

## **P7\_TA(2010)0333**

### **Placing on the market and use of biocidal products \*\*\*I**

**European Parliament legislative resolution of 22 September 2010 on the proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products (COM(2009)0267 – C7-0036/2009 – 2009/0076(COD))**

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2009)0267),
  - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C7-0036/2009),
  - having regard to the communication from the Commission to the European Parliament and the Council entitled: 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),
  - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
  - having regard to Article 294(3) and Article 114 of the Treaty on the Functioning of the EU,
  - having regard to the opinion of the European Economic and Social Committee of 17 February 2010<sup>1</sup>,
  - having regard to Rules 55 and 37 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on the Internal Market and Consumer Protection and the Committee on Industry, Research and Energy (A7-0239/2010),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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<sup>1</sup> Not yet published in the Official Journal.

P7\_TC1-COD(2009)0076

**Position of the European Parliament adopted at first reading on 22 September 2010 with a view to the adoption of Regulation (EU) No .../2010 of the European Parliament and of the Council concerning the placing on the market and use of biocidal products and repealing Directive 98/8/EC**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,

Acting in accordance with the ordinary legislative procedure<sup>2</sup>,

Whereas:

- (1) Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured products. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patterns.
- (2) Biocidal products should not be placed on the market or used unless they comply with the authorisation granted in accordance with this Regulation.
- (3) The purpose of this Regulation is to increase the free movement of biocidal products within the Union *and to ensure a high level of protection of both human and animal health and the environment. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The provisions of this Regulation should be underpinned by the precautionary principle in order to ensure that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.* In order to remove as far as possible obstacles to trade in biocidal products **■**, rules should be laid down for the approval of active substances and the placing on the market and use of biocidal products, including the rules on the mutual recognition of authorisations and on parallel trade.

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<sup>1</sup> Opinion of 17 February 2010 (not yet published in the Official Journal).

<sup>2</sup> Position of the European Parliament of 22 September 2010.

- (4) Rules concerning the placing on the market of biocidal products in the Community were initially adopted in 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<sup>1</sup>. It is necessary to adapt that system on the basis of the report from the Commission to the Council and the European Parliament entitled "Evaluation of the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (submitted in accordance with Article 18(5) of the Directive) and progress Report on the work programme referred to in Article 16(2) of the same Directive" on the first seven years of its implementation, which analyses the problems and weaknesses of that Directive.
- (5) Taking into account the main adaptations which are introduced in the existing regulatory system, a Regulation is the appropriate legal instrument to replace Directive 98/8/EC as it imposes clear and detailed rules which do not give room for diverging transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Union.
- (6) A difference should be made between existing active substances which were on the market in biocidal products on 14 May 2000 and new active substances which were not yet on the market in biocidal products by that date. That date was initially set in Directive 98/8/EC as the date by which that Directive had to be transposed into national legislation. A distinction was drawn between substances which were on the market on that date and those which were not. A work programme is being carried out for the review of all existing substances with view to their inclusion in Annex I to Directive 98/8/EC. During that review, biocidal products containing existing substances can continue to be placed on the market in order to prevent a situation where no biocidal products would be available on the market. New active substances should be reviewed before biocidal products containing them can be placed on the market so as to ensure that only safe new products can be placed on the market.
- (7) During the work programme, and at most up until the decision on inclusion of the active substance in Annex I to Directive 98/8/EC, Member States may temporarily authorise biocidal products that do not comply with the provisions of this Regulation under certain conditions. Following the decision on inclusion, Member States should grant, cancel or modify authorisations in accordance with this Regulation.
- (8) In order to ensure legal certainty, it is necessary to establish a Union list of active substances permitted for use in biocidal products. A procedure should be laid down for assessing whether or not an active substance can be entered in the Union list. The information that interested parties should submit in support of an inclusion of an active substance in the Union list should be specified.
- (9) The risks associated with the production, use and disposal of a chemically active substance and materials and articles treated with it are to be assessed and managed in a similar way as they are in Regulation (EC) No 1907/2006 of

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<sup>1</sup> OJ L 123, 24.4.1998, p. 1.

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<sup>1</sup>.

- (10) With a view to achieving a high level of environmental and human health protection, active substances with the worst hazard profiles should not be approved for use in biocidal products except in specific situations. These should include situations when the approval is justified because of a negligible exposure of humans to the substance, public health reasons or disproportionate negative impacts of a possible non-inclusion provided no alternatives exist.
- (11) In order to prevent the use of active substances with the worst hazard profiles, in particular when their use is not authorised under Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market<sup>2</sup>, it is appropriate to restrict their approval to situations when the exposure of humans to the substance is negligible or the substance is necessary for public health reasons.
- (12) The active substances in the Union list should be regularly examined to take account of developments in science and technology. Where there are serious indications that an active substance used in biocidal products may pose a higher risk than previously thought, the Commission should be able to review the inclusion of the active substance.
- (13) Active substances can, on basis of their intrinsic hazardous properties, be designated as candidates for substitution with other active substances, whenever such substances considered as effective towards the targeted harmful organisms become available in sufficient variety to avoid the development of resistance amongst harmful organisms. In order to allow for a regular examination of substances identified as candidates for substitution, the inclusion period for these substances should not, even in the case of renewal, exceed *seven years*. Furthermore, the identification of substances which are considered as candidates for substitution should be considered as a first step of a comparative assessment.
- (14) In the course of the authorisation or renewal of biocidal product authorisations, it should be possible to compare two or more biocidal products with regard to risks posed by them and benefits accrued through their use. As a result of such a comparative assessment, authorised biocidal products containing active substances indicated as candidates for substitution could be replaced with others that present significantly less risk to health or to the environment and where there are no significant adverse economic or practical impacts. Appropriate phase-out periods should be provided for in such cases.
- (15) In order to avoid unnecessary administrative and financial burden for the industry as well as competent authorities, a full in-depth evaluation of an application to renew the inclusion of an active substance in the Union list or

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<sup>1</sup> OJ L 396, 30.12.2006, p. 1.

<sup>2</sup> OJ L 309, 24.11.2009, p. 1.

the authorisation should be carried out only if the competent authority that was responsible for the initial evaluation decides so on the basis of the available information.

- (16) There is a need to ensure effective coordination and management of the technical, scientific and administrative aspects of this Regulation at Union level. The European Chemicals Agency set up under Regulation (EC) No 1907/2006 (hereinafter the 'Agency') should carry out specified tasks with regard to the evaluation of active substances as well as the authorisation of certain categories of biocidal products and related tasks in the Union territory. Consequently, a Biocidal Products Committee should be established within the Agency to carry out the tasks attributed to the Agency by this Regulation.
- (17) It is recognised that biocidal products intended to be used not only for purposes of this Regulation but also in connection with medical devices, such as disinfectants used for the disinfection of surfaces in hospitals as well as medical devices, may pose risks different from those covered by this Regulation. Therefore, such biocidal products should be required to comply, in addition to the requirements laid down in this Regulation, with the relevant essential requirements of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices<sup>1</sup>, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices<sup>2</sup> or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices<sup>3</sup>.
- (18) As the costs of the application of this Regulation to food or feedingstuffs used for biocidal purposes would be disproportionate to the benefits thereof, food and feedingstuffs used for biocidal purposes should not be covered by this Regulation. Furthermore, the safety of food and feedingstuffs is subject to Union legislation, in particular Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>4</sup>.
- (19) Processing aids are covered by existing Union legislation, in particular Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption<sup>5</sup> and Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition<sup>6</sup>. Therefore, it is appropriate to exclude them from the scope of this Regulation.
- (20) As products used for the preservation of food or feedstocks by the control of

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<sup>1</sup> OJ L 189, 20.7.1990, p. 17.

<sup>2</sup> OJ L 169, 12.7.1993, p. 1.

<sup>3</sup> OJ L 331, 7.12.1998, p. 1.

<sup>4</sup> OJ L 31, 1.2.2002, p. 1.

<sup>5</sup> OJ L 40, 11.2.1989, p. 27.

<sup>6</sup> OJ L 268, 18.10.2003, p. 29.

harmful organisms, which were previously covered by product type 20, are now covered by Directive 89/107/EEC and Regulation (EC) No 1831/2003, it is not appropriate to maintain this product type.

- (21) As the International Convention for the Control and Management of Ships' Ballast Water and Sediments provides for an effective assessment of the risks posed by ballast water management systems, the final approval and subsequent type approval of such systems should be considered equivalent to the product authorisation required under this Regulation.
  - (22) In order to take account of the specific nature of some biocidal products and the low level of risk associated with their proposed use, and to encourage the development of biocidal products containing new active substances, it is appropriate to provide for a Union authorisation of those products.
  - (23) In order to ensure that only biocidal products that comply with the relevant provisions of this Regulation are placed on the market, biocidal products should be subject to authorisation either by competent authorities for placing on the market or use in the territory of a Member State, or a part of it, or by the Commission for placing on the market or use in the Union.
  - (24) In order to facilitate access to the internal market and to avoid the additional costs and time involved in obtaining separate national authorisations in separate Member States, **the scope of the Union authorisation procedure *should be extended to all categories of biocidal products with the exception of biocidal products that contain certain active substances.***
  - (25) In order to ensure a harmonised application of the low-risk criteria by competent authorities, it is necessary to specify those criteria in the Regulation as far as possible. The criteria should be based on the hazard characteristics of the biocidal products and the exposure to the product associated with its use. The use of low-risk biocidal products should not lead to a high risk of developing resistance in target organisms.
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- (26) In view of the provisions on low-risk biocidal products in this Regulation, it seems appropriate to exempt active substances contained in those products from the registration obligations under Regulation (EC) No 1907/2006. This is, in particular, necessary because these substances do not fulfil the conditions in Article 15(2) of that Regulation.
  - (27) It is necessary to provide common principles for the evaluation and authorisation of biocidal products to ensure a harmonised approach by competent authorities.
  - (28) In order to evaluate the risks that would arise from the proposed uses of biocidal products, it is appropriate that the applicants submit dossiers which contain the necessary information. Defining a data set for active substances and for biocidal products in which they are contained is necessary so as to assist both the applicants seeking authorisation and competent authorities

carrying out the evaluation in deciding on the authorisation.

- (29) In the light of the diversity of both the active substances and the biocidal products, the data and test requirements should suit the individual circumstances and allow an overall risk assessment. Therefore, an applicant should be able to request adaptations of the data requirements, as appropriate, including the waiving of data requirements which are unnecessary or impossible to submit in view of the nature or the proposed uses of the product. Applicants should provide the appropriate technical and scientific justification to support their requests.
- (30) In order to ensure that the applicant can effectively exercise his right to request an adaptation of the data requirements, the competent authorities should inform the applicant about this possibility and the grounds on which such request could be made. Furthermore, in order to facilitate the preparation of the request, in particular by small- and medium-sized enterprises (SMEs), the competent authority should assist the applicant, where possible, in preparing such a request.
- (31) ***In order to help applicants, and in particular SMEs, to comply with the requirements of this Regulation, Member States should establish national helpdesks. These should be in addition to the operational guidance documents provided by the Agency.***
- (32) In order to facilitate access to the market of biocidal products belonging to one group of products, it should be possible to authorise such groups of biocidal products with similar uses and allow limited variations with regard to the reference biocidal product provided that those variations do not affect the level of the risk and the efficacy of the products.
- (33) When biocidal products are being authorised, it is necessary to ensure that, when properly used for the purpose intended, they are sufficiently effective and have no unacceptable effect on the target organisms such as resistance, and, in the case of vertebrate animals, unnecessary suffering and pain, and have, in the light of current scientific and technical knowledge, no unacceptable effect on the environment and on human or animal health. When deciding whether a biocidal product should be authorised, due consideration should be given to the benefits resulting from its use.
- (34) ***Infestation with harmful organisms should be avoided by means of suitable deterrents to banish or repel such organisms. In addition, other precautionary steps should be taken, such as proper warehousing of goods, compliance with hygiene standards and immediate disposal of waste. Only if such measures have no effect should further steps be taken. Biocidal products that pose lower risks for humans, animals and the environment should always be used in preference to other products where those lower risk products provide an effective remedy in particular situations. Biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress should be used as a last resort.***
- (35) In order to avoid duplication of the evaluation procedures and to ensure free

movement of biocidal products, as well as of materials and articles treated with them, within the Union, procedures should be established to ensure that authorisations of products granted in one Member State are recognised in all other Member States.

- (36) Specific provisions should lay down procedures to ensure the smooth operation of mutual recognition of authorisations granted by Member States, and in particular the resolution of any disagreements without undue delay.
- (37) In order to enable Member States to co-operate in the evaluation of biocidal products and to facilitate the access of biocidal products to the market, it should be possible to launch the process of mutual recognition together with the application for the first authorisation.
- (38) There is a need to provide for a dispute settlement mechanism at Union level to ensure the effective functioning of mutual recognition. If a competent authority refuses to mutually recognise an authorisation or proposes to restrict it, the Commission should be empowered to take a decision. In the event of technical or scientific questions, the Commission may consult the Agency before preparing the decision.
- (39) While envisaging harmonised provisions for all biocidal product types, including those intended to control vertebrates, the actual use of such product types might give rise to concern. Therefore, Member States should be allowed to derogate from the principle of mutual recognition for biocidal products that fall under certain particular types of biocides when intended to control particular kinds of vertebrates, in so far as such derogations are justified and do not jeopardise the purpose of this Regulation regarding an appropriate level of protection of the internal market.
- (40) In order to facilitate the functioning of the authorisation and mutual recognition procedures, it is appropriate to establish a system for the mutual exchange of information, and Member States, the Commission and the Agency should make available to each other on request the particulars and scientific documentation submitted in connection with applications for authorisation of biocidal products.
- (41) If the use of a biocidal product is in the interest of a Member State, but there is no applicant interested in the placing on the market of such product in the Member State, pest control bodies and other professional organisations should be allowed to apply for an authorisation. In the event that they are granted an authorisation, they should possess the same rights and obligations as any other authorisation holder.
- (42) In order to take account of the scientific and technical developments as well as the needs of the authorisation holders, it should be specified under what conditions authorisations can be cancelled, reviewed or amended. Provisions on the notification and exchange of information which may affect the authorisations should be set out so as to enable the competent authorities and the Commission to take appropriate action.



- (43) In the event of an unforeseen danger threatening public health or the environment which cannot be contained by other means, it should be possible for Member States to authorise, for a limited period of time, biocidal products which do not comply with the requirements laid down in this Regulation.
- (44) In order to encourage the development of new active substances, the procedure for the evaluation of a newly developed active substance should not prevent Member States or the Union from authorising, for a limited period of time, biocidal products containing that active substance before the active substance is entered in Annex I, provided that a dossier meeting all requirements has been submitted and it is believed that the active substance and the biocidal product satisfy the conditions set for them.
- (45) In order to encourage research and development in active substances and biocidal products, it is necessary to establish rules under which unauthorised biocidal products or active substances may be placed on the market for the purposes of research and development.
- (46) In view of the benefits for the internal market and for the consumer, it is desirable to establish harmonised rules for parallel trade of identical biocidal products that are authorised in different Member States.
- (47) For the purposes of ensuring the protection of human and animal health and of the environment, and non-discrimination between articles or materials originating in the Union and articles or materials imported from third countries, all treated articles or materials placed on the internal market should contain only authorised biocidal products.
- (48) For the purposes of enabling consumers to make informed choices and facilitating the enforcement of this Regulation by competent authorities, articles or materials treated with biocidal products should be appropriately labelled.
- (49) Applicants that have invested in supporting the inclusion of an active substance in Annex I or in the authorisation of a biocidal product in accordance with the provisions of this Regulation *or in accordance with Directive 98/8/EC* should be able to recover part of their investment by receiving equitable compensation whenever use is made of proprietary information that they submitted in support of such inclusions or authorisations for the benefit of subsequent applicants.
- (50) With a view to ensuring that all proprietary information submitted in support of the inclusion of an active substance in Annex I or an authorisation of a biocidal product is protected from the moment of its submission, and to prevent situations where some information is without protection, the provision on information protection periods should also apply to information submitted for the purposes of Directive 98/8/EC.
- (51) In order to encourage the development of new active substances and biocidal products containing them, it is necessary to provide for a period of protection with respect to the proprietary information submitted in support of the

inclusion of active substances or authorisations of products which is longer than the period of protection for information concerning existing active substances and products containing them.

- (52) It is essential to minimise the number of tests on animals and to ensure that testing *with biocidal products or active substances contained in biocidal products* should be made dependent on the purpose and use of a product. Applicants should share, and not duplicate, vertebrate animal studies in exchange for equitable compensation. In the absence of an agreement on sharing vertebrate animal studies between the data owner and the prospective applicant, the Agency should allow the use of the studies by the prospective applicant without prejudice to the decision on the compensation made by national courts. A Union register listing the contact details of the owners of such studies should be established and put at the disposal of all authorities to inform prospective applicants.
- (53) The generation of information by alternative means that do not involve tests on animals and that are equivalent to prescribed tests and test methods should also be encouraged. In addition, the adaptation of data requirements should be used to prevent unnecessary costs related to testing.
- (54) In order to ensure that the requirements laid down in respect of authorised biocidal products are satisfied when they are placed on the market, the Member States should take measures for appropriate control and inspection arrangements.
- (55) It is necessary to provide for the effective communication of information on risks resulting from biocidal products and risk management measures as it forms an essential part of the system established by this Regulation. While facilitating access to information, competent authorities, the Agency and the Commission should respect the principle of confidentiality and avoid any disclosure of information which could be harmful for the commercial interests of the person concerned, *except where it is necessary for the protection of human health and the environment*.
- (56) In order to increase the effectiveness of monitoring and control, and to provide information relevant for addressing the risks of biocidal products, producers, importers and professional users should be required to keep records of the products they produce, place on the market or use. The Commission should adopt implementing rules on data collection, transmission and processing.
- (57) In order to facilitate the exchange of information between competent authorities, the Agency and the Commission, a Union Register for Biocidal Products should be established.
- (58) It is necessary to specify that provisions concerning the Agency laid down in Regulation (EC) No 1907/2006 should apply accordingly in the context of biocidal active substances and products. Where separate provisions need to be made with respect to the tasks and functioning of the Agency under this Regulation, it should be specified in the provisions of this Regulation.

(59) The costs of the procedures associated with the operation of this Regulation need to be recovered from those who seek to place or do place biocidal products on the market and from those supporting the inclusion of active substances in Annex I. In order to promote the smooth operation of the internal market, the Commission should adopt measures to harmonise the structure of fee systems established by the Member States and the Agency taking into account the special needs of SMEs.

(60) It is necessary to provide for the possibility of an appeal against certain decisions of the Agency. The Board of Appeal set up within the Agency by Regulation (EC) No 1907/2006 should also guarantee the processing of appeals against decisions adopted by the Agency under this Regulation.

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(61) *There is scientific uncertainty about the safety of nanomaterials for human health and the environment and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has identified some specific health hazards as well as toxic effects on environmental organisms for some nanomaterials. SCENIHR has furthermore found a general lack of high-quality exposure data for both humans and the environment, concluding that the knowledge on the methodology for both exposure estimates and hazard identification needs to be further developed, validated and standardised. More and more biocidal products contain nanosilver. The use of nanomaterials in biocidal products may increase with the further development of technology. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials at international level. The Union should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly. At present, there is inadequate information on the risks associated with nanomaterials. In order to better assess their safety, the Scientific Committee for Consumer Safety (SCCS) should provide guidance in cooperation with relevant bodies on test methodologies which take into account the specific characteristics of nanomaterials. The Commission should regularly review the provisions on nanomaterials in the light of scientific progress.*

(62) *In view of the environmental impact that anti-fouling products can have in water, the Commission should take steps at international level to ensure that the AFS Convention (International Convention on the Control of Harmful Anti-Fouling Systems on Ships) is ratified worldwide and adapted to this Regulation.*

(63) *According to Article 291 of the Treaty on the Functioning of the European Union, rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers are to be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, and given the necessity to adopt as soon as possible this Regulation, Council*

*Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>1</sup> continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable. References to provisions of that Decision should nevertheless be replaced with references to the rules and principles set out in the new regulation as soon as that regulation enters into force.*

- (64) It is appropriate to provide for a deferred application of this Regulation so as to facilitate the smooth transition to the new system applying to the inclusion of active substances in Annex I and authorisation of biocidal products.
- (65) Due to the limited number of new submissions of applications for inclusion of active substances in Annex I, the Agency should take over the co-ordination and facilitation tasks for new submissions as of the date of applicability of this Regulation. However, in view of the high number of historical dossiers and in order to allow some time for the Agency to prepare for the new role, it should take over the tasks related to dossiers submitted under Directive 98/8/EC as of 1 January 2014.
- (66) In order to respect the legitimate expectations of companies with respect to the placing on the market and use of low-risk biocidal products covered by Directive 98/8/EC, those companies should be allowed to place such products on the market if they comply with the rules on the registration of low-risk biocidal products under that Directive. However, this Regulation should apply after the expiry of the first registration.
- (67) Taking into consideration that some products were not previously covered by the Union legislation in the field of biocidal products, it is appropriate to allow for a transitional period for the companies to be prepared to apply the rules concerning *in situ* generated active substances **and** treated articles and materials .
- (68) In order to ensure an equal treatment of persons placing on the market biocidal products containing one or more existing active substances, they should be required to hold a dossier or have a letter of access to a dossier, or to each component of the dossier, for each of the active substances contained in the product. Those persons who do not comply with this obligation by 1 January 2014 should no longer be allowed to place their products on the market. Appropriate phase-out periods for disposal, storage and use of existing stocks of biocidal products should be laid down in such cases.
- (69) This Regulation should take account, as appropriate, of other work programmes concerned with the review or authorisation of substances and products, or relevant international conventions,

HAVE ADOPTED THIS REGULATION:

## Chapter I

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<sup>1</sup> *OJ L 184, 17.7.1999, p. 23.*

## Scope and definitions

### Article 1 Subject matter

This Regulation lays down rules for:

- (1) the placing on the market and use of biocidal products within the Member States or the Union;
- (2) the mutual recognition of authorisations within the Union;
- (3) the establishment at Union level of a list of active substances which may be used in biocidal products.

