can be made, then the need for any such information or data shall be justified. This additional information or data shall be the minimum necessary to carry out a further appropriate risk assessment.

58. The Member State shall comply with the principles of mutual recognition as detailed in regulation 4 of these Regulations.

59. The Member State shall apply the rules concerning the concept of `frame formulations' when making an authorisation decision on a biocidal product.

60. The Member State shall apply the rules concerning the concept of `low risk' products when making an authorisation decision on such a biocidal product.

61. The Member State shall only grant authorisation to those biocidal products which, when used according to their conditions of authorisation, do not present an unacceptable risk to humans, animals or the environment, are efficacious and which contain active substances permitted at Community level to be used in such biocidal products.

62. The Member State shall impose, where appropriate, conditions or restrictions when giving authorisations. The nature and severity of these shall be selected on the basis of, and be appropriate to, the nature and extent of the expected advantages and the risks likely to arise from the use of the biocidal product.

63. In the decision-making process the Member State shall take into consideration the following:

— the results of the risk assessment, in particular the relationship between exposure and effect,

— the nature and severity of the effect,

— the risk management which can be applied,

— the field of use of the biocidal product,

— the efficacy of the biocidal product,

— the physical properties of the biocidal product,

— the benefits of using the biocidal product.

64. The Member State shall, when taking a decision concerning the authorisation of a biocidal product, take into account the uncertainty arising from the variability in the data used in the evaluation and decision-making process.

65. The Member State shall prescribe that biocidal products shall be used properly. Proper use shall include application at an efficacious dose and minimisation of use of biocidal products where possible.

66. The Member State shall take the necessary measures to ensure that the applicant proposes a label, and, where relevant, the safety-data sheet, for the biocidal product which:

— fulfils the requirements of regulation 19 and 20 of these Regulations,

— contains the information on the protection of users required by Community legislation on worker protection,

— specifies in particular the conditions or restrictions under which the biocidal product may or may not be used.

Before issuing an authorisation the Member State shall confirm that these requirements must be satisfied.

67. The Member State shall take the necessary measures to ensure that the applicant proposes packaging and, where appropriate, the procedures for destruction or decontamination of the biocidal product and its packaging or any other relevant material associated with the biocidal product, which conforms to the relevant regulatory provisions.

Effects on humans

68. The Member State shall not authorise a biocidal product if the risk assessment confirms that, in foreseeable application including a realistic worst possible scenario, the product presents an unacceptable risk to humans.

69. The Member State shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environment when making a decision on the authorisation of a biocidal product.

70. The Member State shall examine the relationship between the exposure and the effect, and use this in the decision-making process. A number of factors need to be considered when examining this relationship and one of the most important is the nature of the adverse effect of the substance. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, reproduction toxicity together with physico-chemical properties, and any other adverse properties of the active substance or substance of concern.

71. The Member State shall, where possible, compare the results obtained with those obtained from previous risk assessments for an identical or similar adverse effect and decide on an appropriate margin of safety (MOS) when making an authorisation decision.

    An appropriate MOS is typically 100 but an MOS higher or lower than this may be appropriate depending on, among other things, the nature of the critical toxicological effect.

72. The Member State shall, if appropriate, impose, as a condition of authorisation, the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles in order to reduce exposure for professional operators. Such equipment must be readily available to them.

73. If for non-professional users the wearing of personal protective equipment would be the only possible method for reducing exposure, the product shall not normally be authorised.

74. If the relationship between the exposure and the effect cannot be reduced to an acceptable level then no authorisation can be given by the Member State for the biocidal product.

75. No biocidal product classified according to regulation 21(1) of these 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 be authorised for use by the general public.

Effects on animals

76. The Member State shall not authorise a biocidal product if the risk assessment confirms that, in normal use, the biocidal product presents an unacceptable risk to non-target animals.

77. Using the same relevant criteria as described in the section dealing with effects on humans, the MemberState shall consider the risks posed to animals from the biocidal product when making an authorisation decision.

Effects on the environment

78. The Member State shall not authorise a biocidal product if the risk assessment confirms that the active substance, or any substance of concern, or any degradation, or reaction product presents an unacceptable risk in any of the environmental compartments, water (including sediment), soil and air. This shall include the assessment of risks to non-target organisms in these compartments.

In considering whether there is an unacceptable risk Member States shall, when coming to a final decision in accordance with paragraph 96, take into account the criteria in paragraphs 81 to 91.

79. The basic tool used in the decision making is the PEC/PNEC ratio or, if this is not available, a qualitative estimation. Due consideration shall be given to the accuracy of this ratio due to variability in the data used both in measurements of concentration and of estimation.

In the determination of the PEC the most appropriate model should be used taking into account the environmental fate and behaviour of the biocidal product.

80. For any given environmental compartment if the PEC/PNEC ratio is equal to or less than 1 the risk characterisation shall be that no further information and/or testing are necessary.

If the PEC/PNEC ratio is greater than 1 the Member State shall judge, on the basis of the size of that ratio and on other relevant factors, if further information and/or testing are required to clarify the concern or if risk reduction measures are necessary or if the product cannot be

given an authorisation at all. Relevant factors to be considered are those previously mentioned in paragraph 38.