***The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market and use of biocidal products. The provisions of this Regulation are underpinned by the precautionary principle, in order to ensure that active substances or products placed on the market do not have harmful effects on humans, non-target species and the environment. Special attention shall be paid to protecting children, pregnant women and the sick.***

### Article 2 Scope

1. This Regulation shall apply to biocidal products as defined in point (a) of Article 3(1).

A list of the types of biocidal products covered by this Regulation and their descriptions is set out in Annex V.

2. This Regulation shall not apply to biocidal products that are within the scope of the following instruments:
  - (a) Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products<sup>1</sup>;
  - (b) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition<sup>2</sup>;
  - (c) Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production<sup>3</sup>;
  - (d) Regulation (EC) No 1333/2008 of the European Parliament and of the

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<sup>1</sup> OJ L 262, 27.9.1976, p. 169.

<sup>2</sup> OJ L 213, 21.7.1982, p. 8.

<sup>3</sup> OJ L 184, 15.7.1988, p. 61.

Council of 16 December 2008 on food additives<sup>1</sup>;

- (e) Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community<sup>2</sup>;
- (f) Directive 90/385/EEC;
- (g) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market<sup>3</sup>;
- (h) Directive 93/42/EEC;
- (i) European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners<sup>4</sup>;
- (j) Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials<sup>5</sup>;
- (k) Directive 98/79/EC;
- (l) ***Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption***<sup>6</sup>;
- (m) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products<sup>7</sup>;
- (n) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<sup>8</sup>;
- (o) Regulation (EC) No 1831/2003;
- (p) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs<sup>9</sup>;
- (q) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin<sup>10</sup>;

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<sup>1</sup> OJ L 354, 31.12.2008, p. 16.

<sup>2</sup> OJ L 92, 7.4.1990, p. 42.

<sup>3</sup> OJ L 230, 19.8.1991, p. 1.

<sup>4</sup> OJ L 61, 18.3.1995, p. 1.

<sup>5</sup> OJ L 125, 23.5.1996, p. 35.

<sup>6</sup> ***OJ L 330, 5.12.1998, p. 32.***

<sup>7</sup> OJ L 311, 28.11.2001, p. 1.

<sup>8</sup> OJ L 311, 28.11.2001, p. 67.

<sup>9</sup> OJ L 139, 30.4.2004, p. 1.

<sup>10</sup> OJ L 139, 30.4.2004, p. 55.

(r) ***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<sup>1</sup>.***

3. Subject to any explicit provision to the contrary, this Regulation shall be without prejudice to the following instruments:

(a) Council Directive 67/548/EEC 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances<sup>2</sup>;

(b) Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances<sup>3</sup>;

(c) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work<sup>4</sup>;

(d) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>5</sup>;

(e) Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations<sup>6</sup>;

(f) Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>7</sup>;

(g) ***Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy<sup>8</sup>.***

(h) Regulation (EC) No 1907/2006;

(i) Directive 2006/114/EC of the European Parliament and of the Council of

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<sup>1</sup> ***OJ L 338, 13.11.2004, p. 4.***

<sup>2</sup> OJ 196, 16.8.1967, p. 1.

<sup>3</sup> OJ L 33, 8.2.1979, p. 36.

<sup>4</sup> OJ L 183, 29.6.1989, p. 1.

<sup>5</sup> OJ L 131, 5.5.1998, p. 11.

<sup>6</sup> OJ L 200, 30.7.1999, p. 1.

<sup>7</sup> OJ L 262, 17.10.2000, p. 21.

<sup>8</sup> ***OJ L 327, 22.12.2000, p. 1.***

12 December 2006 concerning misleading and comparative advertising<sup>1</sup>;

- (j) Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals<sup>2</sup>;
  - (k) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides<sup>3</sup>;
  - (l) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures<sup>4</sup>.
4. Article 58 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.
  5. This Regulation shall not apply to food or feedingstuffs that are used for biocidal purposes.
  6. This Regulation shall not apply to processing aids that are used for biocidal purposes.
  7. Where a biocidal product is intended by its manufacturer to be used for the purpose of exerting a controlling effect on any harmful organism present on medical devices and for other purposes covered by this Regulation, the relevant essential requirements of Directives 90/385/EEC, 93/42/EEC or 98/79/EC shall also be fulfilled.
  8. Biocidal products which obtained the final approval under the International Convention for the Control and Management of Ships' Ballast Water and Sediments shall be considered as authorised under Chapter VII of this Regulation. Articles 38 and 57 shall apply accordingly.

### Article 3 Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

- (a) 'biocidal products' means

active substances or mixtures containing one or more active substances, put up in the form in which they are supplied to the user, *primarily* 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.

All substances, mixtures and devices placed on the market with the intention

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<sup>1</sup> OJ L 376, 27.12.2006, p. 21.

<sup>2</sup> OJ L 204, 31.7.2008, p. 1.

<sup>3</sup> OJ L 309, 24.11.2009, p. 71.

<sup>4</sup> OJ L 353, 31.12.2008, p. 1.



to generate active substances shall also be considered biocidal products;

(b) 'micro-organism' means

any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including lower fungi, viruses, bacteria, yeasts, moulds, algae, protozoa and microscopic parasitic helminths;

(c) 'active substance' means

a substance or a micro-organism with an action against harmful organisms;

(d) 'existing active substance' means

a substance which was on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product- and process-orientated research and development;

(e) 'new active substance' means

a substance which was not on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product- and process-orientated research and development;

(f) 'substance of concern' means

any substance, other than an active substance, which has an inherent capacity to cause an adverse effect, *immediately or in the more distant future*, on humans, *especially children*, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present a risk of causing such an effect.

*Such a substance would, unless there are other grounds for concern, normally be a substance classified as dangerous according to Directive 67/548/EEC and be present in the biocidal product at a concentration leading to the product being regarded as dangerous within the meaning of Directive 1999/45/EC or Regulation (EC) No 1272/2008;*

(g) 'harmful organism' means

organisms, including pathogenic agents, which have an unwanted presence or a detrimental effect, *immediately or in the more distant future*, on humans, *especially children*, human activities or the products they use or produce, or on animals or the environment;

(h) 'residues' means

substances present in or on plants or products of plant origin, edible animal products, *water resources*, drinking water or elsewhere in the environment and resulting from the use of a biocidal product, including their metabolites, breakdown or reaction products;

- (i) 'placing on the market' means
- the **■** supply of a biocidal product *to third parties*, whether in return for payment or free of charge, *or the making available of a biocidal product to third parties. Importation shall be deemed to be placing on the market. No supply to third parties is involved when* in the course of a commercial activity *treated materials or products are individually manufactured and then incorporated by the manufacturer;*
- (j) 'use' means
- all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with view to exporting the biocidal product outside the Union;
- (k) 'treated material or article' means
- any substance, mixture, material or article which was treated with or incorporates one or more biocidal products **■** ;
- (l) *'external biocidal effect' means*
- the effect of applications whereby the incorporated biocidal product is intended to be released under normal or reasonably foreseeable conditions of use;*
- (m) 'national authorisation' means
- an administrative act by which the competent authority of a Member State authorises the placing on the market and the use of a biocidal product in its territory or in a part thereof;
- (n) 'Union authorisation' means
- an administrative act by which the Commission authorises the placing on the market and the use of a biocidal product in the territory of the Union or in a part thereof;
- (o) 'authorisation' means
- national authorisation or Union authorisation;
- (p) 'unique product formulation' means
- a biocidal product with no variations as to the percentage of the active substance, the percentage composition of the non-active substances, or the perfumes, dyes or pigments it contains;
- (q) 'frame formulation' means
- a group of biocidal products that have similar uses and that present limited variations in their composition with regard to a reference biocidal product

belonging to that group which contains the same active substances of the same specifications, where such permitted variations do not adversely affect the level of risk or the efficacy of these products;

(r) 'letter of access' means

an original document, signed by the owner or owners of information *or their authorised representative*, which states that the information may be used by the *designated* competent *authority*, the Agency, or the Commission for the purpose of evaluating an active substance or granting an authorisation *for the benefit of a third party*;

(s) 'food and feedingstuff' means

food as defined in Article 2 of Regulation (EC) No 178/2002 and feedingstuff as defined in Article 3(4) of that Regulation.

(t) 'food contact materials' means

any material or article, intended to come into contact with food, that is covered by Regulation (EC) No 1935/2004;

(u) 'processing aid' means

any substance which:

- (i) is not consumed as a food or feedingstuff by itself;
- (ii) is intentionally used in the processing of raw materials, foods or feedingstuff or their ingredients to fulfil a certain technological purpose during treatment or processing; and
- (iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives, provided they do not present any health risk and do not have any technological effect on the final product;

(v) '*administrative change*' means

*a modification of an existing authorisation of a purely administrative nature, which does not involve a re-assessment of the risk for public health or the environment or the efficacy of the product;*

(w) '*minor change*' means

*a modification of an existing authorisation which cannot be deemed to be an administrative change as it involves a limited re-assessment of the risk for public health or the environment or of the efficacy of the product, and does not adversely affect the level of risk for public health or the environment and the efficacy of the product;*

(x) '*major change*' means

*a modification of an existing authorisation which cannot be deemed to be an administrative change or a minor change;*

(y) 'technical equivalence' means

similarity as regards the chemical composition and hazard profile of a substance produced from a new manufacturing source, compared to the substance of the reference source with respect to which the initial risk assessment was carried out;

(z) '*nanomaterial*' means

*any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale. Properties that are characteristic of the nanoscale include:*

- (i) *those related to the large specific surface area of the materials considered; and/or*
- (ii) *specific physico-chemical properties that are different from those of the non-nanoform of the same material;*

(za) '*manufacturer*' means

- (i) *in the case of an active substance produced within the Union and placed on the market, the manufacturer of that active substance or a person established within the Union designated by the manufacturer as his sole representative for the purposes of this Regulation,*
- (ii) *in the case of an active substance produced outside the Union, the person established within the Union and designated by the manufacturer of that active substance as his sole representative for the purposes of this Regulation or, where no such person has been so designated, the importer into the Union of that active substance,*
- (iii) *in the case of a biocidal product produced outside the Union, the person established within the Union and designated by the manufacturer of that biocidal product as his sole representative for the purposes of this Regulation or, where no such person has been so designated, the importer into the Union of that biocidal product;*

(zb) '*professional user*' means

*any natural or legal person who uses biocidal products in the framework of his professional activity;*

(zc) '*vulnerable groups*' means

*persons needing specific consideration when assessing the acute and chronic health effects of biocidal products. These include pregnant and nursing women, the unborn, infants and children, the elderly and workers and residents subject to high biocide exposure over the long term;*

(zd) *'SMEs' means*

*small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises<sup>1</sup>.*

2. For the purposes of this Regulation, the definitions laid down in Article 3 of Regulation (EC) No 1907/2006 shall apply for the following terms:
  - (a) substance;
  - (b) mixture;
  - (c) article;
  - (d) product and process-orientated research and development;
  - (e) scientific research and development.

## Chapter II

### Inclusion of an active substance in Annex I

#### Article 4

##### Conditions for inclusion

1. An active substance shall be included in Annex I for an initial period not exceeding 10 years if ***at least one of*** the biocidal products containing that active substance ***fulfils*** the conditions laid down in point (b) of Article 16(1). ***An active substance referred to in Article 5 may be included in Annex I only for an initial period of 5 years.***
2. The inclusion in Annex I of an active substance shall be restricted to those product types in Annex V for which relevant data have been submitted in accordance with Article 6.
3. ***Active substances, as such or in biocidal products, may be placed on the market in the Union for use in biocidal products only if they have been included in Annex I in accordance with the provisions of this Regulation.***
4. ***Unless otherwise provided in this Regulation, all manufacturers of an active substance, as such or in a biocidal product, shall submit to the Agency an application for inclusion in Annex I.***
5. An active substance ***and the definition of the reference source for the active substance for the purposes of determining technical equivalence*** shall, where

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<sup>1</sup> *OJ L 124, 20.5.2003, p. 36.*

appropriate, be included in Annex I together with conditions relating to any of the following:

- (a) the minimum degree of purity of the active substance;
- (b) the nature and maximum content of certain impurities;
- (c) the product type as outlined in Annex V;
- (d) manner and area of use;
- (e) designation of categories of users;
- (f) ***characterisation of the chemical identity with regard to stereoisomers;***
- (g) other particular conditions based on the evaluation of the information related to that active substance.

6. Where appropriate, maximum residue limits shall be established with respect to active substances included in Annex I in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin<sup>1</sup> and Regulation (EC) No 470/2009 of the European Parliament and the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin<sup>2</sup>.

#### Article 5 Exclusion criteria

1. ***Without prejudice to paragraph 2, the following*** active substances **█** shall ***not*** be included in Annex I **█** :

- (a) ***active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B;***
- (b) ***active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;***
- (c) ***active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;***
- (d) ***active substances which, on the basis of the assessment of Union or internationally agreed test guidelines or other peer-reviewed scientific data and information, including a review of the scientific literature, reviewed by the Agency, are considered as having endocrine-disrupting properties that may cause adverse effect in humans, or which are***

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

<sup>2</sup> OJ L 152, 16.6.2009, p. 11.

*identified under Article 57(f) of Regulation (EC) No 1907/2006 as having endocrine-disrupting properties.*

*Not later than 13 December 2013, the Commission shall adopt, by means of delegated acts in accordance with Articles 73 and subject to the conditions of Articles 74 and 75, measures on specific scientific criteria for determining endocrine-disrupting properties. Pending the adoption of those criteria, substances that are, or are to be, classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties. In addition, substances such as those that are, or are to be, classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered as having such endocrine-disrupting properties;*

- (e) active substances that are persistent, bio-accumulative and toxic;*
  - (f) active substances that are very persistent and very bio-accumulative;*
  - (g) persistent organic pollutants (POP) under Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants<sup>1</sup>.*
2. The **■** active substances *referred to in paragraph 1* may be included in Annex I *only if* at least one of the *following* conditions **■** is met:
- (a) the exposure of humans or the environment to the active substance in question in a biocidal product, under normal conditions of use, is negligible, meaning that the product is used in closed systems or under other conditions excluding contact with humans;*
  - (b) it is shown by evidence that the active substance is necessary to prevent or control a serious danger to public or animal health or to the environment, to food and feed safety, or to the public interest and that there are no effective alternative substances or technologies available.*

*The use of any biocidal product containing active substances included in Annex I pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment is minimised.*

*A Member State authorising a biocidal product containing an active substance included in Annex I pursuant to this paragraph shall draw up a substitution plan concerning the control of the serious danger by other means including non-chemical methods that are as effective as the biocidal product concerned, and shall without delay transmit that plan to the Commission. The use of the biocidal product with the active substance*

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<sup>1</sup> OJ L 158, 30.4.2004, p. 7.

*concerned shall be restricted to those Member States where the serious danger has to be prevented or, if it occurs, controlled.*

#### Article 6

##### Data requirements for an application

1. An application to include an active substance in Annex I shall contain at least the following elements:
  - (a) a dossier, *or a letter of access to a dossier*, for the active substance satisfying the requirements set out in Annex II;
  - (b) a dossier, *or a letter of access to a dossier*, for at least one representative biocidal product that contains the active substance satisfying the requirements set out in Annex III.

The application shall be accompanied by the fees payable under Article 71.

2. Notwithstanding paragraph 1, the applicant need not provide data required under that paragraph if any of the following grounds applies:
  - (a) the information is not necessary *as all relevant* exposure *can be ruled out under* the proposed uses;
  - (b) it is not scientifically necessary to supply the information;
  - (c) it is not technically possible to supply the information.
3. An applicant may propose to adapt the data required under paragraph 1 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with a reference to the specific rules in Annex IV.

The competent authority shall inform the applicant about the possibility of proposing the adaptation of data requirements, the grounds on which such an adaptation can be requested and, where possible, shall provide assistance in preparing such a proposal.

4. *In order to define* what constitutes adequate justification to adapt the data required under paragraph 1 on the ground referred to in paragraph 2(a), *the Commission shall adapt the criteria by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75.*

#### Article 7

##### Submission and validation of applications

1. The applicant shall submit an application for inclusion of an active substance in Annex I, or for subsequent amendments to the conditions of inclusion of an active substance, to the Agency. *The Agency shall indicate* the name of the competent authority of the Member State that *it has chosen* to evaluate *the*



application. That competent authority (hereinafter the 'evaluating competent authority') shall be responsible for the evaluation of the application.

2. ***The Agency shall provide a submission number to be used in all correspondence relating to the application until the active substance is included in Annex I, and a submission date, which shall be the date on which the application is received by the Agency.***
3. The Agency shall, within one month from the receipt of the application, notify the evaluating competent authority that the application is available in the Agency database.
4. Within ***three weeks*** after receipt of an application, the Agency shall validate the application if it complies with the following requirements:
  - (a) dossiers referred to in points (a) and (b) of Article 6(1) have been submitted;
  - (b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

5. If the Agency considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a **time limit of up to two months** for the submission of that information.

The Agency shall, within ***three weeks*** after receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

The Agency shall reject the application if the applicant fails to submit the requested information by the deadline and shall inform the applicant thereof. In such cases a part of the fee paid to the Agency in accordance with Article 71 shall be reimbursed.

***Within two months of receiving the application, the Agency shall assign a unique identification code to all the information in the dossier.***

6. An appeal may be brought, in accordance with Article 68, against Agency decisions under the third subparagraph of paragraph 5.
7. If the Agency, on the basis of the validation made pursuant to paragraph 4, considers that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

## Article 8 Evaluation of applications

1. The evaluating competent authority shall, within 12 months after the validation, evaluate the dossiers in accordance with Article 4, including, where

relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3).

The evaluating competent authority shall provide the applicant with an opportunity to provide written or oral comments on the conclusions of the evaluation within two months. The evaluating competent authority shall take due account of these comments when finalising its evaluation.

The evaluating competent authority shall send the conclusions of the evaluation to the Agency.

2. If, when the dossiers are evaluated, it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit *that shall not exceed six months. In exceptional circumstances and following proper justification, the time limit may be extended by up to a further six months. The evaluating competent authority shall inform the Agency about its request to the applicant and the extension of the time limit. Where such additional information includes animal testing, the applicant shall be advised by experts from the Agency or competent authorities regarding suitable alternative methods and testing strategies to replace, reduce or refine the use of vertebrate animals.*

The 12-month period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received.

3. If the evaluating competent authority considers that there are concerns with regard to the cumulative effects from the use of biocidal products containing the same active substance, *or different substances with similar or common effects on the same endpoints, whether by the same or different mechanism of action*, it shall document its concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 and include this as part of its conclusions.
4. Within nine months after receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the inclusion of the active substance in Annex I, *having regard to the conclusions of the evaluating competent authority.*
5. *In order to keep the list of authorised active substances updated*, on receipt of the opinion of the Agency, the Commission shall adopt, *by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75*, a decision  to include the active substance in Annex I.
6. Notwithstanding Article 7(1), the evaluation of the application may be carried out by the competent authority other than the one which has received the copy of the application.

The competent authority that has been notified of the application for the evaluation may submit a duly substantiated request to appoint another evaluating competent authority to the Commission within one month after

receipt of the notification referred to in Article 7(3). The Commission shall take the decision in accordance with the procedure referred to in Article 76(2). The 12-month period referred to in paragraph 1 shall commence on the date when this decision is taken.

#### Article 9

##### Active substances which are candidates for substitution

1. An active substance that fulfils at least one of the following criteria shall be considered a candidate for substitution in accordance with the procedure referred to in paragraph 2:
  - (a) its acceptable daily intake, acute reference dose or acceptable operator exposure level is significantly lower than those of the majority of the active substances included in Annex I for the same product type;
  - (b) it meets two of the criteria to be considered as a persistent, bio-accumulative and toxic substance as set out in Annex XIII of Regulation (EC) No 1907/2006;
  - (c) there are reasons for concern linked to the nature of the critical effects, in particular developmental neurotoxic or immunotoxic effects, which, in combination with the use patterns, amount to use that could still cause concern, *such as high potential of risk to groundwater*, even with very restrictive risk management measures;
  - (d) *it is very persistent and very bioaccumulative according to the criteria set out in Annex XIII to Regulation (EC) No 1907/2006;*
  - (e) it is classified or meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as *respiratory sensitisers*, carcinogen category 1A or 1B, mutagen category 1A or 1B or toxic for reproduction category 1A or 1B;
  - (f) it is considered to have endocrine-disrupting properties that may cause adverse effect on humans *or the environment* on the basis of the assessment of Union or internationally agreed test guidelines or other available data.
2. When preparing an opinion on the inclusion, or renewal of the inclusion, of an active substance in Annex I, the Agency shall examine whether the active substance fulfils any of the criteria listed in paragraph 1 and shall address the matter in its opinion.
3. Prior to submitting the opinion on the inclusion, or renewal of the inclusion, of an active substance in Annex I to the Commission, the Agency shall make publicly available information on potential candidates for substitution with a reasonable period during which relevant information, including information on available substitutes, may be submitted by interested third parties. The Agency shall take due account of the information received when finalising its opinion.
4. By way of derogation from *Articles 4(1) and 10(3)*, the inclusion of an active

substance in Annex I that is considered as a candidate for substitution shall be ***granted or*** renewed for a period not exceeding ***seven years***.

5. Active substances that are considered as candidates for substitution in accordance with paragraph 1 shall be identified as such in Annex I.

### Chapter III

#### Renewal and review of inclusion of an active substance

#### Article 10

##### Conditions for renewal

1. The Commission shall renew the inclusion of an active substance in Annex I if the active substance still complies with the requirements referred to in Articles 4 ***and*** 5.
2. Based on new elements examined or adaptations to technical progress, the renewal of the inclusion may be accompanied, as appropriate, by conditions and restrictions.
3. Unless ***more strictly*** specified in the decision to renew the inclusion of an active substance in Annex I, the renewal ***may*** be ***renewed*** for a period ***not exceeding 10 years***.