Water

81. The Member State shall not authorise a biocidal product, if under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in water (or its sediments) has an unacceptable impact on non-target species in the aquatic, marine or estuarine environment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

82. The Member State shall not authorise a biocidal product if, under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in groundwater exceeds the lower of the following concentrations:

(a) the maximum permissible concentration laid down by Legal Notice 17 of 2009, or

(b) the maximum concentration as laid down following the procedure for including the active substance in Schedule I to these regulations, on the basis of appropriate data, in particular toxicological data unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

83. The Member State shall not authorise a biocidal product if the foreseeable concentration of the active substance or a substance of concern or of relevant metabolites, breakdown or reaction products to be expected in surface water or its sediments after use of the biocidal product under the proposed conditions of use:

— exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by

- Subsidiary Legislation 435.36 - Legal Notice 339 of 2001, as amended by Legal Notice 426 of 2007, Quality Required of Surface Water intended for the Abstraction of Drinking Water Regulations,

- Legal Notice 17 of 2009 or

— has an impact deemed unacceptable on non-target species unless it is scientifically demonstrated that under relevant field conditions this concentration is not exceeded.

84. The proposed instructions for use of the biocidal product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of water or its sediments is minimised.

Soil

85. Where unacceptable contamination of soil is likely to occur, the Member State shall not authorise a biocidal product if the active substance or substance of concern contained in it, after use of the biocidal product:

— during tests in the field, persists in soil for more than one year, or

— during laboratory tests, forms non-extractable residues in amounts exceeding 70% of the initial dose after 100 days with a mineralisation rate of less than 5% in 100 days,

— has unacceptable consequences or effects on non-target organisms,

unless it is scientifically demonstrated that under field conditions there is no unacceptable accumulation in soil.

Air

86. The Member State shall not authorise a biocidal product where there is a foreseeable possibility of unacceptable effects on the air compartment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Effects on non-target organisms

87. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of non-target organisms being exposed to the biocidal product if for any active substance or substance of concern:

— the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur

after use of the biocidal product according to the proposed conditions of use, or

— the bioconcentration factor (BCF) related to fat tissues in non-target vertebrates is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur, either directly or indirectly, after use of the product according to the proposed conditions of use.

88. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of aquatic organisms including marine and estuarine organisms being exposed to the biocidal product if for any active substance or substance of concern in it:

— the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions the viability of aquatic organisms including marine and estuarine organisms is not threatened by the biocidal product according to the proposed conditions of use, or

— the bioconcentration factor (BCF) is greater than 1 000 for substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of exposed organisms including marine and estuarine organisms after use of the biocidal product according to the proposed conditions of use.

By way of derogation from this paragraph, Member States may, however, authorise an anti-fouling product used on commercial, public service and naval seagoing vessels for a period of up to 10 years from the date on which Directive 98/8/EC of the European Parliament and
of the Council of 16 February 1998 concerning the placing of biocidal products on the market enter into force if similar fouling control cannot be achieved by other practicable means. When implementing this provision, Member States shall, if appropriate, take into account relevant International Maritime Organisation (IMO) resolutions and recommendations.

89. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of micro-organisms in sewage treatment plants being exposed to the biocidal product if for any active substance, substance of concern, relevant metabolite, breakdown or reaction product the PEC/PNEC ratio is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of such micro-organisms.

Unacceptable effects

90. If the development of resistance to the active substance in the biocidal product is likely the Member State shall take steps to minimise the consequences of this resistance. This may involve modification of the conditions of authorisation or even refusal of any authorisation.

91. An authorisation for a biocidal product intended to control vertebrates shall not be given unless:

— death is synchronous with the extinction of consciousness, or,

— death occurs immediately, or,

— vital functions are reduced gradually without signs of obvious suffering.

For repellent products, the intended effect shall be obtained without unnecessary suffering and pain for the target vertebrate.

Efficacy

92. Member States shall not authorise a biocidal product which does not possess acceptable efficacy when used in accordance with the conditions specified on the proposed label or with other conditions of authorisation.

93. The level, consistency and duration of protection, control or other intended effects must, as a minimum, be similar to those resulting from suitable reference products, where such products exist, or to other means of control. Where no reference products exist, the biocidal product must give a defined level of protection or control in the areas of proposed use. Conclusions as to the performance of the biocidal product must be valid for all areas of proposed use and for all areas in the Member State except where the proposed label prescribes that the biocidal product is intended for use in specific circumstances. Member States shall evaluate dose response data generated in trials (which must include an untreated control) involving dose rates lower than the recommended rate, in order to assess if the recommended dose is the minimum necessary to achieve the desired effect.

Summary

94. In each of the areas where risk assessments have been carried out, i.e. effects on humans, animals, and the environment, the Member State shall combine the conclusions arrived at for the active substance and the substances of concern to produce an overall conclusion for the biocidal product itself. A summary should also be made of the efficacy assessment and of the unacceptable effects.

The result shall be:

— a summary of the effects of the biocidal product on humans,

— a summary of the effects of the biocidal product on animals,

— a summary of the effects of the biocidal product on the environment,

— a summary of the efficacy assessment,

— a summary of the unacceptable effects.

OVERALL INTEGRATION OF CONCLUSIONS

95. The Member State shall combine the individual conclusions arrived at with regard to effects of the biocidal product on the three sectors namely, humans, animals and the environment to arrive at an overall conclusion for the global effect of the biocidal product.

96. The Member State shall then take due consideration of any relevant unacceptable effects, the efficacy of the biocidal product and the benefits of using the biocidal product before taking an authorisation decision on the biocidal product.

97. The Member State shall ultimately decide whether or not the biocidal product can be authorised and whether this authorisation shall be subject to any restrictions or conditions in conformity with this Schedule and these regulations.

VERŻJONI ELETTRONIKA

Ippubblikat mid-Dipartiment tal-Informazzjoni (doi.gov.mt) — Valletta — ***Published by the Department of Information (doi.gov.mt) — Valletta***
Mitbugħ fl-Istamperija tal-Gvern fuq karta riċiklata — ***Printed at the Government Printing Press on recycled paper***

Prezz/*Price*
€13.79