#### Article 11

##### Submission and validation of applications

1. The applicant shall submit the application for renewal of the inclusion of an active substance in Annex I to the Agency at least 18 months before the expiry of the inclusion in Annex I for a given product-type.

The application shall be accompanied by the fees payable under Article 71.

When applying for renewal, the applicant shall submit a list of all data relating to the active substance that have been generated since the inclusion of the active substance in Annex I and a justification as to whether the conclusions of the initial assessment of the active substance are still valid. The evaluating competent authority may require the applicant to submit the data referred to in this list at any time.

2. The Agency shall, within one month after receipt of the application, notify the evaluating competent authority that carried out the initial evaluation of the application for inclusion in Annex I that the application is available in the Agency database.
3. Within two months after receipt of an application, the Agency shall validate the application if it complies with the following requirements:
  - (a) information referred to paragraph 1 has been submitted;
  - (b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

4. If the Agency considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a time limit *of up to two months* for the submission of that information.

The Agency shall, within two months after receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

The Agency shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant thereof. In such cases a part of the fee paid to the Agency in accordance with Article 71 shall be reimbursed.

5. An appeal may be brought, in accordance with Article 68, against Agency decisions under the third subparagraph of paragraph 4.
6. If the Agency considers, on basis of the validation made pursuant to paragraph 3, that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

## Article 12

### Evaluation of applications for renewal

1. On the basis of the available information and the need to review the conclusions of the initial evaluation of the application for inclusion in Annex I, the evaluating competent authority that carried out the initial evaluation shall, within one month after the validation referred to in Article 11, decide whether a full evaluation of the application for renewal is necessary.

If the evaluating competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1 to 4 of Article 8. The decision on the application shall be adopted in accordance with paragraphs 5, 6 and 7 of this Article.

2. If the evaluating competent authority decides that a full evaluation of the application is not necessary, it shall, within six months, prepare and submit to the Agency a recommendation on the renewal of the inclusion of the active substance in Annex I.

Prior to submitting the recommendation to the Agency, the evaluating competent authority shall provide the applicant with an opportunity to provide written or oral comments on the recommendation within one month. The evaluating competent authority shall take due account of these comments when finalising its recommendation.

3. On receipt of the recommendation from the evaluating competent authority, the Agency shall make it available to the Commission, the competent authorities of other Member States and the applicant and allow a period of

three months during which they may submit written comments to it.

4. The Commission may ask the Agency for an opinion on scientific or technical matters raised by a competent authority objecting to the recommendation referred to in paragraph 2. The Agency shall issue an opinion within six months from the date on which the matter was referred to it.
5. ***In order to keep the list of authorised active substances updated***, at the end of the period referred to in paragraph 3 or on receipt of the opinion of the Agency, the Commission shall adopt, ***by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75***, a decision concerning the renewal of the inclusion of the active substance in Annex I. █
6. Where, for reasons beyond the control of the applicant, the inclusion of the active substance in Annex I is likely to expire before a decision has been taken on its renewal, the Commission shall, in accordance with the procedure referred to in Article 76(2), adopt a decision postponing the expiry date of inclusion for a period sufficient to enable it to examine the application.
7. Where the Commission decides not to renew the inclusion of an active substance in Annex I, it may grant a period of grace for the disposal, storage, placing on the market and use of existing stocks of biocidal products containing that active substance.

The period of grace shall not exceed six months for the placing on the market and an additional maximum of twelve months for the disposal, storage, and use of existing stocks of the biocidal products containing that active substance.

### Article 13

#### Review of inclusion of an active substance in Annex I

1. ***In order to keep the list of authorised active substances updated***, the Commission may review the inclusion of an active substance in Annex I at any time where there are █ indications that ***any of*** the requirements █ in ***Articles 4 and 5*** are no longer complied with. ***It shall review the inclusion also in cases where there are indications that the objectives of Article 4(1)(a)(iv), Article 4(1)(b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may not be achieved.*** Where those indications are confirmed, the Commission shall adopt, ***by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75***, a decision amending the entry of an active substance in Annex I or removing it from that Annex.
- █
2. The Commission may consult the Agency on any questions of a scientific or technical nature relating to the review of the inclusion of an active substance in Annex I. The Agency shall, within nine months of the request, prepare an opinion and submit it to the Commission.
3. Where the Commission removes the entry of an active substance from Annex

I, it may grant a period of grace for the disposal, storage, placing on the market and use of existing stocks of biocidal products containing that active substance.

The period of grace shall not exceed six months for the placing on the market and an additional maximum of twelve months for the disposal, storage, and use of existing stocks of the biocidal products containing that active substance.

#### Article 14

##### *Detailed procedures for renewal and review*

*In order to ensure the smooth functioning of the renewal and review procedures, the Commission may adopt further detailed measures by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75.*



#### Chapter IV


##### General principles of authorisation of biocidal products

#### Article 15

##### Placing on the market and use of biocidal products

1. No biocidal product may be placed on the market or used unless an authorisation has been issued for that biocidal product in accordance with this Regulation.
2. Application for authorisation shall be made by, or on behalf of, the person who *will be the authorisation holder. The person may be, but is not necessarily, the person* responsible for the placing on the market of a biocidal product in a particular Member State or in the Union.



Application for  authorisation shall be submitted to the Agency. *When an applicant submits an application for national authorisation, that applicant shall, with the agreement of the Member State concerned on whose territory the national authorisation would be applicable, identify in the application itself, as laid down in Article 22, the competent authority of the Member State of his choice which shall be responsible for the evaluation of, and decision on, the application (hereinafter the 'receiving competent authority').*

Authorisation holders shall have a permanent office within the Union.

*A single application for authorisation may be made by the applicant for a group of products intended to be authorised under a frame formulation.*

3. An authorisation may be granted for a unique product formulation or for a frame formulation.
4. An authorisation shall be granted for a maximum period of 10 years.

5. Biocidal products shall be used properly. Proper use shall include compliance with the conditions for granting an authorisation established in Article 16 and labelling requirements laid down in Article 58.

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.

***Infestation with harmful organisms shall be avoided by suitable measures of deterrence to banish or repel such organisms. In addition, other precautionary steps shall be taken, such as proper warehousing of goods, compliance with hygiene standards and immediate disposal of waste. Only if those measures show no effect shall further steps be taken. Biocidal products that pose low risks for humans, animals and the environment shall always be used in preference to others. Biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress shall be applied only as a last resort.***

***Mandatory measures shall be established through a framework directive for Union action and thereafter implemented in order to achieve the sustainable professional use of biocidal products including the introduction of National Action Plans, integrated pest management, risk-reduction measures and the promotion of alternatives.***

***By ...\*, the Commission shall submit a proposal for such a framework directive to the European Parliament and the Council.***

#### Article 16

##### Conditions for granting an authorisation

1. A biocidal product shall be authorised only if the following conditions are met:
- (a) the active substances included therein are listed in Annex I and any conditions included in that Annex together with those active substances are complied with;
  - (b) it is established according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI, that the biocidal product, when used as authorised and having regard to the factors referred to in paragraph 2, complies with the following criteria:
    - (i) it is sufficiently effective;
    - (ii) it has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
    - (iii) it has no ***immediate or delayed harmful effect*** itself or as a result of its residues ***on groundwater or on human health, including the***

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\* ***Two years after entry into force of this Regulation.***



*health of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Agency to assess such effects are available;*

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

- its fate and distribution in the environment;
- contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, *taking into account locations distant from its use following long-range environmental transportation;*
- its impact on non-target organisms;
- its impact on biodiversity and the ecosystem;

(c) the *chemical identity*, the quantity and the technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant impurities and non-active substances, and its *metabolites and* residues of toxicological or environmental significance, which result from uses that are to be authorised, can be determined according to the relevant requirements in Annexes II and III;

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

(e) *where nanomaterials are used in the product, the risk to the environment and to health has been assessed separately.*

2. The evaluation of the compliance of the biocidal product with the criteria set out in point (b) of paragraph 1 shall take into account the following factors:

- (a) all normal conditions under which the biocidal product may be used;
- (b) how any material or article treated with it or containing it may be used;
- (c) the consequences of its use and disposal;
- (d) *cumulative or synergistic effects.*

3. *When evaluating whether the criteria in point (b) of paragraph 1 have been fulfilled, information should whenever possible be derived from information already available on the substance of concern contained in the biocidal*

*product, in order to keep tests on animals to a minimum. In particular, the provisions of Directive 1999/45/EC or Regulation (EC) No 1272/2008 should wherever possible be applied for the purpose of ascertaining the adverse effects of the biocidal product and for the subsequent risk assessment.*

4. *The evaluation of the compliance of the biocidal product with the criteria set out in points (b) and (c) of paragraph 1 shall not take into account a substance contained in the biocidal product if it is present in a preparation at a concentration lower than any of the following:*
  - (a) *the applicable concentrations laid down in Article 3(3) of Directive 1999/45/EC;*
  - (b) *the concentration limit values laid down in Annex I to Directive 67/548/EEC;*
  - (c) *the concentration limit values laid down in Part B of Annex II to Directive 1999/45/EC;*
  - (d) *the concentration limit values laid down in Part B of Annex III to Directive 1999/45/EC;*
  - (e) *the concentration limit values laid down in an agreed entry in the classification and labelling inventory established under Title V of Regulation (EC) No 1272/2008;*
  - (f) *0.1% weight by weight (w/w), if the substance meets the criteria in Annex XIII to Regulation (EC) No 1907/2006.*
5. An authorisation to place a low-risk biocidal product on the market *may be granted only if the active substances are evaluated as low-risk active substances and included in Annex I in accordance with Articles 4 and 5. The authorisation* shall be subject to compliance with the requirements of points (a) to (d) of paragraph 1.
6. A biocidal product shall be authorised only for uses for which relevant information has been submitted in accordance with Article 18.
7. A biocidal product shall not be authorised for placing on the market to, or use by, the general public if it fulfils any of the following criteria for classification:
  - (a) it is toxic, very toxic or a category 1 or 2 carcinogen, or a category 1 or 2 mutagen or toxic for reproduction category 1 or 2 according to Directive 1999/45/EC;
  - (b) it is toxic, very toxic or a category 1A or 1B carcinogen, or a category 1A or 1B mutagen or toxic for reproduction category 1A or 1B according to Regulation (EC) No 1272/2008;
  - (c) *it is considered to have endocrine-disrupting properties;*

- (d) *it has developmental neurotoxic or immunotoxic effects.*
8. In the case of a frame formulation, *the following variations in composition with regard to a reference biocidal product are possible:*
- (a) *elimination of an active substance in a reference biocidal product with at least two active substances;*
- (b) *a reduction in the percentage of the active substances;*
- (c) *elimination of one or more non-active substances;*
- (d) *an alteration in percentage composition of one or more non-active substances;*
- (e) *the replacement of one or more non-active substances by others presenting the same or lower risk.*
9. *The Commission should, in accordance with the procedure set out in Article 76(2), provide technical and scientific guidance for product authorisation, with particular regard to harmonised data requirements, evaluation procedures and decisions by the Member States.*
10. *In order to facilitate the harmonisation of authorisation practices throughout the Union and to reduce the administrative burden on companies and competent authorities, the Commission shall adopt, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75, measures specifying the conditions, criteria and procedures for regulating the authorisation and placing on the market of the same product for the same use, under different trade names and by different companies. The criteria and the procedures for such measures shall be based on, but not limited to, the following principles:*
- (a) *no additional evaluation will be performed as it concerns an already authorised product;*
- (b) *authorisation decisions shall be taken within a short timeframe;*
- (c) *authorisation fees shall be low in accordance with the limited administrative work required.*

#### Article 17

##### Criteria for low-risk biocidal products

1. A biocidal product shall be considered a low-risk biocidal product *if the active substances therein are included in Annex I and if all of the following conditions are fulfilled:*
- (a) *for any given environmental compartment, the ratio of the predicted environmental concentration (PEC) to predicted no-effect concentration (PNEC) may be derived and does not exceed 0.1;*

- (b) for any effect to human health, the margin of exposure (the ratio of no observed adverse effect level (NOAEL) and exposure concentration) is higher than 1 000;
- (c) *the cumulative effects of both active substances and non-active substances are taken into consideration and defined as low-risk.*

However, a biocidal product shall not be considered a low-risk biocidal product if at least one of the following conditions is met:

- (a) it contains one or more **■** substances which fulfil the criteria for being *a persistent organic pollutant under Regulation (EC) No 850/2004, for being* persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII of Regulation (EC) No 1907/2006;
- (b) it contains one or more active substances qualified as endocrine disrupters;
- (c) it contains one or more active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as or which meet the criteria to be classified as one of the following:
  - (i) carcinogenic;
  - (ii) mutagenic;
  - (iii) neurotoxic;
  - (iv) immunotoxic;
  - (v) toxic to reproduction;
  - (vi) sensitising;
  - (vii) corrosive;*
  - (viii) very toxic or toxic.*
- (d) *it contains a nanomaterial;*
- (e) *it is explosive;*
- (f) *it contains any substance of concern;*
- (g) *it is highly flammable;*
- (h) *it is self-igniting at application temperature.*

**■**

2. For a low-risk biocidal product it shall be demonstrated that the potential for the development of resistance in target organisms due to the use of the biocidal

product is low.

3. In addition to the active substances referred to in Article 15(2) of Regulation (EC) No 1907/2006, active substances manufactured or imported for use in low-risk biocidal products that are authorised for placing on the market in accordance with Article 15 shall be regarded as being registered, and the registration as completed, for manufacture or import for use in a low-risk biocidal product, and therefore as fulfilling the requirements of Chapters 1 and 5 of Title II of that Regulation.

#### Article 18

##### Data requirements for an application for authorisation

1. The applicant for an authorisation shall submit the following documents together with the application:
  - (a) a dossier or letter of access for the biocidal product satisfying the requirements set out in Annex III;
  - (b) a proposal for a summary of the biocidal product characteristics that includes the information referred to in points (a), (b) and (e) to (m) of Article 20(2);
  - (c) for biocidal products other than low-risk biocidal products, a dossier or a letter of access to a dossier satisfying the requirements set out in Annex II for each active substance in the biocidal product;
  - (d) for low-risk biocidal products, any relevant information in support of the conclusion that the biocidal product is to be considered a low-risk biocidal product;
  - (e) *if the active substance contained in a low-risk biocidal product has been included in Annex I, a letter of access if the appropriate protection period for information according to Article 49 has not expired.*
2. The application for authorisation shall be accompanied by the fees payable under Article 71.
3. The **Agency** may require applications for a national authorisation to be submitted in *an* official **language** of the Member State in which *the receiving* competent authority is situated.
4. If the application concerns a biocidal product that is intended by its manufacturer to be used inter alia for the purposes referred to in Article 2(7), it shall be accompanied by a declaration of conformity regarding the compliance with the relevant essential requirements of Directives 90/385/EEC, 93/42/EEC or 98/79/EC.
5. The Commission shall, in accordance with the procedure referred to in Article 76(2), draw up technical notes for guidance to facilitate the implementation of point (d) of paragraph 1. *The Commission shall, in accordance with the*

*procedure set out in Article 76(2), provide technical and scientific guidance and tools, in particular to support applications for authorisation under Articles 18, 19 and 20, above all for SMEs.*

The technical notes shall be published in the 'C' series of the *Official Journal of the European Union*.

#### Article 19

##### Waiving of data requirements

1. Notwithstanding Article 18, the applicant need not provide data required under that Article if any of the following grounds applies:
  - (a) the information is not necessary owing to the exposure associated with the proposed uses;
  - (b) it is not scientifically necessary to supply the information;
  - (c) it is not technically possible to supply the information.
2. The applicant may propose to adapt the data required under Article 18 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with reference to the specific rules in Annex IV.

The competent authority shall inform the applicant about the possibility of proposing the adaptation of data requirements, the grounds on which such an adaptation can be requested and, where possible, shall provide assistance in preparing such a proposal.

3. ***In order to define*** what constitutes adequate justification to adapt the data required under Article 18 on the grounds referred to in point (a) of paragraph 1, ***the Commission shall adapt the criteria by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75.***



#### Article 20

##### Content of authorisation

1. An authorisation shall stipulate the terms and the conditions relating to the placing on the market and use of the biocidal product.
2. An authorisation shall include the summary of the biocidal product characteristics listing the following information:
  - (a) trade name of the biocidal product;
  - (b) name and address of the authorisation holder;
  - (c) date of the authorisation and its date of expiry;

- (d) authorisation number;
- (e) *where required for proper use of the biocidal product, the qualitative and quantitative composition in terms of the active substances and non-active substances, taking account of the concentration limits in Article 16(4);*
- (f) manufacturers of the biocidal product (names and addresses including location of manufacturing sites);
- (g) manufacturers of the active substances (names and addresses including location of manufacturing sites);
- (h) physical state and nature of the biocidal product;
- (i) hazard and precautionary statements;
- (j) the product-type in accordance with Annex V and the target harmful organisms;
- (k) application doses and instructions for use;
- (l) categories of users;
- (m) particulars of likely direct or indirect adverse effects and first aid instructions;
- (n) instructions for safe disposal of the product and its packaging;
- (o) in the case of a biocidal product that is intended by its manufacturer to be used inter alia for the purposes referred to in Article 2(7), any specific conditions of use and a statement that the biocidal product is in conformity with the relevant essential requirements of Directives 90/385/EEC, 93/42/EEC or 98/79/EC;
- (p) *for toxicologically and ecotoxicologically relevant components of biocidal products and residues thereof, analytical methods including recovery rates and the limits of determination (LOD).*

3. In addition to paragraph 2, in the case of a frame formulation, the authorisation shall indicate, as appropriate, the following information:

- (a) the reference biocidal product within the group of products comprising the frame formulation **■** ;
- (b) the permitted alteration of the composition of this reference biocidal product expressed *as a reduction in the percentage of the active substances or as an alteration in the percentage of the* non-active substances contained in the biocidal products which are considered to belong to that frame formulation;
- (c) the non-active substances that may be substituted in the authorised

biocidal products belonging to that frame formulation.

4. ***In the case of a frame formulation, one single authorisation number shall be provided for all biocidal products which belong to that frame formulation.***

#### Article 21

##### Comparative assessment of biocidal products

1. The receiving competent authority or, in the case of evaluation of an application for a Union authorisation, the evaluating competent authority shall perform a comparative assessment as part of the evaluation of an application for an authorisation or a renewal of an authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 9(1). ***The comparative assessment shall be carried out in relation to all biocidal products that have the same purpose, when sufficient experience has been gained in their use and they have been in use for at least five years.***
2. The results of the comparative assessment shall be forwarded, without delay, to the competent authorities of other Member States and the Agency and, in the case of evaluation of an application for a Union authorisation, also to the Commission.
3. The receiving competent authority or, in the case of a decision on an application for a Union authorisation, the Commission shall prohibit or restrict the placing on the market or use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment weighing up the risks and benefits in accordance with Annex VI demonstrates that all the following criteria are met:
  - (a) for the uses specified in the application, ***other*** authorised biocidal ***products*** already ***exist*** which ***present*** significantly lower risk for human or animal health or the environment ***and which prove equally effective and involve no significant increase in the risks for any other parameter;***
  - (b) the biocidal product or non-chemical control or prevention method referred to in point (a) does not present significant economic or practical disadvantages;
  - (c) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.
4. ***The Commission shall, on the basis of paragraph 3, adopt measures laying down the procedure necessary for the definition of an application for comparative assessment of biocidal products. Those measures shall define the criteria and algorithms to be used in a comparative assessment to ensure that there is uniform application throughout the Union.***
5. Where the comparative assessment involves a question which, by reason of its scale or consequences, would be better addressed at Union level, in particular



where it is relevant to two or more competent authorities, the receiving competent authority may refer the question to the Commission for a decision. The Commission shall adopt its decision in accordance with Article 76(3).

***In order to specify*** the procedures relating to comparative assessments involving questions of Union interest, ***the Commission shall adapt the criteria by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75.***

6. Notwithstanding Article 15(4), an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted for ***periods*** not exceeding five years.

***Member States shall establish and implement a substitution plan in order to ensure that the application of the relevant biocidal product is phased out within the authorisation period and that the relevant active substance or product can be replaced with sound chemical or non-chemical alternatives.***

7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or modification of the authorisation shall take effect ***three years*** after the decision or at the end of the inclusion period of the candidate for substitution, whichever is the earlier.

## Chapter V

### National authorisations of biocidal products

#### Article 22

##### Submission and validation of application

1. ***The person responsible for the placing of a biocidal product on the market, or his representative, shall submit an application for a national or Union authorisation to the Agency and inform the Agency of the name of the receiving competent authority. The Agency shall, within three weeks after receipt of the application, notify the receiving competent authority or, in the case of an application for a Union authorisation, the evaluating competent authority, that the application is available in the Agency database.***
2. ***Within three weeks after receipt of an application, the Agency shall validate the application if it complies with the following requirements:***
  - (a) ***the documents referred to in Article 18 have been submitted;***
  - (b) ***it is accompanied by the fees payable under Article 71.***

***The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.***

3. ***If the Agency considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information.***

*The Agency shall, within three weeks after receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.*

*The Agency shall reject the application if the applicant does not submit the required additional information on time, and shall notify the applicant and the receiving competent authority of the rejection.*

*In such cases, part of the fees payable to the Agency under Article 71 shall be reimbursed.*

4. *An applicant may, in accordance with Article 68, submit an appeal against the decision of the Agency under the third subparagraph of paragraph 3.*
5. *If the Agency considers, on the basis of the validation made pursuant to paragraph 2, that the application is complete, it shall without delay inform the applicant and the receiving competent authority to that effect.*

#### Article 23

##### Evaluation of application

1. The receiving competent authority shall, within **six months** of the validation referred to in Article 22, decide on the application in accordance with Article 16.
2. If an application relating to the same biocidal product is being examined by the competent authority of another Member State or if the competent authority of another Member State has already authorised the same biocidal product, the receiving competent authority shall decline to assess the application and inform the applicant thereof.

However, the applicant may request that his application be assessed in accordance with Article 25 or Article 28.

3. If it appears that additional information is necessary in order to carry out a full evaluation of the application, the receiving competent authority shall request the applicant to submit such information. The **six-month** period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received.
4. The receiving competent authority shall draft a report summarising the conclusions of its assessment and the reasons for authorising a biocidal product or for refusing to grant an authorisation. The receiving competent authority shall send the draft assessment report to the applicant who shall be provided with the opportunity to submit oral or written comments within one month. The receiving competent authority shall take due account of these comments when finalising its assessment.

The receiving competent authority shall approve the summary of the biocidal product characteristics referred to in Article 20(2). It shall forward the

applicant a copy of the final assessment report.

5. As soon as the receiving competent authority has taken a decision on an application, it shall enter the following information in the Union Register of Biocidal Products:
  - (a) the summary of biocidal product characteristics;
  - (b) the report summarising the conclusions of the assessment of the biocidal product and the reasons for authorising, or refusing to authorise, the biocidal product;
  - (c) the administrative decisions taken by the receiving competent authority concerning the application.

#### Article 24

##### Renewal of a national authorisation

1. The authorisation holder or his representative shall submit an application for renewal of a national authorisation to the receiving competent authority at least **12 months** before the expiry date of the authorisation.

The application shall be accompanied by the fees payable under Article 71.

2. The receiving competent authority shall renew the national authorisation, provided that the conditions set out in Article 16 are still satisfied.
3. When applying for renewal, the applicant shall submit a list of all data relating to the biocidal product that have been generated since the previous authorisation and a justification as to whether the conclusions of the initial assessment of the biocidal product are still valid.

The receiving competent authority may require the applicant to submit the data referred to in the list at any time.

4. Within one month after receipt of an application for a renewal of a national authorisation, the receiving competent authority shall validate the application if it complies with the following requirements:
  - (a) the information referred to in paragraph 3 has been submitted;
  - (b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

5. If the receiving competent authority considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information.

The receiving competent authority shall, within one month of receipt of the

additional information, determine whether the additional information submitted is sufficient to validate the application.

The receiving competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and inform the applicant thereof.

If the receiving competent authority considers, on basis of the validation made pursuant to paragraph 4, that the application is complete, it shall without delay inform the applicant thereof.

6. The decision on the application for renewal of the national authorisation shall be taken within six months of the validation.
7. If, when the application for renewal is evaluated, it appears that additional information is necessary in order to carry out a full evaluation of the application, the receiving competent authority shall ask the applicant to submit such information. The six-month period referred to in paragraph 6 shall be suspended from the date of the request until the date the information is received.
8. Where, for reasons beyond the control of the holder of the national authorisation, no decision is taken on the renewal of the national authorisation before its expiry, the receiving competent authority shall grant the renewal of the national authorisation for the period necessary to complete the evaluation.
9. As soon as the competent authority has taken a decision concerning the renewal of a national authorisation, it shall enter the information referred to in Article 23(5) in the Union Register of Biocidal Products.

## Chapter VI Mutual recognition procedures

### Article 25 Mutual recognition of national authorisations in sequence

1. The holder of a national authorisation for a biocidal product granted by a competent authority in accordance with Article 15 (hereinafter the 'reference competent authority') may apply for a national authorisation of the biocidal product in another Member State under the procedure for mutual recognition in sequence.
2. The application for mutual recognition shall be accompanied by:
  - (a) a reference to the national authorisation granted by the reference competent authority;
  - (b) an electronic summary of the dossier satisfying the requirements set out in Annex III;
  - (c) a reference to the report of the reference competent authority summarising the conclusions of its assessment and the reasons for

authorising the biocidal product.

The application shall be accompanied by the fees payable under Article 71.

3. The receiving competent authority may require a translation of the national authorisation and application into one of the official languages of the Member State where that competent authority is situated.

***Applications for a national authorisation which involve a mutual recognition procedure, including the documents referred to in Article 18, may be submitted to the competent authority in English.***

4. The receiving competent authority shall decide on the application within four months of receipt of the application.
5. The receiving competent authority shall authorise the biocidal product concerned under the same conditions as the reference competent authority, ***unless specific national circumstances justify a deviation according to Article 29.***

***A single authorisation number shall be used in all the Member States involved.***

6. ***The Commission shall adopt, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75, measures specifying the criteria and procedures for assigning the single authorisation number referred to in paragraph 5.***
7. As soon as the competent authorities have taken a decision on an application for mutual recognition of a national authorisation under this Article, they shall enter the information referred to in points (a) and (c) of Article 23(5) in the Union Register of Biocidal Products.

## Article 26

### Application for mutual recognition by pest control bodies

1. Where no application for a national authorisation has been submitted in a Member State for a biocidal product that is already authorised in another Member State, official or scientific bodies involved in pest control activities or professional organisations may apply, with the consent of the authorisation holder in another Member State, for a national authorisation for the same biocidal product, the same use and under the same conditions for use in that Member State under the mutual recognition procedure provided for in Article 25.

The applicant shall demonstrate that the use of such a biocidal product is of general interest for that Member State.

The application shall be accompanied by the fees payable under Article 71.

2. By way of derogation from paragraph 1, where the authorisation holder does not give his consent, the applicant may indicate that in the application and the

competent authority of the Member State concerned may accept the application on grounds of public interest.

3. If the competent authority of the Member State concerned considers that the biocidal product fulfils the conditions referred to in Article 16 and the conditions under this Article are complied with, the competent authority shall authorise the placing of the biocidal product on the market.
4. The official or scientific bodies involved in pest control activities or professional organisations shall have the rights and obligations of the authorisation holder.

#### Article 27

##### Objections regarding the conditions for a national authorisation

1. Where, within four months of receipt of the application for mutual recognition, the competent authority considers that a biocidal product, which has been authorised in another Member State, does not satisfy the requirements of Article 16, it shall without delay notify the Commission, the competent authorities of the other Member States and the applicant thereof, and shall provide them with an explanatory document identifying the biocidal product and its specifications and setting out the grounds on which it proposes to refuse to recognise or to restrict the national authorisation.

The Commission shall, *after consultation with the applicant*, adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 76(3).

***Within three months of receipt of the notification, the Commission shall make a proposal for a decision. Should the Commission ask the Agency for an opinion under the procedure set out in Article 30, the three-month period shall be suspended until the Agency has forwarded its opinion.***

2. If the Commission decision confirms the grounds presented for refusing or restricting the subsequent authorisation, the competent authority that had previously authorised the biocidal product shall without delay review its national authorisation to comply with that decision.

If the Commission decision confirms the initial national authorisation, the competent authority that proposed to refuse to recognise a national authorisation, or to recognise the national authorisation subject to certain conditions, shall without delay authorise the biocidal product concerned in accordance with the initial authorisation.

#### Article 28

##### Mutual recognition of national authorisations in parallel

1. If the applicant seeks to receive national authorisations for a biocidal product in more than one Member State in parallel, he shall submit to a reference competent authority of his choice an application containing:

- (a) the documents referred to in Article 18;
- (b) a list of all other Member States where a national authorisation is sought (hereinafter the 'other Member States concerned').

The application shall be accompanied by the fees payable under Article 71.

The reference competent authority shall be responsible for the evaluation of the application.

2. The applicant shall submit to the competent authorities of the other Member States concerned an application for mutual recognition of the authorisation for which it has applied to the reference competent authority. This application shall contain:

- (a) an electronic summary of the dossier as required in Annex III;
- (b) the names of the reference competent authority and of the other Member States concerned.

3. The reference competent authority shall, within one month after receipt of an application referred to in paragraph 1, validate the application if it complies with the following requirements:

- (a) the information referred to in paragraph 1 has been submitted;
- (b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

4. If the reference competent authority considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. The reference competent authority shall also inform the other Member States concerned.

The reference competent authority shall, within one month after receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

The reference competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the other Member States concerned thereof.

5. If the reference competent authority considers, on the basis of the validation made pursuant to paragraph 3, that the application is complete, it shall without delay inform the applicant and the other Member States concerned.

6. The reference competent authority shall evaluate the information referred to in paragraph 1 and prepare a report summarising the conclusions of its assessment and a draft of the summary of the biocidal product characteristics

within 12 months from the receipt of a valid application and shall communicate the report and the draft summary to the competent authorities of other Member States concerned and the applicant. The reference competent authority shall send the draft assessment report to the applicant who shall be provided with the opportunity to submit oral or written comments within one month. The reference competent authority shall take due account of these comments when finalising its assessment.

7. Within four months after receipt of the documents referred to in paragraph 6, the competent authorities of other Member States concerned shall approve the assessment report and the summary of the product characteristics, and shall inform the reference competent authority accordingly.
8. The reference competent authority and the competent authorities of the other Member States concerned shall authorise the biocidal product on the basis of the approved assessment report and the summary of the biocidal product characteristics within one month after the end of the period referred to in paragraph 7.

***A single authorisation number shall be used in all the Member States involved.***

***The Commission shall adopt, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75, measures specifying the criteria and procedures for assigning the single authorisation number.***

9. If one or more competent authorities of other Member States concerned have not approved the assessment report and the summary of the biocidal product characteristics within four months after receipt of the documents referred to in paragraph 6, they shall notify the Commission, the applicant, the reference competent authority and the competent authorities of other Member States concerned and shall provide them with an explanatory document identifying the biocidal product and its specifications and setting out the grounds on which they propose to refuse to recognise, or to restrict, the national authorisation.

The Commission shall, ***following consultation of the applicant***, adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 76(3).

***This decision shall be taken within three months of the notification by the competent authority referred to in the first subparagraph. If the Commission requests an opinion from the Agency pursuant to Article 30, the three-month period shall be suspended until the Agency submits its opinion.***

If the Commission decision ***confirms*** the grounds presented for refusing or restricting the ***subsequent*** authorisation, the competent authority that ***had previously authorised the biocidal product*** shall without delay ***review its*** national authorisation ***to comply with that decision.***



***If the Commission decision confirms the initial national authorisation, the competent authority that proposed to refuse to recognise a national authorisation, or to recognise the national authorisation subject to certain conditions, shall without delay authorise the biocidal product concerned in accordance with the initial authorisation.***

10. As soon as the competent authorities have taken a decision on an application for a national authorisation in more than one Member State in parallel, they shall enter information referred to in Article 23(5), where applicable, in the Union Register of Biocidal Products.

#### Article 29

##### Adjustment to local circumstances

1. The competent authority that has received an application for mutual recognition in accordance with Articles 25 or 28 may, within two months from the receipt of the application, propose to the applicant that certain conditions referred to in points (e), (f), (g), (j), (l), (m) and (n) of Article 58(2) in the authorisation be adjusted to local circumstances, so that conditions for issue of an authorisation laid down in Article 16 are satisfied, and shall inform the Commission thereof, if it establishes that, in its territory, one of the following conditions is met:
  - (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;
  - (c) the relevant circumstances of use, in particular the climate or the breeding period of the target species, differ significantly from those in the Member State where the initial evaluation was carried out or the Member State where the initial national authorisation was issued ;
  - (d) ***an unchanged national authorisation presents harmful effects on human health or unacceptable effects on the environment.***

The competent authorities shall communicate to the Commission all proposals concerning adjustment of conditions in national authorisations to local circumstances and the reasons for proposing adjustment.

2. ***Subject to Union law, appropriate conditions may be imposed with respect to the requirements referred to in Article 15 and other risk-mitigation measures deriving from specific conditions of use.***
3. If, within 2 months, an agreement on the proposed adjustments is not reached between the applicant and the competent authority that has received an application for mutual recognition, that competent authority shall without delay inform the Commission thereof and provide an explanatory document on the proposed adjustments identifying the biocidal product and its specifications and setting out the grounds on which it proposes to adjust the conditions of the national authorisation.

## Article 30 Opinion of the Agency

1. The Commission may ask the Agency for an opinion on scientific or technical matters raised by a Member State objecting to the mutual recognition of a national authorisation or seeking to adjust the authorisation to local circumstances. The Agency shall issue an opinion within six months from the date on which the matter was referred to it.
2. Before issuing its opinion, the Agency shall provide the applicant or the authorisation holder with an opportunity to present written or oral explanations within a specified time limit not exceeding one month.

The Agency may suspend the time limit referred to in paragraph 1 to allow the applicant or the authorisation holder to prepare the explanations.

## Article 31 Derogation regarding certain *active substances or* product-types

By way of derogation from *Articles 25 to 29*, competent authorities of Member States may refuse mutual recognition of national authorisations granted for *biocidal products containing active substances referred to in Articles 5 and 9 and for* product types 15, 17 and 23 of Annex V, provided that such a refusal can be justified on grounds of the protection of health of humans, *particularly the health of vulnerable groups, the protection of the health of* animals or plants, the protection of *the environment*, national treasures possessing artistic, historic or archaeological value, or the protection of industrial and commercial property. Competent authorities of Member States shall without delay inform each other and the Commission of any decision taken in this respect and shall indicate the reasons thereof.

## Chapter VII Union authorisations of biocidal products

### Section 1 Granting of Union authorisations

#### Article 32 Union authorisation

A Union authorisation issued by the Commission in accordance with this Section shall be valid throughout the Union unless otherwise specified. It shall confer the same rights and obligations in each of the Member States as an authorisation issued by the competent authority of that Member State.

#### Article 33 Biocidal products for which Union authorisation may be granted

1. **From 2013**, the Union authorisation may be granted to the following categories of biocidal products:

- (a) biocidal products containing one or more new active substances;
  - (b) low-risk biocidal products.
2. ***From 2017, the Union authorisation may be granted to all categories of biocidal products with the exception of biocidal products that contain active substances that fall under Article 5.***

#### Article 34

##### Submission and validation of application

1. The person responsible for the placing of a biocidal product on the market, or his representative, shall submit an application for a Union authorisation to the Agency and inform the Agency of the name of the competent authority of the Member State of his choice which shall be responsible for the evaluation of the application (hereinafter the 'evaluating competent authority').

The Agency shall, within one month after receipt of the application, notify the evaluating competent authority that the application is available in the Agency database.

2. Within two months after receipt of an application, the Agency shall validate the application if it complies with the following requirements:

- (a) the documents referred to in Article 18 has been submitted;
- (b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

3. If the Agency considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information.

The Agency shall, within two months from the receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

The Agency shall reject the application if the applicant fails to complete the application within the deadline and shall inform the applicant and the evaluating competent authority thereof. In such cases a part of the fee paid to the Agency in accordance with Article 71 shall be reimbursed.

4. An appeal may be brought, in accordance with Article 68, against Agency decisions under the third subparagraph of paragraph 3 of this Article.
5. If the Agency considers, on the basis of the validation made pursuant to paragraph 2, that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

Article 35  
Evaluation of applications

1. The evaluating competent authority shall, within twelve months after the validation, evaluate the dossiers in accordance with Article 16 including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 19(2).

The evaluating competent authority shall provide the applicant with an opportunity to provide written or oral comments on the conclusions of the evaluation within one month. The evaluating competent authority shall take due account of these comments when finalising its evaluation.

The evaluating competent authority shall send the conclusions of the assessment and the assessment report to the Agency.

2. If, when the dossiers are evaluated, it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency thereof.

The twelve-month period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received.

3. Within **three** months from receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product.

If the Agency recommends the authorisation of the biocidal product, the opinion shall contain at least the following elements:

- (a) a statement on whether the conditions of points (b), (c) and (d) of Article 16(1) are fulfilled, and a draft summary of the biocidal product characteristics, as referred to in Article 20(2);
  - (b) where relevant, details of any terms or conditions which should be imposed on the placing on the market or use of the biocidal product;
  - (c) the final assessment report on the biocidal product.
4. On receipt of the opinion of the Agency, the Commission shall adopt a decision on the Union authorisation of the biocidal product in accordance with the procedure referred to in Article 76(3). As soon as the Commission has taken a decision to grant a Union authorisation, it shall enter the information referred to in Article 23(5) in the Union Register of Biocidal Products.

The █ Member State ***shall notify the Commission where it restricts or prohibits*** the Union authorisation █ for a biocidal product of the product-types 15, 17 or 23 of Annex V ***in the territory of that Member State. Such restriction or prohibition must*** be justified on grounds of the protection of:

- (a) ***human*** health, ***particularly the health of vulnerable groups,***

- (b) *the environment, particularly vulnerable ecosystems,*
- (c) animals,
- (d) plants,
- (e) national treasures possessing artistic, historic or archaeological value, or
- (f) industrial and commercial property.

***If a Member State decides*** that ■ the Union authorisation should be adjusted to the different local circumstances in that Member State in accordance with Article 29, ***it shall inform the Commission thereof.***

5. If the decision referred to in the first subparagraph of paragraph 4 is to refuse to grant a Union authorisation to a biocidal product because it does not fulfil the criteria for a low-risk biocidal product in accordance with Article 17, the applicant may apply, if relevant, for a Union authorisation in accordance with point (a) of Article 33(1) or a national authorisation in accordance with Chapter V.
6. The competent authority that has been notified of the application for the evaluation as referred to in Article 34(1) may, within one month after receipt of the notification, submit a duly substantiated request to the Commission to appoint another evaluating competent authority. The Commission shall take a decision in accordance with the procedure referred to in Article 76(2).

## Section 2

### Renewal of Union authorisations

#### Article 36

##### Submission and validation of applications

1. The authorisation holder or his representative shall submit an application for renewal of a Union authorisation to the Agency at least ***12 months*** before the expiry date of the authorisation.  
  
The application shall be accompanied by the fees payable under Article 71.
2. The Agency shall, within one month after receipt of the application, notify the evaluating competent authority that carried out the initial evaluation of the application for Union authorisation that the application is available in the Agency database.
3. The Commission shall renew a Union authorisation, provided that the conditions set out in Article 16 are still satisfied.
4. When applying for renewal, the applicant shall submit a list of all data relating to the biocidal product that have been generated since the previous authorisation and a justification as to whether the conclusions of the initial assessment of the biocidal product are still valid.

The evaluating competent authority that carried out the initial evaluation may require the applicant to submit the data referred to in the list at any time.

5. Within two months after receipt of an application, the Agency shall validate the application if it complies with the following requirements:
  - (a) the documents referred to paragraph 4 has been submitted;
  - (b) it is accompanied by the fees payable under Article 71.

The validation shall not include an assessment of the quality or the adequacy of any data or justifications for the adaptation of data requirements submitted.

6. If the Agency considers that the application is incomplete, it shall inform the applicant what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information.

The Agency shall, within two months after receipt of the additional information, determine whether the additional information submitted is sufficient to validate the application.

The Agency shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant thereof. In such cases a part of the fee paid to the Agency in accordance with Article 71 shall be reimbursed.

7. An appeal may be brought, in accordance with Article 68, against Agency decisions under the third subparagraph of paragraph 6 of this Article.
8. If the Agency, on basis of the validation made pursuant to paragraph 5, considers that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

#### Article 37

##### Evaluation of applications for renewal

1. On the basis of the available information and a need to review the conclusions of the initial assessment of the application for Union authorisation, the evaluating competent authority that carried out the initial evaluation of the application for Union authorisation shall, within one month after the validation referred to in Article 36(5), decide whether a full evaluation of the application for renewal is necessary.

If the evaluating competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1 to 3 of Article 35. The decision on the application shall be adopted in accordance with paragraph 5 of this Article.

2. If the evaluating competent authority that carried out the initial evaluation of the application for Union authorisation decides that a full evaluation of the application is not necessary, it shall, within *six months* after the validation,

prepare and submit to the Agency a recommendation on the renewal of the authorisation.

Prior to submitting the recommendation to the Agency, the evaluating competent authority shall provide the applicant with an opportunity to provide written or oral comments on the recommendation within one month. The evaluating competent authority shall take due account of these comments when finalising its recommendation.

3. On receipt of the recommendation from the evaluating competent authority, the Agency shall make it available to the competent authorities of other Member States and the applicant and allow a period of three months during which they may submit written comments to it.
4. The Commission may ask the Agency for an opinion on scientific or technical matters raised by a competent authority objecting to the recommendation referred to in paragraph 2. The Agency shall issue an opinion within six months from the date on which the matter was referred to it.
5. At the end of the period referred to in paragraph 3 or on receipt of the opinion of the Agency, the Commission shall adopt a decision to renew, or to refuse to renew, the Union authorisation in accordance with the procedure referred to in Article 76(3). As soon as the Commission has taken a decision, it shall update the information referred to in Article 23(5) in the Union Register of Biocidal Products.
6. Where, for reasons beyond the control of the holder of the Union authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Commission shall grant the renewal of the Union authorisation for the period necessary to complete the evaluation in accordance with the procedure referred to in Article 76(2).

## Chapter VIII

### Cancellation, review and modifications of authorisations

#### Article 38

##### Obligation for notification of new information

1. If the authorisation holder becomes aware of information concerning the authorised biocidal product or the active substance(s) it contains which may affect the authorisation, he shall without delay notify the competent authority that granted the national authorisation and the Agency or, in the case of a Union authorisation, the Commission and the Agency. In particular, the following shall be notified:
  - (a) new knowledge or information on the effects of the active substance or biocidal product for humans, *especially for vulnerable groups*, or the environment;
  - (b) data indicating the potential of the active substance for the development of resistance;

- (c) new knowledge or information indicating that the biocidal product is not sufficiently effective;
  - (d) *changes in the source or composition of the active substance.*
2. The competent authority that granted the national authorisation or in the case of a Union authorisation, the Agency, shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 39.
  3. The competent authority that granted the national authorisation or, in the case of a Union authorisation, the Agency, shall without delay notify competent authorities of other Member States and, where appropriate, the Commission of any such information it received.

Competent authorities of Member States that have issued national authorisations for the same biocidal product under the mutual recognition procedure shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 39.

#### Article 39

##### Cancellation or modification of an authorisation

1. The competent authority of a Member State or, in the case of a Union authorisation, the Commission, may at any time cancel or amend an authorisation it has granted in the following cases:
  - (a) *where there is failure to comply with the requirements referred to in Article 16 or with Union standards for the protection of human health and the environment, particularly those laid down in Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for Community action in the field of marine environmental policy (Marine Strategy Framework Directive)<sup>1</sup>, Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration<sup>2</sup>, Directive 2000/60/EC, Directive 98/83/EC and Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control<sup>3</sup>;*
  - (b) false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted;
  - (c) a condition included in the authorisation has not been complied with;
  - (d) the authorisation holder fails to comply with his obligations resulting from this Regulation;
  - (e) *there are indications that the objectives of Article 4(1)(a)(iv), Article*

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<sup>1</sup> OJ L 164, 25.6.2008, p. 19.

<sup>2</sup> OJ L 372, 27.12.2006, p. 19.

<sup>3</sup> OJ L 24, 29.1.2008, p. 8.



***4(1)(b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may not be achieved.***

2. Where the competent authority or, in the case of a Union authorisation, the Commission, intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give him the opportunity to submit written or oral comments or additional information within a specified time limit. The evaluating competent authority shall take due account of these comments when finalising its decision.
3. Where the competent authority or, in the case of a Union authorisation, the Commission, cancels or amends an authorisation in accordance with paragraph 1, it shall without delay notify the authorisation holder, the competent authorities of other Member States and, where relevant, the Commission.

Competent authorities which have issued authorisations for the same biocidal product under the mutual recognition procedure shall, within four months, cancel or amend the authorisations accordingly, taking into account local circumstances, and shall notify the Commission thereof.

In the case of disagreement between competent authorities of certain Member States, the points of disagreement shall be referred without delay to the Commission and the procedure laid down in Articles 27 and 30 shall apply *mutatis mutandis*.

4. As soon as the competent authority or the Commission in the case of a Union authorisation, has taken a decision to cancel or amend an authorisation, it shall update the information referred to in Article 23(5) relating to the biocidal product concerned in the Union Register of Biocidal Products.

#### Article 40

##### Cancellation of an authorisation at the request of the authorisation holder

The competent authority that has granted the national authorisation or, in case of Union authorisation, the Commission, shall cancel the authorisation at the request of its holder, who shall state the reasons for such request. If such a request concerns a Union authorisation, it shall be submitted to the Agency.

As soon as the competent authority or the Commission in the case of a Union authorisation, has taken a decision to cancel an authorisation, it shall update the information referred to in Article 23(5) information relating to the biocidal product concerned in the Union Register of Biocidal Products.

#### Article 41

##### Modification of an authorisation at the request of the authorisation holder

1. The terms and conditions of an authorisation shall not be changed unless the authorisation has been amended by the competent authority which has previously authorised the biocidal product concerned, or in the case of a Union authorisation, by the Commission.
2. An application by an authorisation holder to amend the terms and conditions

of an authorisation shall be submitted to the competent authorities of all the Member States which have previously authorised the biocidal product concerned, or in the case of a Union authorisation, to the Agency.

The application shall be accompanied by the fees payable under Article 71.

3. ***A modification of an existing authorisation shall fall under one of the following categories of changes:***
  - (a) *administrative change;*
  - (b) *minor change;*
  - (c) *major change.*

#### Article 42

##### ***Detailed procedures on cancellation and modifications***

1. ***In order to ensure the smooth functioning of the cancellation and modification procedures,*** the Commission shall adopt ***further detailed*** measures specifying the criteria and procedures relating to a cancellation of an authorisation or modifications of the terms and conditions of an authorisation under Articles 39 to 41, including a dispute settlement mechanism, ***by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75.***
2. ***The criteria and the procedures referred to in paragraph 1 shall be based on, but not limited to, the following principles:***
  - (a) *a simplified notification procedure shall be applied for administrative changes to the authorisation;*
  - (b) *a reduced evaluation period shall be established for minor changes to the authorisation;*
  - (c) *in the case of major changes the evaluation period shall be proportionate to the extent of the proposed change.*

#### Article 43

##### Period of grace

Notwithstanding Article 82, where the competent authority or, in the case of a biocidal product authorised at Union level, the Commission, cancels or amends an authorisation or decides not to renew it, it shall grant a period of grace for the disposal, storage, placing on the market and use of existing stocks except in cases where continued placing on the market or use of the product would constitute an unacceptable risk to human health or the environment.

The period of grace shall not exceed six months for the placing on the market and an additional maximum period of twelve months for the disposal, storage, and use of existing stocks of the biocidal products concerned.

Article 44  
Parallel trade

1. A competent authority of a Member State (hereinafter 'Member State of introduction') may grant a parallel trade permit for a biocidal product that is authorised in another Member State (hereinafter 'Member State of origin') to be placed on the market and used in the Member State of introduction, if it determines that the biocidal product is ■ identical in composition to a biocidal product already authorised in that Member State (hereinafter the 'reference product').

The applicant who intends to place the biocidal product on the market in the Member State of introduction shall submit the application for a parallel trade permit to the competent authority of the Member State of introduction.

The application shall be accompanied by all the information necessary to demonstrate that the biocidal product is ■ identical to the reference product as defined in paragraph 3.

2. A parallel trade permit shall be granted within two months from submission of an application. The competent authority of the Member State of introduction may request from the competent authority of the Member State of origin additional information necessary to determine whether the product is ■ identical to the reference product. The competent authority of the Member State of origin shall provide the requested information within one month of receiving the request.
3. A biocidal product shall be considered as ■ identical to the reference product if *all* of the following conditions *are* met:
  - (a) *it has been manufactured by the same company or by an associated undertaking or under licence in accordance with the same manufacturing process;*
  - (b) it is *identical* with regard to the *specification and content of the active substances* ■ and *in* the type of formulation;
  - (c) it is either the same or equivalent *with regard to the co-formulants present and the packaging size, material or form*, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.
4. An application for a parallel trade permit shall include the following information and items:
  - (a) name and authorisation number of the biocidal product in the Member State of origin;
  - (b) *the registration numbers of the active substances contained in the product and a letter of access in accordance with Article 50 from the applicant referred to in Article 7;*

- (c) the competent authority of the Member State of origin that authorised the reference product;
- (d) name and address of the authorisation holder in the Member State of origin **and a letter of access in accordance with Article 50 from the authorisation holder**;
- (e) original label and instructions for use with which the biocidal product is distributed in the Member State of origin if it is considered as necessary for the examination by the competent authority of the Member State of introduction;
- (f) name and address of the applicant;
- (g) name to be given to the biocidal product to be distributed in the Member State of introduction;
- (h) a draft label for the product intended to be placed on the market in the Member State of introduction;
- (i) a sample of the product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;
- (j) name and authorisation number of the reference product in the Member State of introduction.

The competent authority of the Member State of introduction may require a translation of the relevant parts of the original instructions for the use referred to in point (e).

5. The parallel trade permit shall prescribe the same conditions for placing on the market and use as the authorisation of the reference product.
6. The parallel trade permit shall be valid for the duration of authorisation of the reference product in the Member State of introduction.

If the authorisation holder of the reference product applies for cancellation of authorisation in accordance with Article 40 and the requirements of Article 16 are still fulfilled, the validity of the parallel trade permit shall expire on the date on which the authorisation of the reference product would have normally expired.

7. Without prejudice to specific provisions in this Article, Articles 38 to 41 and Chapter XIII shall apply *mutatis mutandis* to biocidal products placed on the market under a parallel trade permit.
8. The competent authority of the Member State of introduction may withdraw a parallel trade permit if the authorisation of the introduced biocidal product is withdrawn in the Member State of origin because of safety or efficacy reasons.
9. Where a decision concerning the application for a parallel trade permit is taken

in accordance with the provisions of this Article, the competent authorities of Member States which have taken such a decision shall enter the information referred to in Article 23(5) in the Union Register of Biocidal Products.

## Chapter IX Derogations

### Article 45 Derogation from the requirements

1. By way of derogation from Articles 15 and 16, a competent authority may authorise, for a period not exceeding **four months**, the placing on the market of a biocidal product not complying with the provisions of this Regulation for a limited and controlled use if ***all of the following conditions are met:***
  - (a) such a measure is necessary because of a danger to public health or the environment which cannot be contained by other means;
  - (b) ***the active substances concerned are approved for inclusion in Annex I or evaluated according to Article 4 and a full dossier is provided;***
  - (c) ***if the relevant active substances fall under Article 5 or are classified as candidates for substitution according to Article 9, a mandatory substitution plan has been established and implemented by the applicant or competent authority in order to replace the relevant substances with non-hazardous chemical or non-chemical alternatives within two years of the date of approval; and***
  - (d) ***the application of the product is restricted to professional users who are certified pursuant to the requirements for integrated pest management and the use is appropriately monitored.***

The competent authority referred to in the first subparagraph shall without delay inform the other competent authorities and the Commission of its action and the justification for it. The competent authority shall without delay inform the other competent authorities and the Commission of a revocation of such action.

The Commission shall without delay decide whether, and under what conditions, the action taken by the competent authority may be extended for a period not exceeding 18 months in accordance with the procedure referred to in Article 76(3).

2. In addition to the active substances referred to in Article 15(2) of Regulation (EC) No 1907/2006, active substances manufactured or imported for use in biocidal products which are authorised for placing on the market in accordance with this Article shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of Title II of Regulation (EC) No 1907/2006.

Article 46  
Research and development

1. By way of derogation from Article 15, an experiment or a 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 may only take place in the case of scientific research and development or in the case of product and process-oriented research and development, and under the conditions laid down in the second and third subparagraphs of this paragraph.

In the case of scientific research and development, the person who intends to carry out the experiment or the test shall notify the competent authority prior to the start. The person shall 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 shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The persons concerned shall, if requested, make this information available to the competent authority.

In the case of product and process-oriented research and development, the person who intends to carry out the experiment or the test shall, prior to the placing of the biocidal product or the active substance on the market, notify the information required in the second subparagraph to the competent authority of the Member State where the placing on the market occurs.

2. An unauthorised biocidal product or an active substance for exclusive use in a biocidal product shall not be placed on the market for the purpose of any experiment or test which may involve, or result in, release of the biocidal product into the environment unless the competent authority has assessed the data submitted by the person interested in the placing of such product on the market and issued a national authorisation for this purpose which limits the quantities to be used and the areas to be treated and which may impose further conditions. The competent authority shall without delay inform the Commission and other competent authorities about the issued national authorisation.
3. Where any experiment or test takes place in a Member State other than the Member State where placing on the market of the biocidal product occurs, the applicant shall obtain experiment or test authorisation from the competent authority of the Member State in the territory of which the experiments or tests are to be conducted.

If the proposed experiments or tests referred to in paragraphs 1 and 2 may have harmful effects, *whether immediate or delayed*, on human **health, in particular on the health of children**, or animal health or any unacceptable adverse effect on the environment, **humans, or animals**, the competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The competent authority shall without delay inform the


Commission and other competent authorities about such measures.

4. ***In order to encourage research and development in active substances and biocidal products***, the Commission shall adopt, ***by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75***, measures to specify the overall applicable maximum quantities of active substances or biocidal products that may be released during experiments and the minimum data to be submitted in accordance with paragraph 2 of this Article.



## Chapter X Treated articles or materials

### Article 47 Placing on the market of treated articles or materials

1. Treated materials or articles that incorporate one or more biocidal products shall not be placed on the market unless the ***active substances*** used for treating the materials or articles are ***included in Annex I***.
2. ***The person responsible for placing treated articles or materials on the market shall obtain a letter of certification by the authorisation holder in respect of all biocidal products which have been used in the treatment of those articles or materials or which have been inserted into the articles or materials.***
3. Treated articles or materials shall be labelled with the following information:
  - (a) the words ***"treated with biocidal products"***, followed by the name, ***using wherever possible common nomenclature (e.g. INCI)***, of all active substances that were used to treat the article or materials or that were incorporated in the articles or materials, ***where relevant, and of all active substances which are intended to be released under normal or foreseeable conditions of use from the treated article or material, unless at least equivalent labelling requirements or alternative means to meet information requirements already exist under sector-specific legislation, the names of all nanomaterials being followed by the word "nano" in brackets;***
  - (b)  the biocidal property attributed to treated articles or materials, ***if the biocidal product contained therein will come into direct contact with people and the environment;***
  - (c) any hazard statement or precautionary statement set out in the authorisation for the biocidal product ***if the biocidal product is intended to be released under normal or reasonably foreseeable conditions of use.***

The labelling shall be clearly visible, easily legible, appropriately durable *and* printed *on the article or material*, on the packaging, on the instructions for use or on the warranty of the treated article or material *in the national language or languages of the Member State on whose market the treated article or material is to be placed*.

*In the case of treated materials or articles which are not produced as part of a series, but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the customer with the relevant information.*

*This paragraph shall not apply where such labelling requirements already exist under other Union legislation.*

## Chapter XI

### Data protection and data-sharing

#### Article 48

Protection of information held by competent authorities or the Agency

1. Information submitted for the purposes of this Regulation shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except in one of the following cases:
  - (a) the subsequent applicant has written agreement in the form of a letter of access *in accordance with Article 50* that he can use that information,
  - (b) the relevant time limit for data protection has expired;
  - (c) *the subsequent applicant is also an owner of the information.*
2. When an applicant submits any information to a competent authority or to the Agency, he shall also provide a list of all the information submitted. In the list he shall specify whether he is the owner of the information or whether he only holds a letter of access to that information. In the latter case, the list shall contain the name and contact details of the owner. The applicant shall inform the competent authority or the Agency about any changes in the ownership of the information.
3. On receipt of the list referred to in paragraph 2, the competent authorities shall send it to the Agency.
4. *Each item of information in* the list referred to in paragraph 2 shall be *identified by a unique code and* entered by the Agency, *with all relevant details and linked to the identity of the initial applicant and the information owner*, in the Biocides Data Sharing Register.
5. The Commission, the Agency, the advisory scientific committees set up under Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the



environment<sup>1</sup> and the competent authorities shall have access to the information referred to in paragraph 1.

#### Article 49 Information protection periods

1. Information submitted for the purposes of Directive 98/8/EC or of this Regulation shall benefit from data protection under the conditions laid down in this Article. The protection period for this information shall start when the information is submitted.

Information protected under Directive 98/8/EC **■** for which the protection period expired under Directive 98/8/EC or *information protected under this Article* shall, *on application*, be protected again.

*An entry date shall be individually established for each document that has been given a unique code in accordance with Article 48(4).*

2. The protection period for information submitted in view of the inclusion of an existing active substance in Annex I shall end 10 years after the date of the inclusion of the relevant active substance in Annex I for the particular product-type.

The protection period for information submitted in view of the inclusion of a new active substance in Annex I shall end 15 years after the date of the inclusion of the relevant active substance in Annex I for the particular product-type.

The protection period for information submitted in view of the renewal or review of the inclusion of an active substance in Annex I shall end 5 years after the date of the decision concerning the renewal or the review being taken.

3. The protection period for information submitted in view of the authorisation of a biocidal product containing only existing active substances shall end 10 years after the date of the first authorisation of the product.

The protection period for information submitted in view of the authorisation of a biocidal product containing a new active substance shall end 15 years after the date of the first authorisation of the product.

The protection period for information submitted in view of the renewal or modification of the authorisation of a biocidal product shall end 5 years after the date of the renewal or modification of the authorisation.

**■**

#### Article 50 Letter of access

1. A letter of access shall contain at least the following information:

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<sup>1</sup> OJ L 66, 4.3.2004, p. 45.

- (a) name and contact details of the data owner and the beneficiary;
  - (b) date on which the letter of access takes effect and its expiry date;
  - (c) the submitted information to which the letter of access grants citation rights;
  - (d) the address of the manufacturing facility where the active substance or biocidal product is produced;
  - (e) the conditions under which it may be revoked.
2. Revocation of a letter of access prior to its expiry date shall not affect the validity of the authorisation issued on the basis of the letter of access in question.

#### Article 51

##### Mandatory information sharing

1. ***Given that*** animal testing ***should be avoided***, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort ***where no alternative solution can be employed without producing an impact on humans or animals***. Testing on vertebrate animals shall not be repeated for the purposes of this Regulation.
2. Any person intending to perform tests or studies involving vertebrate animals or non-vertebrate animals (hereinafter the 'prospective applicant'), shall ask the competent authority or the Agency whether such tests or studies have already been submitted in connection with a previous application. The competent authority or the Agency shall verify if there is any data on such tests or studies in the Biocides Data Sharing Register.

Where those tests or studies have already been submitted in connection with a previous application, ***the competent authority or the Agency shall, without delay, assess technical equivalence in relation to the comparison source. If the technical equivalence assessment is positive***, the competent authority or the Agency shall without delay communicate the name and contact details of the owner of the information to the prospective applicant.

Where the data acquired under those tests or studies are still protected under Article 49, and involve tests on vertebrate animals, the prospective applicant shall request from the owner of the information the right to refer to the tests or studies.

Where the data acquired under those tests or studies are still protected under Article 49, and do not involve tests on vertebrate animals, the prospective applicant may request from the owner of the information the right to refer to the tests or studies.

#### Article 52

##### Compensation for mandatory information sharing

1. Where a request has been made in accordance with Article 51(2), the prospective applicant and the owner of the information shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.
2. Where such agreement is reached, the owner of the information shall make available to the prospective applicant the information and shall give the prospective applicant permission to refer to the data owner's tests or studies.
3. Where no such agreement is reached two months after the request was made according to Article 51(2), the prospective applicant shall without delay inform the Agency and the owner of the information thereof. Within two months of being informed about the failure to reach an agreement, the Agency shall give the prospective applicant the right to refer to the tests or studies involving tests on vertebrate animals. National courts shall decide on the proportionate share of the cost that the prospective applicant shall pay to the data owner.
4. The costs of sharing the tests or studies shall be determined in a fair, transparent and non-discriminatory manner.
5. An appeal may be brought, in accordance with Article 68, against Agency decisions under paragraph 3 of this Article.

#### Article 53

##### Use of data for subsequent applications for authorisations

1. In the case of a biocidal product which has already been authorised in accordance with Articles 15, 25 or 28, and where all periods of protection of information according to Article 49 have expired, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant, ***and if the periods of protection of information according to Article 49 have not expired, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant pursuant to Article 52, in both cases*** in so far as the subsequent applicant can provide evidence that the biocidal product is similar to, and its active substances technically equivalent to, the one formerly authorised, including in terms of degree of purity and nature of impurities.

An appeal may be brought, in accordance with Article 68, against Agency decisions under the first subparagraph of this paragraph.

2. Notwithstanding paragraph 1, subsequent applicants shall provide the following information accordingly to the receiving competent authority or the Agency:
  - (a) all data necessary for the identification of the biocidal product, including its composition;

- (b) the information needed to identify the active substance and to establish technical equivalence of the active substance;
- (c) all data necessary for the evaluation of substances of concern contained in the biocidal product;
- (d) the data needed to demonstrate that the biocidal product has comparable efficacy to the biocidal product formerly authorised in accordance with Articles 15, 25 or 28.

Chapter XII  
Information and communication

Section 1  
Monitoring and reporting

Article 54  
Compliance with requirements

1. ***Competent authorities shall perform official controls in order to ensure that manufacturers of active substances which are placed on the market for use in biocidal products have submitted to the Commission the information about the active substances referred to in Annex II or are in the possession of a letter of access to a dossier which complies with the requirements of Annex II.***
2. Competent authorities shall make the necessary arrangements for biocidal products which have been placed on the market on their own or incorporated in treated materials to be monitored to establish whether they comply with the requirements of this Regulation. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products<sup>1</sup> shall apply accordingly.
3. Competent authorities shall carry out official controls in order to enforce compliance with this Regulation.
4. Every *year*, starting in 2013, competent authorities shall submit to the Commission a report on the implementation of this Regulation in their respective territories. ***The implementation reports shall be published annually on the relevant website of the Commission.*** The reports shall include:
  - (a) information on the results of official controls carried out in accordance with paragraph 3;
  - (b) information on any poisonings involving biocidal products, ***especially regarding vulnerable groups, and the actions undertaken to lower the risk of future cases arising;***

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<sup>1</sup> OJ L 218, 13.8.2008, p. 30.

***(c) information on the impact on the environment.***

5. The Commission shall draw up a report on the implementation of this Regulation and, in particular, on the functioning of the Union authorisation procedure and mutual recognition, by ***1 January 2019 and every three years thereafter***. The Commission shall submit the report to the European Parliament and the Council.

***On the basis of the report, the Commission shall assess the desirability of proposing amendments to this Regulation.***

6. ***Not later than ...\****, the Commission shall submit to the European Parliament and Council a report on the assessment of the risks to human health and the environment presented by the use of nanomaterials in biocidal products and on specific measures to be taken with regard to them.
7. ***Not later than...\*\****, the Commission shall draw up a report on the impact of the spread of biocidal products in the environment. The Commission shall submit the report to the European Parliament and the Council.

#### Article 55 Confidentiality

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents<sup>1</sup> and the rules of the Management Board of the Agency, adopted in accordance with Article 118(3) Regulation (EC) No 1907/2006, shall apply to documents held by the Agency for the purposes of this Regulation.
2. Disclosure of the following information shall be deemed to undermine the protection of the commercial interests of the person concerned:
  - (a) details of the full composition of a biocidal product;
  - (b) the precise use, function or application of a substance or mixture;
  - (c) the precise tonnage of the substance or mixture manufactured or placed on the market;
  - (d) links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;
  - (e) ***names and addresses of manufacturers of the active substances, including location of manufacturing sites;***

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\* ***Two years after the entry into force of this Regulation.***

\*\* ***Five years after the entry into force of this Regulation.***

<sup>1</sup> OJ L 145, 31.5.2001, p. 43.

***(f) the location of a biocidal product's manufacturing site.***

However, where urgent action is essential to protect human health, safety or the environment, the Agency or the competent authorities ***shall take the necessary measures to*** disclose the information referred to in this paragraph.

3. Any person who submits information related to an active substance ***or a biocidal product*** to the Agency or a competent authority for the purposes of this Regulation can request that the information in Article 56(2) not be made available including a justification as to why the disclosure of the information could be harmful for his or any other concerned party's commercial interests.
4. Information accepted as confidential by a competent authority or the Agency shall be treated as confidential by the other competent authorities, the Agency and the Commission.

Article 56

Electronic public access

1. The following information held by the competent authorities, the Agency or, as appropriate, the Commission on active substances shall be made, free of charge, publicly available ***in a single database, in a structured format, at least on the relevant website of the Commission:***
  - (a) without prejudice to point (f) of paragraph 2, the name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature for active substances fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/ 2008:
    - (i) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
    - (ii) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
    - (iii) hazard class 4.1;
    - (iv) hazard class 5.1;
  - (b) if applicable, the name of the active substance as given in European Inventory of Existing Commercial Chemical Substances (EINECS);
  - (c) the classification and labelling of the active substance;
  - (d) physicochemical data concerning the active substance and data on pathways and environmental fate;
  - (e) ***where the active substance qualifies as persistent, bio-accumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in***

*accordance with Annex XIII to Regulation (EC) No 1907/2006 or as an endocrine disrupter or where it has been classified in accordance with Regulation (EC) No 1272/2008 as carcinogenic, mutagenic, neurotoxic, immunotoxic, toxic to reproduction or sensitising, a clear reference to that effect;*

- (f) the result of each toxicological and ecotoxicological study;
- (g) acceptable exposure level or predicted no-effect concentration established in accordance with Annex VI to this Regulation;
- (h) the guidance on safe use provided in accordance with Annex II and Annex III to this Regulation;
- (i) analytical methods if requested in accordance with Annex II or III to this Regulation which make it possible to detect a dangerous substance when discharged into the environment, *including water resources and drinking water*, as well as to determine the direct exposure of humans.

If the information listed in the first subparagraph concerns a new active substance, it shall be made publically available only after the date on which the inclusion of the new active substance in Annex I to this Regulation becomes effective.

2. The following information on active substances whether on their own, in mixtures or in materials or articles, or information on biocidal products shall be made publicly available, free of charge, except where a party submitting the information submits a justification in accordance with Article 55(3), accepted as valid by the competent authority, the Agency or, as appropriate, the Commission, as to why such publication is potentially harmful for the commercial interests of the applicant or any other party concerned:
  - (a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;
  - (b) the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e);
  - (c) information, other than that listed in paragraph 1, contained in the safety data sheet;
  - (d) the trade name(s) of the substance;
  - (e) subject to Article 24 of Regulation (EC) No 1272/2008, the name in the IUPAC nomenclature for active substances referred to in point (a) of paragraph 1 that are only used as one or more of the following:
    - (i) in scientific research and development;
    - (ii) in product and process orientated research and development.

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 content of the active substance or substances in the biocidal product and the name of the biocidal product;
  - (e) physical and chemical data concerning the biocidal product;
  - (f) any ways of rendering the active substance or biocidal product harmless;
  - (g) a summary of the results of the tests required pursuant to Article 18 to establish the product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;
  - (h) recommended methods and precautions to reduce dangers from handling, storage, transport and use as well as from fire or other hazards;
  - (i) safety data sheets;
  - (j) methods of analysis referred to in point (c) of Article 16(1);
  - (k) methods of disposal of the product and of its packaging;
  - (l) procedures to be followed and measures to be taken in the case of spillage or leakage;
  - (m) first aid and medical advice to be given in the case of injury to persons.
4. ***Public access shall be granted free of charge to an inventory containing details of biocidal products authorised pursuant to Article 16(5) and of the corresponding manufacturers.***

#### Article 57

##### Record-keeping and reporting

1. Producers, importers and professional users of biocidal products shall keep records of the biocidal products they produce, place on the market or use for at least **10 years**. They shall make available the relevant information contained in these records to the competent authority on request.
2. The Commission shall adopt implementing measures to specify the form and content of the information in the records, and to ensure the uniform application of paragraph 1 in accordance with the procedure referred to in Article 76(3).

#### Section 2

##### Information about biocidal products



## Article 58

### Classification, packaging and labelling of biocidal products

1. Biocidal products shall be classified, packaged and labelled in accordance with Directive 1999/45/EC and, where applicable, Regulation (EC) No 1272/2008 and the approved summary of the biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 20(2).

In addition, products which may be mistaken for food, drink or feedingstuffs shall be packaged to minimise the likelihood of such a mistake being made. If they are available to the general public, they shall contain components to discourage their consumption.

2. Labels shall not be misleading and, in any case, shall not mention indications such as 'low-risk biocidal product', 'non-toxic' or 'harmless'. In addition, the label must show clearly and indelibly the following information:
  - (a) the identity of every active substance and its concentration in metric units;
  - (b) the authorisation number allocated to the biocidal product by the competent authority;
  - (c) ***whether the product contains nanomaterials and any specific related risks, and, following each reference to nanomaterials, the word "nano" in brackets;***
  - (d) the type of mixture;
  - (e) the uses for which the biocidal product is authorised;
  - (f) directions for use and the dose rate, expressed in metric units ***or in another manner which is meaningful and comprehensible to the user,*** for each use provided for under the terms of the authorisation;
  - (g) particulars of likely direct or indirect adverse side effects and any directions for first aid;
  - (h) if accompanied by a leaflet, the sentence "Read attached instructions before use";
  - (i) ***where applicable, warnings for vulnerable groups;***
  - (j) directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging;
  - (k) the formulation batch number or designation and the expiry date relevant to normal conditions of storage;
  - (l) 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;

- (m) where applicable, the categories of users to which the biocidal product is restricted;
- (n) where applicable, information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water;
- (o) for biocidal products containing micro-organisms, labelling requirements in accordance with Directive 2000/54/EC.

By way of derogation from the first subparagraph, where this is necessary because of the size or the function of the biocidal product, the information referred to in points (d), (f), (g), (j), (k), (l) and (n) may be indicated on the packaging or on an accompanying leaflet integral to the packaging.

3. **Biocidal products placed on the market of *the territories of the Member States shall be* labelled in *the* national language or languages *of the country where they are marketed.***

#### Article 59 Safety Data Sheets

The safety-data sheets shall be prepared and made available in accordance with Annex II of Regulation (EC) No 1907/2006, for biocidal products classified as hazardous, and in accordance with the requirements of Article 31 of that Regulation, for active substances used exclusively in biocidal products.

***Safety data sheets shall contain the following information:***

- (a) ***important categories of product whose active substance has been included in Annex I;***
- (b) ***the name of at least one Member State where the biocidal product has been authorised;***
- (c) ***the authorisation number of the biocidal product as such or present in a treated article or material.***

#### Article 60 Union Register of Biocidal Products

1. A Union Register for Biocidal Products shall be established and maintained by the Commission.
2. The Union Register for Biocidal Products shall be used for the exchange of

information between competent authorities, the Agency and the Commission.

3. Applicants shall use the Union Register for Biocidal Products to generate the application form for all procedures relating to the authorisation of biocidal products, the mutual recognition and the parallel trade permit.
4. Competent authorities shall update in the Union Register for Biocidal Products the information relating to biocidal products which have been authorised within their territory or for which a national authorisation has been refused, amended, renewed or cancelled. The Commission shall update the information relating to biocidal products which have been authorised in the Union or for which a Union authorisation has been refused, amended, renewed or cancelled.
5. ***In order to ensure the proper functioning of the Union Register for Biocidal Products***, the Commission may adopt, ***by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75***, detailed rules on the types of information to be entered in the **Register** and the procedures related to it **.**

#### Article 61

##### Biocides Data Sharing Register

1. The Biocides Data Sharing Register shall be established and maintained by the Agency.
2. The Biocides Data Sharing Register shall contain information provided by competent authorities and the Agency in accordance with paragraphs 3 and 4 of Article 48.

The Register shall only be accessible to competent authorities, the Agency and the Commission. Competent authorities and the Agency shall respond to all enquiries by prospective applicants concerning information contained in the Biocides Data Sharing Register in order to facilitate sharing of information and shall on request provide the contact details of the owner of the information in question and a statement whether and for how long the information is subject to data protection under this Regulation.

#### Article 62

##### *Access to information*

1. ***Member States shall ensure that all professional users, distributors and advisers have access to appropriate information on the benefits, risks and safe use of biocidal products.***
2. ***Member States shall take the necessary measures to provide the public with information about the benefits and risks associated with biocidal products and ways of minimising the use of those products.***
3. ***The Commission shall make available on the internet a list of all active substances available within the internal market.***

***The persons responsible for the placing on the market of biocidal products***

*shall make a list of such products available on the internet. This website shall serve to increase transparency for consumers and to facilitate an easy and fast collection of data on the properties and conditions of use of these products.*

*Access to those websites shall not be subject to any restriction or condition and their content shall be kept up to date. The relevant website addresses shall be indicated on the labelling of the biocidal products in a visible manner.*

#### Article 63 Advertising

1. Any advertisement for biocidal products shall be accompanied by the sentences ‘Use biocides safely. Always read the label and product information before use’. The sentences shall be clearly distinguishable in relation to the whole advertisement.
2. Advertisers may replace the word ‘biocides’ in the prescribed sentences with a clear reference to the product-type as set out in Annex V being advertised.
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 human health or the environment. In any case, the advertising of a biocidal product shall not mention indications such as ‘low-risk biocidal product’, ‘non-toxic’ or ‘harmless’.

#### Article 64 Poison control

1. Member States shall appoint a body or bodies 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.

Member States may decide to appoint the body or bodies that have already been appointed in accordance with Article 45 of Regulation (EC) No 1272/2008 to carry out the tasks under this Article.

2. The bodies appointed by the Member States shall provide all the requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used for the following purposes:
  - (a) to meet medical demand by formulating preventive and curative measures, in particular in case of emergency;
  - (b) where requested by the Member State, to undertake statistical analysis to identify where improved risk management measures may be needed.

#### Chapter XIII The Agency

Article 65  
Role of the Agency

The Agency shall carry out the tasks conferred on it by Chapters II, III, IV, VI, VII, VIII, IX, X, XI, XII and XIV of this Regulation.

Article 66  
Biocidal Products Committee

1. A Biocidal Products Committee is hereby established within the Agency.

The Biocidal Products Committee shall be responsible for preparing the opinion of the Agency on the following issues:

- (a) applications for inclusion and renewal of inclusion of active substances in Annex I;
  - (b) review of inclusion of active substances in Annex I;
  - (c) identification of active substances which are candidates for substitution;
  - (d) applications for Union authorisation of biocidal products and for renewal, cancellation and modifications of Union authorisation;
  - (e) scientific and technical matters in the case of objections to mutual recognition;
  - (f) any other questions that arise from the operation of this Regulation relating to risks to human health or the environment.
2. Articles 85, 87 and 88 of Regulation (EC) No 1907/2006 concerning the establishment, the composition and the qualification and interests of the Committee for Risk Assessment shall apply *mutatis mutandis* to the Biocidal Products Committee.

The Biocidal Products Committee may establish working groups and delegate certain tasks to those working groups.

The members of the Biocidal Products Committee shall be supported by the scientific and technical resources available to the Member States. Member States shall provide adequate scientific and technical resources to the members of the Biocidal Products Committee that they have nominated. Competent authorities of Member States shall facilitate the activities of the Biocidal Products Committee and their working groups.

Article 67  
Operation of the Biocidal Products Committee and the Secretariat of the Agency

1. Articles 78 to 84, 89 and 90 of Regulation (EC) No 1907/2006 shall apply *mutatis mutandis* taking into account the role of the Agency with respect to this Regulation.

2. The Secretariat of the Agency referred to in point (g) of Article 76(1) of Regulation (EC) No 1907/2006 shall undertake the following tasks:
  - (a) establishing and maintaining the Biocides Data Sharing Register;
  - (b) performing the tasks relating to the validation of the applications referred to in Articles 7(4), 11(3) and 34(2) of this Regulation;
  - (c) providing technical and scientific guidance and tools for the application of this Regulation by the Commission and the competent authorities of Member States;
  - (d) providing advice and assistance to applicants, *and in particular to SMEs*, for the inclusion of an active substance in Annex I of this Regulation or for a Union authorisation;
  - (e) preparing explanatory information on this Regulation;
  - (f) establishing and maintaining database(s) with information on active substances and biocidal products;
  - (g) at the request of the Commission, providing technical and scientific support to improve cooperation between the Union, the competent authorities, international organisations and third countries on scientific and technical issues relating to biocidal products;
  - (h) notification of decisions taken by the Agency;
  - (i) provision of formats for submission of information to the Agency;
  - (j) *providing guidance and tools for the use phase, particularly:*
    - *measures for integrated pest management, for specified vermin,*
    - *monitoring biocidal product use,*
    - *best practice of biocidal product use to limit use of such products to the minimum necessary dose,*
    - *pest management in sensitive areas like schools, workplaces, kindergartens, public spaces, lake, canal and river sides, geriatric care centres,*
    - *technical equipment for biocidal product application and its inspection.*
3. The Secretariat shall make the information identified in Article 56(1) and (2) in the database(s) publicly available, free of charge, over the internet, except where a request made under Article 55(3) is considered justified. The Agency shall make other information in the databases available on request in accordance with Article 55.

## Article 68 Appeal

1. An appeal against decisions of the Agency taken pursuant to Articles 7(5), 11(4), 34(3), 36(6), 52(3) and 53(1) shall lie with the Board of Appeal.

Articles 92(1) and (2), 93 and 94 of Regulation (EC) No 1907/2006 shall apply to appeal procedures lodged under this Regulation.

A fee may be payable by a person bringing an appeal in accordance with Article 71(2) of this Regulation.

2. An appeal lodged pursuant to paragraph 1 shall have suspensive effect.

## Article 69 The budget of the Agency

1. For the purposes of this Regulation, the revenues of the Agency shall consist of:
  - (a) a subsidy from the Union, entered in the general budget of the European Union (Commission Section);
  - (b) the fees paid by undertakings;
  - (c) any charges paid to the Agency for services provided under this Regulation;
  - (d) any voluntary contribution from the Member States.
2. Revenue and expenditure for activities related to this Regulation and those relating to activities under Regulation (EC) No 1907/2006 shall be dealt with separately in the Agency's budget with a separate budgetary and accounting reporting.

Revenue of the Agency referred to in Article 96(1) of Regulation (EC) No 1907/2006 shall not be used for carrying out tasks under this Regulation.

## Article 70 Formats and software for submission of information to the Agency

The Agency shall specify formats and make them available free of charge, and shall specify software packages and make them available on its website for submissions to the Agency. The competent authorities and applicants shall use these formats and packages in their submissions to the Agency pursuant to this Regulation.

The format of the technical dossier referred to in Articles 6(1), 11(1), 18 and 36(4) shall be IUCLID.

## Chapter XIV Final provisions

Article 71  
Fees and charges

1. The Commission shall establish rules concerning:
  - (a) the system of fees payable to the Agency;
  - (b) the harmonised structure of fees;
  - (c) the circumstances under which a proportion of the fees is to be transferred to the competent authority of the evaluating Member State;
  - (d) the partial reimbursement of the fee in the event that the applicant fails to submit the information requested within the deadline during validation of the application.

Those measures shall be adopted *by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75.*

2. The harmonised structure of fees and conditions of payment shall be based on the following principles:
    - (a) a reduced fee shall be set for small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC; *this shall have no bearing on the responsibility of the relevant competent authority to carry out a careful assessment in accordance with the provisions of this Regulation;*
    - (b) the fee structure shall take into account whether information has been submitted jointly or separately;
    - (c) *the fee structure shall take into account whether the product submitted for authorisation complies with the criteria for a low-risk product;*
    - (d) in duly justified circumstances and where it is accepted by the competent authority or the Agency, it shall be possible to waive the fee;
- 
- (e) the structure and amount of the fees shall take account of the work required by this Regulation to be carried out by the Agency and the competent authorities and shall be fixed at such level as to ensure that the revenue derived from the fees when combined with other sources of the Agency's revenue pursuant to this Regulation is sufficient to cover the cost of the services delivered.
3. Member States shall oblige those who have placed or are seeking to place biocidal products on the market and those supporting inclusion of active substances in Annex I to pay fees in accordance with the harmonised structure of fees and conditions of payment to be adopted in accordance with paragraph 1.



4. In accordance with the rules referred to in paragraph 1, the Agency shall oblige those who have placed or are seeking to place biocidal products on the market and those supporting inclusion of active substances in Annex I to pay fees. The structure and the amount of fees payable to the Agency shall be determined in accordance with paragraph 1.

The Agency may collect charges for other services it provides.

#### Article 72 Competent authorities

1. Member States shall designate a competent authority or competent authorities responsible for the application of this Regulation.

Member States shall inform the Commission of the names and addresses of the designated competent authorities by 1 January 2013. Member States shall, without undue delay, inform the Commission of any changes to the names and addresses of the competent authorities.

2. The Commission shall make publicly available the list of the competent authorities.

#### Article 73 *Exercise of the delegation*

1. *The power to adopt the delegated acts referred to in Articles 5(1)(d), 6(4), 8(5), 12(5), 13(1), 14, 16(10), 19(3), 21(5), 25(6), 28(8), 42(1), 46(4), 60(5), 71(1), 77 and 82(1) shall be conferred on the Commission for a period of five years following the entry into force of this Regulation. The Commission shall draw up a report in respect of the delegated power at the latest six months before the end of the five year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 74.*
2. *As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.*
3. *The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 74 and 75.*

#### Article 74 *Revocation of the delegation*

1. *The delegation of power referred to in Articles 5(1)(d), 6(4), 8(5), 12(5), 13(1), 14, 16(10), 19(3), 21(5), 25(6), 28(8), 42(1), 46(4), 60(5), 71(1), 77 and 82(1) may be revoked at any time by the European Parliament or by the Council.*
2. *The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the*

*final decision is taken, indicating the delegated power which could be subject to revocation and possible reasons for a revocation.*

- 3. The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the Official Journal of the European Union.*

#### *Article 75*

##### *Objections to delegated acts*

- 1. The European Parliament or the Council may object to a delegated act within a period of three months from the date of notification.*

*At the initiative of the European Parliament or the Council that period shall be extended by one month.*

- 2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the Official Journal of the European Union and shall enter into force on the date stated therein.*
- 3. If either the European Parliament or the Council objects to a delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.*

#### *Article 76*

##### *Standing Committee*

- 1. The Commission shall be assisted by the Standing Committee on Biocidal Products.*
- 2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.*
- 3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.*

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.



#### *Article 77*

##### *Adaptation to scientific and technical progress*

*In order to take account of technical progress, the Commission shall, by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75, adapt the Annexes to scientific and technical progress.*

Article 78  
Updating of Annex I

By 1 January 2013, the Commission shall, in accordance with the procedure referred to in Article 76(3), amend Annex I with effect from the date of applicability of this Regulation in order to take into account any amendment to Annex I adopted under Directive 98/8/EC since the entry into force of this Regulation.

Article 79  
Penalties

Member States shall lay down the provisions on penalties applicable to infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than 1 December 2015 and shall notify the Commission without delay of any subsequent amendment affecting them.

*Article 80  
National helpdesks in Member States*

*Member States shall establish national helpdesks to provide advice to applicants, in particular to SMEs, and any other interested parties on their respective responsibilities and obligations under this Regulation. Those national helpdesks shall be in addition to any assistance provided by the Agency under Article 67(2)(d).*

Article 81  
Safeguard clause

Where, on the basis of new evidence, a Member State has justifiable grounds to consider that a biocidal product, although satisfying the requirements of this Regulation, constitutes a serious *immediate or long-term* risk to human *health, in particular as regards children and vulnerable groups*, or animal health or to the environment, *or to achieving the quality standards laid down in Directive 2000/60/EC*, it may take appropriate provisional measures. The Member State shall without delay inform the Commission and the other Member States thereof and give reasons for its decision **█**.

Article 82  
Transitional measures

1. The Commission shall carry on with the work programme for the systematic

examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC and achieve it by 14 May 2014. ***In order to ensure a smooth transition***, the Commission may adopt, ***by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75 of this Regulation***, implementing rules to carry out the work programme and to specify the related rights and obligations of the competent authorities and the participants in the programme, ***and, depending upon the progress of the work programme, a decision to extend the duration of the work programme for a determined period.***

***In order to progress with*** the work programme, the Commission shall decide, ***by means of delegated acts in accordance with Article 73 and subject to the conditions of Articles 74 and 75 of this Regulation***, that an active substance shall be included in Annex I of this Regulation and under which conditions, or, in cases where the requirements of Article 4 of this Regulation are not satisfied or where the requisite information and data have not been submitted within the prescribed period, that such active substance shall not be included in Annex I of this Regulation. The decision shall specify the date on which the inclusion in Annex I becomes effective.

2. By way of derogation from Articles 15(1), 16(1) and 18(1), and without prejudice to paragraphs 1 and 3, a Member State may continue to apply its current system or practice of placing biocidal products on the market until two years after the date on which the inclusion in Annex I becomes effective. It may, in particular, according to its national rules, authorise the placing on the market in its territory of a biocidal product containing existing active substances which are evaluated under Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC<sup>1</sup> but which are not yet listed in Annex I to this Regulation for that product type.

In derogation from the first subparagraph, in the case of a decision not to include an active substance in Annex I of this Regulation, a Member State may continue to apply its current system or practice of placing biocidal products on the market no longer than 12 months after the applicability date of a decision taken in accordance with the third subparagraph of paragraph 1.

3. Following a decision to include a particular active substance in Annex I of this Regulation Member States shall ensure that authorisations for biocidal products containing that active substance are granted, modified or cancelled as appropriate in accordance with this Regulation within two years from the date on which the inclusion becomes effective.

To that effect, applications for authorisation of biocidal products containing only existing active substances shall be submitted to the competent authorities of the Member States no later than the date which the inclusion of the active substance(s) in Annex I becomes effective. In the case of biocidal products

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<sup>1</sup> OJ L 325, 11.12.2007, p. 3.

containing more than one active substance, applications for authorisation shall be submitted no later than the date on which the inclusion of the last active substance becomes effective.

Biocidal products, for which an application for a product authorisation has not been submitted in accordance with the second subparagraph, shall no longer be placed on the market after the date on which the inclusion becomes effective. Disposal, storage and use of existing stocks of biocidal products for which an application for authorisation has not been submitted in accordance with the second subparagraph are allowed until *six months* after the date on which the inclusion becomes effective.

4. Biocidal products for which the competent authority of the Member State has rejected an application for authorisation submitted under paragraph 3 or has decided not to grant authorisation, shall no longer be placed on the market with effect from six months after such a rejection or a decision.

#### Article 83

##### Transitional measures concerning active substances evaluated under Directive 98/8/EC

1. The Agency shall be responsible for coordinating the evaluation process of dossiers submitted after 1 January 2012 and shall facilitate the preparation of the evaluation by providing organisational and technical support to the Member States and the Commission.
2. Dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by 1 January 2013 shall continue to be evaluated by the competent authorities in accordance with the provisions of Directive 98/8/EC and, where relevant, Regulation (EC) No 1451/2007.

Notwithstanding paragraph 1, the Agency shall also be responsible for coordinating the evaluation process of dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by 1 January 2013 and shall facilitate the preparation of the evaluation by providing organisational and technical support to the Member States and the Commission from 1 January 2014.

#### Article 84

##### Transitional measures concerning low-risk biocidal products registered under Directive 98/8/EC

1. Low-risk biocidal products as defined in Article 2(1) (b) of Directive 98/8/EC shall be registered in accordance with point (i) of Article 3(2) of Directive 98/8/EC. The provisions of Directive 98/8/EC shall apply to these products until the expiry of the registration. The registration shall not be renewable.
2. Applications for the registration of low-risk biocidal products as defined in point (b) of Article 2(1) of Directive 98/8/EC shall be submitted at the latest twelve months after the date on which the inclusion in Annex IA becomes effective.

Low-risk biocidal products as defined in point (b) of Article 2(1) of Directive 98/8/EC for which an application was submitted in accordance with the first subparagraph may continue to be placed on the market until the date of the decision granting the registration or refusing to grant the registration. In the case of a refusal to grant a registration to place such low-risk biocidal product on the market, such low-risk biocidal product shall no longer be placed on the market within six months after such decision.

Low-risk biocidal products as defined in point (b) of Article 2(1) of Directive 98/8/EC for which an application was not submitted in accordance with the first subparagraph may continue to be placed on the market until six months after the date referred to in paragraph 1 of this Article.

Disposal, storage and use of existing stocks of low-risk biocidal products which are not authorised for the relevant use by the competent authority are allowed until twelve months after the date of the decision referred to in the second subparagraph or twelve months after the date referred to in the third subparagraph, whichever is the later.

3. This Regulation shall apply to low-risk biocidal products as defined in point (b) of Article 2(1) of Directive 98/8/EC as of the expiry of the registration referred to in paragraph 1 of this Article.

#### Article 85

##### Transitional measures concerning in situ generated active substances

1. Applications for the authorisation of substances, mixtures and devices considered as biocidal products in accordance with the second sentence of point (a) of Article 3(1) which were available on the market on ...\* shall be submitted at the latest by 1 January 2017. ***This paragraph shall not apply to active substances generated in situ for the purpose of disinfecting drinking water.***
2. Substances, mixtures and devices considered as biocidal products in accordance with the second sentence of point (a) of Article 3(1) which were available on the market on ...\* and for which an application was submitted in accordance with paragraph 1 may continue to be placed on the market until the date of the decision granting the authorisation or refusing to grant the authorisation. In the case of a refusal to grant an authorisation to place such biocidal product on the market, such biocidal product shall no longer be placed on the market within six months after such decision.

Substances, mixtures and devices considered as biocidal products in accordance with the second sentence of point (a) of Article 3(1) which were available on the market on ...\* and for which an application was not submitted in accordance with paragraph 1 may continue to be placed on the market until six months after the date referred to in paragraph 1.

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\* Date of entry into force of this Regulation.

\* Date of entry into force of this Regulation.

Disposal, storage and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission are allowed until 12 months after the date of the decision referred to in the first subparagraph or 12 months after the date referred to in the second subparagraph, whichever is the later.

#### Article 86

##### Transitional measures concerning treated articles and materials

By way of derogation from Article 47, treated articles and materials that incorporate biocidal products which are not authorised in the Union or in at least one Member State and which were available on the market on ...\* may, until the date of a decision granting authorisation to these biocidal products, continue to be placed on the market if the application for authorisation is submitted at the latest by **1 January 2015**. In the event of a refusal to grant an authorisation to place a biocidal product on the market, treated articles and materials that incorporate such biocidal product shall no longer be placed on the market within six months after such decision.

***Disposal and storage of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission shall be allowed until 12 months after the date of the decision referred to in the first subparagraph of Article 85(2) or 12 months after the date referred to in the second subparagraph of Article 85(2), whichever is the later.***

#### Article 87

##### Transitional measures concerning food contact materials

1. Applications for the authorisation of biocidal products which are food contact materials and which were available on the market on ...\* shall be submitted at the latest 1 January 2017.

Food contact materials which were available on the market on ...\* for which an application was submitted in accordance with paragraph 1 may continue to be placed on the market until the date of the decision granting the authorisation or refusing to grant the authorisation. In the event of a refusal to grant an authorisation to place such biocidal product on the market, such biocidal product shall no longer be placed on the market within six months after such decision.

Food contact materials which were available on the market on ...\* for which an application was not submitted in accordance with paragraph 1 may continue to be placed on the market until six months after the date referred to in paragraph 1.

2. Disposal, storage and use of existing stocks of biocidal products which are not

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\* Date of entry into force of this Regulation.

authorised for the relevant use by the competent authority or the Commission is allowed until 12 months after the date of the decision referred to in the second subparagraph of paragraph 1 or 12 months after the date referred to in the third subparagraph of paragraph 1, whichever is the later.

#### Article 88

Transitional measures concerning access to the active substance dossier

1. ***By 1 January 2015, manufacturers of existing active substances which are on the market for use in biocidal products shall submit to the Agency a dossier or a letter of access to a dossier which complies with the requirements of Annex II for each of these active substances.***

***For the purpose of subparagraph 1, Article 52(3) shall apply to all data included in the dossier.***

***The applicant for the authorisation of a biocidal product containing an active substance for which a letter of access has been submitted in accordance with subparagraph 1 shall be allowed to use that letter of access for the purposes of Article 18(1).***

2. ***The Agency shall make publicly available the list of manufacturers which have submitted a dossier or a letter of access to a dossier in accordance with paragraph 1.***
3. ***Biocidal products containing existing active substances for which a dossier or a letter of access to a dossier has not been submitted in accordance with paragraph 1 shall not be placed on the market after 1 January 2015.***

***Disposal, storage and use of existing stocks of biocidal products for which a dossier or a letter of access to a dossier has not been submitted in accordance with paragraph 1 is allowed until 1 January 2016.***

4. ***For the purpose of paragraph 3, competent authorities shall carry out official controls as required by Article 54(3).***

#### Article 89

Repeal

Without prejudice to Article 83 and 84, Directive 98/8/EC is hereby repealed.

References to the repealed Directive shall be construed as references to this Regulation and be read in accordance with the correlation table set out in Annex VII.

#### Article 90

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.



It shall apply from 1 January 2013.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at

For the European Parliament  
The President

For the Council  
The President

## ANNEX I

### LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS FOR INCLUSION IN BIOCIDAL PRODUCTS

*Substances listed in Annex I do not cover nanomaterials, except where specifically mentioned.*

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 82(3) (except for products containing more than one active substance, for which the deadline to comply with Article 82(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 (*)
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	<p>Authorisations are subject to the following conditions:</p> <ol style="list-style-type: none"> <li>(1) the product may only be sold to and used by professionals trained to use it;</li> <li>(2) appropriate risk mitigation measures are included for operators and bystanders;</li> <li>(3) concentrations of sulfuryl fluoride in remote tropospheric air are monitored.</li> </ol> <p>Reports of the monitoring referred to in point (3) are to be transmitted by authorisation holders directly to the Commission every fifth year starting from 1 January 2009.</p>
dichlofluanid	N- (Dichlorofluoromethyl	960 g/kg	1 March 2009	28 February 2011	28 February 2019	8	Authorisations are subject to the following

	thio)-N',N'-dimethyl-N-phenylsulfamide EC No: 214-118-7 CAS No: 1085-98-9						conditions:  (1) Products authorised for 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.
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	Authorisations are subject to the following conditions:  In view of the risk identified for the soil, surface water and groundwater compartments, products shall not 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 16 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 shall be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses shall be collected for reuse or disposal.
Difethialone	3-[3-(4'-bromo[1,1'biphenyl]-4-yl)-1,2,3,4-tetrahydronaphth-1-yl]-4-hydroxy-2H-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 shall be considered a candidate for substitution in

	<p>benzothioapyran-2-one</p> <p>EC No: n/a</p> <p>CAS No: 104653-34-1</p>						<p>accordance with Article 9.</p> <p>Authorisations are subject to the following conditions:</p> <ol style="list-style-type: none"> <li>(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.</li> <li>(2) Products shall contain an aversive agent and, where appropriate, a dye.</li> <li>(3) Products shall not be used as tracking powder.</li> <li>(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.</li> </ol>
etofenprox	<p>3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether</p> <p>EC No: 407-980-2</p> <p>CAS No: 80844-07-1</p>	970 g/kg	1 February 2010	31 January 2012	31 January 2020	8	<p>Authorisations are subject to the following conditions:</p> <p>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 shall be used with appropriate personal protective equipment.</p>
tebuconazole	<p>1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol</p>	950 g/kg	1 April 2010	31 March 2012	31 March 2020	8	<p>Authorisations are subject to the following conditions:</p> <p>In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation</p>

	EC No: 403-640-2 CAS No: 107534-96-3						<p>measures shall 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 shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal.</p> <p>In addition, products shall not be authorised for the <i>in situ</i> 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 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures.</p>
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	
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	<p>Authorisations are subject to the following conditions:</p> <p>In view of the assumptions made during the risk assessment, 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 other means.</p> <p>In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall 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 shall be stored after treatment under shelter or on</p>

							<p>impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal.</p> <p>In addition, products shall not be authorised for the <i>in situ</i> 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 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures.</p>
Difenacoum	<p>3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin</p> <p>EC No: 259-978-4</p> <p>CAS No: 56073-07-5</p>	960 g/kg	1 April 2010	31 March 2012	31 March 2015	14	<p>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 shall be considered a candidate for substitution in accordance with Article 9.</p> <p>Authorisations are subject to the following conditions:</p> <ol style="list-style-type: none"> <li>(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.</li> <li>(2) Products shall contain an aversive agent and, where appropriate, a dye.</li> <li>(3) Products shall not be used as tracking powder.</li> <li>(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</li> </ol>

							resistant and secured bait boxes.
K-HDO	Cyclohexylhydroxydi azene 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	<p>Authorisations are subject to the following conditions:</p> <p>(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 16 and Annex VI;</p> <p>(2) in view of the assumptions made during the risk assessment, products shall 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;</p> <p>(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.</p>
IPBC	3-iodo-2-propynyl butylcarbamate  EC No: 259-627-5  CAS No: 55406-53-6	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	<p>Authorisations are subject to the following conditions:</p> <p>In view of the assumptions made during the risk assessment, 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 other means.</p> <p>In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall be taken to protect those</p>

							compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal.
Thiabendazole	2-thiazol-4-yl-1H-benzimidazole EC No: 205-725-8 CAS No: 148-79-8	985 g/kg	1 July 2010	30 June 2012	30 June 2020	8	<p>Authorisations are subject to the following conditions:</p> <p>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, 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 other means.</p> <p>In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall 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 shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal.</p> <p>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 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures.</p>
thiamethoxam	thiamethoxam	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Authorisations are subject to the following



	<p>EC No: 428-650-4</p> <p>CAS No: 153719-23-4</p>					<p>conditions:</p> <p>In view of the assumptions made during the risk assessment, 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 other means.</p> <p>In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall 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 shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal.</p> <p>Products shall not be authorised for the <i>in situ</i> 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 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures.</p>
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(\*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website:

<http://ec.europa.eu/comm/environment/biocides/index.htm>

ANNEX II  
Data requirements for active substances

1. Dossiers on active substances shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL), Predicted Environmental Concentration (PEC) and Predicted No-Effect Concentration (PNEC).

***Dossiers for Tier 1 shall contain all information necessary for identifying the properties and risks of active substances over their life cycle, in particular pursuant to Article 5, 9 and 17 of this Regulation.***

2. Information which is however not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied.
3. A detailed and full description of the studies conducted and of the methods used or a bibliographical reference to those methods shall be included.

The formats made available by the Commission must be used for submission of the dossiers. In addition, the special software package (IUCLID) made available by the Commission must be used for those parts of the dossiers to which IUCLID applies. Formats and further guidance on data requirements and dossier preparation are available on the Agency homepage.

4. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006<sup>1</sup>. ***Methods listed in Annex I do not cover nanomaterials, except where specifically mentioned.*** However, if a method is inappropriate or not described, other methods shall be used which are *scientifically satisfactory* and *the validity of which* must be justified in the application.
5. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes<sup>2</sup>, and, in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances<sup>3</sup> or other international standards recognised as being equivalent by the Commission or the Agency.
6. Where testing is done, a detailed description (specification) of the material used and its impurities must be provided.
7. Where test data exist that have been generated before ...\* by methods other than those

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<sup>1</sup> OJ L 142, 31.5.2008, p.1.

<sup>2</sup> OJ L 358, 18.12.1986, p. 1.

<sup>3</sup> OJ L 50, 20.2.2004, p. 44.

\* Date of entry into force of this Regulation.

laid down in Regulation (EC) No 440/2008, the adequacy of such data for the purposes of this Regulation and the need to conduct new tests according to the Regulation (EC) No 440/2008 must be decided by the competent authority of the Member State concerned, on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrate animals.

8. All available relevant knowledge and information in literature should be provided.
9. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall also be provided.

TITLE 1 – Chemical substances  
Tier I

Information required to support the inclusion of a substance in Annex I is listed in the table below. The standard data package consists of tier I data. Tier II data may need to be submitted depending on the characteristics and intended use of the active substance or on the conclusions of the assessment of the tier I data, in particular if a danger for health or the environment has been identified.

The table also provides specific rules according to which the required information may be omitted, replaced by other information or adapted in another way. If the conditions are met to allow adaptations, the applicant shall clearly state this fact and the reasons for each adaptation under the appropriate headings in the dossier.

Conditions for not requiring a specific test that are set out in the appropriate test methods in the Regulation (EC) No 440/2008 that are not repeated in column 2, also apply.

Before new tests are carried out to determine the properties listed in this Annex, all available in vitro data, in vivo data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. In vivo testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on *intelligent* testing strategies should be *sought from experts in alternatives to animal experimentation* in addition to this Annex.

Information required:	Unless otherwise indicated, all data shall be provided at Tier I.	Specific rules for adaptation from standard information required:
1. Applicant		
1.1. Name and address		
1.2. Active substance manufacturer (name, address, location of plant)		
2. Identity of the active substance		
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 VIIA to Directive 92/32/EEC		
3. Physical and chemical properties of the active substance		
3.1. State of the substance at 20°C and 101,3 kPa		
3.2. Melting/freezing point		3.2. The study does not need to be conducted below a lower limit of -20°C.
3.3. Boiling point		3.3. The study does not need to be conducted: – for gases; or – for solids which either melt above 300°C or decompose before boiling. In such cases the boiling point under reduced pressure may be estimated or measured; or – for substances which decompose before boiling (e.g. auto-oxidation, rearrangement, degradation, decomposition, etc.).
3.4. Relative density		3.4. The study does not need to be conducted if: – the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density is sufficient; or – the substance is a gas. In this case, an estimation based on calculation shall be made from its molecular weight and the Ideal Gas Laws.
3.5. Vapour pressure		3.5. The study does not need to be conducted if the melting point is above 300°C. If the melting point is between 200°C and

		300°C, a limit value based on measurement or a recognised calculation method is sufficient.
3.6. Surface tension		<p>3.6. The study need only be conducted if:</p> <ul style="list-style-type: none"> <li>– based on structure, surface activity is expected or can be predicted; or</li> <li>– surface activity is a desired property of the material.</li> </ul> <p>If the water solubility is below 1 mg/l at 20°C the test does not need to be conducted.</p>
3.7. Water solubility		<p>3.7. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>– the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours); or</li> <li>– the substance is readily oxidisable in water.</li> </ul> <p>If the substance appears "insoluble" in water, a limit test up to the detection limit of the analytical method shall be performed.</p>
3.8. Partition coefficient n-octanol/water		<p>3.8. The study does not need to be conducted if the substance is inorganic. If the test cannot be performed (e.g. the substance decomposes, has a high surface activity, reacts violently during the performance of the test or does not dissolve in water or in octanol, or it is not possible to obtain a sufficiently pure substance), a calculated value for log P as well as details of the calculation method shall be provided.</p>
3.9. Flash-point		<p>3.9. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>– the substance is inorganic; or</li> <li>– the substance only contains volatile organic components with flash-points above 100°C for aqueous solutions; or</li> <li>– the estimated flash-point is above 200°C; or</li> <li>– the flash-point can be accurately predicted by interpolation from existing characterised materials.</li> </ul>
3.10. Flammability		<p>3.10. The study does not need to be conducted:</p> <ul style="list-style-type: none"> <li>– if the substance is a solid which possesses explosive or pyrophoric properties. These properties should always be considered before considering flammability; or</li> <li>– for gases, if the concentration of the flammable gas in a mixture with inert gases is so low that, when mixed with air, the concentration is all time below the lower limit; or</li> <li>– for substances which spontaneously ignite when in contact with air.</li> </ul>

3.11. Explosive properties		<p>3.11. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>– there are no chemical groups associated with explosive properties present in the molecule; or</li> <li>– the substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than –200; or</li> <li>– the organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties, but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500 °C; or</li> <li>– for mixtures of inorganic oxidising substances (UN Division 5.1) with organic materials, the concentration of the inorganic oxidising substance is: <ul style="list-style-type: none"> <li>– less than 15 %, by mass, if assigned to UN Packaging Group I (high hazard) or II (medium hazard)</li> <li>– less than 30 %, by mass, if assigned to UN Packaging Group III (low hazard).</li> </ul> </li> </ul> <p>Note: Neither a test for propagation of detonation nor a test for sensitivity to detonative shock is required if the exothermic decomposition energy of organic materials is less than 800 J/g.</p>
3.12. Self-ignition temperature		<p>3.12. The study does not need to be conducted:</p> <ul style="list-style-type: none"> <li>– if the substance is explosive or ignites spontaneously with air at room temperature; or</li> <li>– for liquids non flammable in air, e.g. no flash point up to 200°C; or</li> <li>– for gases having no flammable range; or</li> <li>– for solids, if the substance has a melting point &lt; 160°C, or if preliminary results exclude self-heating of the substance up to 400°C.</li> </ul>
3.13. Oxidising properties		<p>3.13. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>– the substance is explosive; or</li> <li>– the substance is highly flammable; or</li> <li>– the substance is an organic peroxide; or</li> <li>– the substance is incapable of reacting exothermically with combustible materials, for example on the basis of the chemical structure (e.g. organic substances not containing oxygen or halogen atoms and these elements are not chemically bonded to nitrogen or oxygen, or inorganic substances</li> </ul>

		<p>not containing oxygen or halogen atoms).</p> <p>The full test does not need to be conducted for solids if the preliminary test clearly indicates that the test substance has oxidising properties.</p> <p>Note that as there is no test method to determine the oxidising properties of gaseous mixtures, the evaluation of these properties must be realised by an estimation method based on the comparison of the oxidising potential of gases in a mixture with that of the oxidising potential of oxygen in air.</p>
3.14. Granulometry		3.14. The study does not need to be conducted if the substance is marketed or used in a non solid or granular form.
3.15. Stability in organic solvents and identity of relevant degradation products	Tier II	3.15. Stability in organic solvents and identity of relevant degradation products Only required if stability of the substance is considered to be critical.
3.16. Dissociation constant	Tier II	3.16. Dissociation constant
3.17. Viscosity	Tier II	3.17. Viscosity
3.18. Solubility in organic solvents, including effect of temperature on solubility <sup>1</sup>	Tier II	
3.19. Stability in organic solvents used in biocidal products and identity of relevant breakdown products <sup>2</sup>	Tier II	
4. Methods of 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		
4.3. Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, in/on food or feedingstuffs and other products where relevant	Tier II	
5. Effectiveness against target organisms and intended uses		
5.1. Function, e.g. fungicide, rodenticide, insecticide, bactericide		

<sup>1</sup> These data must be submitted for the purified active substance of stated specification.

<sup>2</sup> These data must be submitted for the active substance of stated specification.

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		
6. Toxicological profile for man and animals including metabolism		
6.1. Skin irritation or skin corrosion		<p>6.1. The assessment of this endpoint shall comprise the following consecutive steps:</p> <ol style="list-style-type: none"> <li>(1) an assessment of the available human and animal data,</li> <li>(2) an assessment of the acid or alkaline reserve,</li> <li>(3) in vitro study for skin corrosion,</li> <li>(4) in vitro study for skin irritation.</li> </ol> <p>Steps 3 and 4 do not need to be conducted if:</p> <ul style="list-style-type: none"> <li>– the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes; or</li> <li>– the substance is flammable in air at room temperature; or</li> <li>– the substance is classified as very toxic in contact with skin; or</li> <li>– an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight).</li> </ul>
6.1.1. In vivo skin irritation		█
6.2. Eye irritation		<p>6.2. The assessment of this endpoint shall comprise the following consecutive steps:</p> <ol style="list-style-type: none"> <li>1) an assessment of the available human and animal data,</li> <li>(2) an assessment of the acid or alkaline reserve,</li> <li>(3) in vitro study for eye irritation.</li> </ol> <p>Step 3 does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>– the available information indicates that the criteria are met for classification as corrosive</li> </ul>



		to the skin or irritating to eyes; or – the substance is flammable in air at room temperature.
6.2.1. In vivo eye irritation		█
6.3. Skin sensitisation		6.3. The assessment of this endpoint shall comprise the following consecutive steps:  (1) an assessment of the available human, animal and alternative data,  (2) In vivo testing.  Step 2 does not need to be conducted if:  – the available information indicates that the substance should be classified for skin sensitisation or corrosivity; or  – the substance is a strong acid (pH < 2,0) or base (pH > 11,5); or  – the substance is flammable in air at room temperature.  The <i>reduced</i> Murine Local Lymph Node Assay ( <i>rLLNA</i> ) is the first-choice method for in vivo testing <i>as a screening test to distinguish between sensitisers and non-sensitisers. The full LLNA should be performed when it is known that an assessment of sensitisation potency is required.</i> Only in exceptional circumstances should another test be used. Justification for the use of another test shall be provided.
6.4. Mutagenicity		6.4. Appropriate in vivo mutagenicity studies shall be considered in case of a positive result in any of the genotoxicity studies in Tier I.  <i>For new substances, it is advisable to assess the parameters of an in-vivo micronucleus test as part of a 28- or 90-day repeated dose toxicity study.</i>
6.4.1. In vitro gene mutation study in bacteria		6.4.1. Further mutagenicity studies shall be considered in case of a positive result. <i>Such a study does not need to be conducted in the case of antimicrobial substances or formulations.</i>
6.4.2. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study		6.4.2. The study does not usually need to be conducted if:  – adequate data from an in vivo cytogenicity test are available or  – the substance is known to be carcinogenic category 1A or 1B or mutagenic category 1A, 1B or 2.
6.4.3. In vitro gene mutation study in mammalian cells, if a negative result in Tier I, sections 6.4.1. and section 6.4.2.		6.4.3. The study does not █ need to be conducted if adequate data from a reliable in vivo mammalian gene mutation test are available <i>elsewhere</i> .
6.4.4. In vivo genotoxicity study	Tier II	6.4.4. If there is a positive result in any of the in vitro genotoxicity studies in Tier I and

		<p>there are no results available from an in vivo study already, an appropriate in vivo somatic cell genotoxicity study shall be proposed by the applicant. <b><i>For new substances, it should be possible to assess the parameters of an in-vivo micronucleus test as part of a 28- or 90-day repeated dose toxicity study.</i></b></p> <p>If there is a positive result from an in vivo somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.</p>
6.5. Acute toxicity		<p>6.5. The study/ies do(es) not generally need to be conducted if:</p> <ul style="list-style-type: none"> <li>– the substance is classified as corrosive to the skin.</li> </ul> <p>In addition to the oral route (6.5.1), for substances other than gases, the information mentioned under 6.5.2 to 6.5.3 shall be provided for at least one other route. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route need be provided.</p>
6.5.1. By oral route		<p>6.5.1. The study need not be conducted if a study on acute toxicity by the inhalation route (6.5.2) is available.</p> <p><b><i>The Acute Toxic Class Method is the first-choice method for in-vivo testing. Only in exceptional circumstances should another test be used, in which case a justification shall be provided.</i></b></p>
6.5.2. By inhalation		<p>6.5.2. Testing by the inhalation route is appropriate <b><i>only if this constitutes the primary route of human exposure</i></b> taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size. <b><i>The Acute Toxic Class Method is the first-choice method for in-vivo testing. Only in exceptional circumstances should the classic “lethal concentration” (LC50) test be used. Justification for the use of another test shall be provided.</i></b></p>
6.5.3. By dermal route		█
6.6. Repeated dose toxicity		
6.6.1. Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure.		<p>6.6.1. The short-term toxicity study (28 days) does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>– a reliable sub-chronic (90 days) or chronic toxicity study is available <b><i>or planned</i></b>, provided that an appropriate species, dosage, solvent and route of administration were <b><i>or</i></b></li> </ul>

		<p><i>are to be</i> used; or</p> <ul style="list-style-type: none"> <li>– where a substance undergoes immediate disintegration and there are sufficient data on the cleavage products; or</li> <li>– relevant human exposure can be excluded in accordance with Annex IV section 3.</li> </ul> <p><b><i>Testing shall be conducted via the oral route unless:</i></b></p> <p><b><i>(1) the primary route of human exposure will be dermal, and one of the following conditions is met:</i></b></p> <ul style="list-style-type: none"> <li>– <i>the physicochemical and toxicological properties, including an in-vitro dermal penetration study (i.e. OECD TG 428), indicate that dermal bioavailability will be substantial; or</i></li> <li>– <i>significant dermal toxicity or dermal penetration is recognised for structurally related substances.</i></li> </ul> <p><b><i>(2) the primary route of human exposure will be inhalation, taking into account the vapour pressure of the substance and likely frequency, magnitude and duration of exposure to aerosols, particles or droplets of an inhalable size.</i></b></p> <p><b><i>Testing shall only be carried out via one exposure route. Estimates of toxicity via other routes shall be based upon pharmacokinetic modelling.</i></b></p>
		<p>The sub-chronic toxicity study (90 days) (Tier II, section 6.6.2) shall be proposed by the applicant <i>in lieu of a 28-day study</i> if: the frequency and duration of human exposure indicates that a <b>█</b> study <i>of &gt; 1 month and &lt; 12 months</i> is appropriate and <b>█</b> available data indicate that the <b><i>kinetics or other properties of a substance or its metabolites are such that adverse effects could go undetected</i></b> in a short-term toxicity study.</p> <p><b><i>For substances related on a molecular level to known organ-specific toxicants (e.g. neurotoxicity), additional relevant parameters should ideally be examined in the context of a 28-day or 90-day study in lieu of a stand-alone, e.g. neurotoxicity study. Further stand-alone studies should be limited to exceptional circumstances.</i></b></p>
<p>6.6.2. Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure.</p>	<p>Tier II</p>	<p>6.6.2. The sub-chronic toxicity study (90 days) does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>– a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the</li> </ul>

		<p>NOAEL-90 days for the same route of exposure; or</p> <ul style="list-style-type: none"> <li>– a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used; or</li> <li>– a substance undergoes immediate disintegration and there are sufficient data on the cleavage products (both for systemic effects and effects at the site of uptake); or</li> <li>– the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day "limit test", particularly if such a pattern is coupled with limited human exposure.</li> </ul>
		<p><b>Testing shall be conducted via the oral route unless:</b></p> <p><b>(1) the primary route of human exposure will be dermal, and one of the following conditions is met:</b></p> <ul style="list-style-type: none"> <li>– the physicochemical and toxicological properties, including an in-vitro dermal penetration study (i.e. OECD TG 428), indicate that dermal bioavailability will be substantial; or</li> <li>– significant dermal toxicity or dermal penetration is recognised for structurally related substances.</li> </ul> <p><b>(2) the primary route of human exposure will be inhalation, taking into account the vapour pressure of the substance and the likely frequency, magnitude and duration of exposure to aerosols, particles or droplets of an inhalable size.</b></p> <p><b>Testing shall be carried out via one exposure route. Estimates of toxicity via other routes shall be based upon pharmacokinetic modelling.</b></p> <p><b>For substances related on a molecular level to known organ-specific toxicants (e.g. neurotoxicity), additional relevant parameters should ideally be examined in the context of a 28-day or 90-day study in lieu of a standalone, e.g. neurotoxicity study. Further stand-alone studies should be limited to exceptional circumstances.</b></p>
6.6.3. Long-term repeated toxicity study (≥ 12 months)	Tier II	<p>6.6.3. A long-term repeated <i>dose</i> toxicity study (≥12 months) may be proposed by the applicant or required <i>only</i> if:</p> <ul style="list-style-type: none"> <li>– the frequency, <i>magnitude</i> and duration of human exposure, <i>indicate</i> that a <i>chronic risk assessment</i> is appropriate; and</li> <li>– <i>if the application of an appropriate uncertainty factor would not be sufficiently</i></li> </ul>

		<p><i>protective for risk assessment purposes.</i></p> <p><i>If carcinogenicity data are also required and are not already available, long-term repeated dose and carcinogenicity studies should be carried out using the OECD TG 453 combination study protocol.</i></p>
6.6.4. Further studies	Tier II	<p>6.6.4. Further studies shall be proposed by the applicant or may be required in case of:</p> <ul style="list-style-type: none"> <li>– toxicity of particular concern (e.g. serious/severe effects); or</li> <li>– indications of an effect for which the available evidence is inadequate for toxicological evaluation and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity); or</li> <li>– particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity is observed).</li> </ul> <p>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered.</p>
6.7. Reproductive toxicity	Tier II	<p>6.7. The studies need not be conducted if:</p> <ul style="list-style-type: none"> <li>– the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or</li> <li>– the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or</li> <li>– the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.</li> </ul> <p>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered.</p>

		<p>If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.</p>
<p>6.7.1. Screening for reproductive/developmental toxicity, one species (OECD 421 or 422), if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from in vitro methods that the substance may be a developmental toxicant.</p>		<p>6.7.1. This study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>– the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or</li> <li>– the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or</li> <li>– <b>there is no significant</b> human exposure in accordance with Annex IV section 3; or</li> <li>– a pre-natal developmental toxicity study (Tier II, 6.7.2) or a <b>one- or</b> two-generation reproductive toxicity study (Tier II, section 6.7.3) is available.</li> </ul> <p>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for <b>pre-natal</b> development toxicity must be considered.</p> <p>If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.</p> <p>In cases where there are serious concerns about the potential for adverse effects on fertility or development, <b>an enhanced one-generation reproductive toxicity study, with or without a pre-natal developmental toxicity module</b> (Tier II, section 6.7.3), may be proposed by the applicant instead of the screening study.</p>
<p>6.7.2. Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (B.31 of the Regulation (EC) No 440/2008 or OECD 414).</p>	Tier II	<p>6.7.2. The study shall be performed on one species <b>only, ideally in combination with an enhanced one-generation reproductive toxicity study as applicable (Tier II, section 6.7.3).</b></p>
<p>6.7.3. <b>Pending EU-level or international acceptance of the test</b></p>	Tier II	<p>█</p>

<i>method, enhanced one-generation</i> reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure		
6.8. Toxicokinetics		
6.8.1. <i>In-vitro</i> dermal absorption study		
6.9. Carcinogenicity study	Tier II	<p>6.9. A carcinogenicity study may be proposed by the applicant or may be required if:</p> <ul style="list-style-type: none"> <li>– the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure; and</li> <li>– the substance is classified as mutagen category 2 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-neoplastic lesions.</li> </ul> <p>If the substance is classified as mutagen category 1A or 1B, the default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required.</p> <p><i>If long-term toxicity data are also required and are not already available, carcinogenicity and long-term repeated dose studies should be carried out using the OECD TG 453 combination study protocol.</i></p>
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		
6.11. Additional studies	Tier II	Additional data which may be required depending on the characteristics and intended use of the active substance.
6.11.1. Neurotoxicity study	Tier II	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.
6.11.2. Toxic effects on livestock and pets	Tier II	
6.11.3. Studies related to the exposure of the active substance to humans	Tier II	
6.11.4. Food and feedingstuffs	Tier II	If the active substance is to be used in mixtures 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 9.1 shall be required.
6.11.5. 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 9.1, Title I of Annex III shall be required	Tier II	
6.11.6. 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	Tier II	
6.11.7. Mechanistic study - any studies necessary to clarify effects reported in toxicity studies	Tier II	
7. Ecotoxicological profile including environmental fate and behaviour		
7.1. Aquatic toxicity		7.1. Long-term toxicity testing shall be proposed by the applicant if the assessment performed under Tier I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate



		test(s) depends on the results of the assessment performed under Tier I.
<p>7.1.1. Short-term toxicity testing on invertebrates (preferred species Daphnia)</p> <p>The applicant may consider long-term toxicity testing instead of short-term.</p>		<p>7.1.1. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>– there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes; or</li> <li>– a long-term aquatic toxicity study on invertebrates is available; or</li> <li>– adequate information for environmental classification and labelling is available.</li> </ul> <p>The long-term aquatic toxicity study on Daphnia (Tier II, section 7.1.5) shall be considered if the substance is poorly water soluble.</p>
7.1.2. Growth inhibition study aquatic plants (algae preferred)		7.1.2. The study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.
7.1.3. Short-term toxicity testing on fish: <i>threshold approach</i> .		<p>7.1.3. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>– there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes; or</li> <li>– a long-term aquatic toxicity study on fish is available.</li> </ul>
7.1.4. Activated sludge respiration inhibition testing		<p>7.1.4. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> <li>– there is no emission to a sewage treatment plant; or</li> <li>– there are mitigating factors indicating that microbial toxicity is unlikely to occur, for instance the substance is highly insoluble in water; or</li> <li>– the substance is found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant.</li> </ul> <p>The study may be replaced by a nitrification inhibition test if available data show that the substance is likely to be an inhibitor of microbial growth or function, in particular nitrifying bacteria.</p>
7.1.5. Long-term toxicity testing on invertebrates (preferred species Daphnia), (unless already provided as part of Tier I requirements)	Tier II	

7.1.6. Long-term toxicity testing on fish, <i>if indicated by substance use profile and/or physical-chemical properties</i>  The information shall be provided for one of the sections 7.1.6.1, 7.1.6.2 or 7.1.6.3.	Tier II	
7.1.6.1. Fish early-life stage (FELS) toxicity test	Tier II	
7.1.6.2. Fish short-term toxicity test on embryo and sac-fry stages	Tier II	
7.1.6.3. Fish, juvenile growth test	Tier II	
7.2. Degradation		7.2. Further biotic degradation testing shall be considered if the assessment performed under Tier I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the assessment performed under Tier I and may include simulation testing in appropriate media (e.g. water, sediment or soil).
7.2.1. Biotic		
7.2.1.1. Ready biodegradability		7.2.1.1. The study does not need to be conducted if the substance is inorganic.
7.2.1.2. Simulation testing on ultimate degradation in surface water	Tier II	7.2.1.2. The study need not be conducted if: – the substances is highly insoluble in water; or – the substance is readily biodegradable.
7.2.1.3. Soil simulation testing (for substances with a high potential for adsorption to soil)	Tier II	7.2.1.3. The study need not be conducted: – if the substance is readily biodegradable; or – if direct and indirect exposure of soil is unlikely.
7.2.1.4. Sediment simulation testing (for substances with a high potential for adsorption to sediment)	Tier II	7.2.1.4. The study need not be conducted: – if the substance is readily biodegradable; or – if direct and indirect exposure of sediment is unlikely.
7.2.2. Abiotic		
7.2.2.1. Hydrolysis as a function of pH.		7.2.2.1. The study does not need to be conducted if: – the substance is readily biodegradable; or – the substance is highly insoluble in water.
7.2.3. Identification of degradation products	Tier II	7.2.3. Unless the substance is readily biodegradable
7.3. Fate and behaviour in the environment		
7.3.1. Adsorption/desorption screening		7.3.1. The study does not need to be conducted if: – based on the physicochemical properties the substance can be expected to have a low

		<p>potential for adsorption (e.g. the substance has a low octanol water partition coefficient); or</p> <p>– the substance and its relevant degradation products decompose rapidly.</p>
7.3.2. Bioaccumulation in aquatic species, preferably fish	Tier II	<p>7.3.2. The study need not be conducted if:</p> <p>– the substance has a low potential for bioaccumulation (for instance a log Kow &lt; 3) and/or a low potential to cross biological membranes; or</p> <p>– direct and indirect exposure of the aquatic compartment is unlikely.</p>
7.3.3. Additional information on adsorption/desorption depending on the results of the study required under Tier I	Tier II	<p>7.3.3. The study need not be conducted if:</p> <p>– the substance has a low potential for bioaccumulation (for instance a log Kow &lt; 3) and/or a low potential to cross biological membranes; or</p> <p>– based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient); or</p> <p>– the substance and its degradation products decompose rapidly.</p>
7.4. Additional studies	Tier II	
7.4.1. Any other biodegradability tests that are relevant from the results in section 7.2.1.1	Tier II	
7.4.2. Phototransformation in air (estimation method), including identification of breakdown products	Tier II	
7.4.3. If the results from section 7.4.2 indicate the need to do so, or the active substance has an overall low or absent abiotic degradation, then the tests described in sections 10.1.1 and 10.2.1 and, where appropriate, section 10.3 shall be required	Tier II	
8. Measures necessary to protect man, animals and the environment	Tier II	Additional data which may be required depending on the characteristics and intended use of the active substance.
8.1. Identification of any substances falling within the scope of List I or List II of the Annex to Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances <sup>1</sup> , <i>Annex I Part B to Directive 98/83/EC on the quality of water intended for human consumption, or Annex X to Directive</i>	Tier II	

<sup>1</sup> OJ L 20, 26.1.1980, p. 43.

<p><b>2000/60/EC.</b></p> <p>Notes:</p> <p>(1) These data must be submitted for the purified active substance of stated specification.</p> <p>(2) These data must be submitted for the active substance of stated specification.</p>		
9. Additional human health-related studies	Tier II	Additional data which may be required depending on the characteristics and intended use of the active substance.
9.1. Food and feedingstuffs studies	Tier II	
9.1.1. Identification of degradation and reaction products and of metabolites of the active substance in treated or contaminated foods or feedingstuffs	Tier II	
9.1.2. Behaviour of the residue of the active substance, its degradation products and, where relevant, its metabolites on the treated or contaminated food or feedingstuffs including the kinetics of disappearance	Tier II	
9.1.3. 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	Tier II	
9.1.4. Estimation of potential or actual exposure of the active substance to humans through diet and other means	Tier II	
9.1.5. 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	Tier II	
9.1.6. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the active substance	Tier II	
9.1.7. Proposed acceptable residues and the justification of their acceptability	Tier II	
9.1.8. Any other available information that is relevant	Tier II	
9.1.9. Summary and evaluation of data submitted under 1.1 to 1.8	Tier II	
9.2. Other test(s) related to the exposure to humans  Suitable test(s) and a reasoned case will be required	Tier II	
10. Additional studies on fate and behaviour in the environment	Tier II	10. 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 this Section shall be conducted.
10.1. Fate and behaviour in soil	Tier II	
10.1.1. 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	Tier II	
10.1.2. Absorption and desorption in at least three soil types and, where relevant, absorption and desorption of metabolites and degradation products	Tier II	
10.1.3. Mobility in at least three soil types and where relevant mobility of metabolites and degradation products	Tier II	
10.1.4. Extent and nature of bound residues	Tier II	
10.2. Fate and behaviour in water	Tier II	
10.2.1. Rate and route of degradation in aquatic systems (as far as is not covered by section 7.2) including identification of metabolites and degradation products	Tier II	
10.2.2. Absorption and desorption in water (soil sediment systems) and, where relevant, absorption and desorption of metabolites and degradation products	Tier II	
10.3. Fate and behaviour in air If the active substance is to be used in mixtures 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 7.4.3	Tier II	
11. Additional ecotoxicological studies	Tier II	11. 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 this Section shall be conducted.
11.1. Effects on birds	Tier II	
█		
11.1.1. Short-term toxicity - eight-day dietary study in █ one species █	Tier II	
11.1.2. Effects on reproduction	Tier II	<i>11.1.2. This test is not required if the dietary toxicity study (section 11.1.1) shows that the LC50 is above 2 000 mg/kg.</i>
█		
11.2. Effects on other non-target organisms	Tier II	

11.2.1. Acute toxicity to honeybees and other beneficial arthropods, e.g. predators. ■	Tier II	
11.2.2. Toxicity to earthworms and to other soil non-target macro-organisms	Tier II	
11.2.3. Effects on soil non-target micro-organisms	Tier II	
11.2.4. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk	Tier II	
12. Classification and labelling		
13. Summary and evaluation of Sections 1 to 12		

## TITLE 2 - Micro-organisms

Dossiers shall be prepared on strain level of the micro-organism unless information is submitted that shows that the species is known to be sufficiently homogeneous regarding all characteristics, or the applicant provides other arguments.

Where the micro-organism has been genetically modified within the meaning of Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC<sup>1</sup>, a copy of the evaluation of the data concerning the assessment of the risks to the environment as established in Article 4(2) of that Directive, shall also be submitted.

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 Title 1.

The following data will be required to support submissions.

1. Identity of the micro-organism
  - 1.1. Applicant
  - 1.2. Manufacturer
  - 1.3. Name and species description, strain characterisation
    - 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

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<sup>1</sup> OJ L 106, 17.4.2001, p. 1.

- 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 micro-organisms
  - 1.4.3. Analytical profile of batches
2. 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
3. Additional 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 Annex 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 micro-organism
  - 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
  - 3.12. Classification of the micro-organism in the relevant risk group specified in Article 2 of Directive 2000/54/EC
4. 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)
  5. 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

***The assessment of this endpoint shall comprise the following consecutive steps:***

- (1) an assessment of the available human, animal and alternative data,***
- (2) in-vivo testing.***

***The reduced Murine Local Lymph Node Assay (rLLNA) is the first-choice method for in vivo testing as a screening test to distinguish between sensitisers and non sensitisers. The full LLNA should be performed when it is known that an assessment of sensitisation potency is required. Only in exceptional circumstances should another test be used, in which case a justification shall be provided.***



5.2.2. Acute toxicity, pathogenicity, and infectiveness

***Testing shall be conducted via the oral route unless the primary route of human exposure is expected to be inhalation. Testing shall be carried out via only a single exposure route.***

5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness

5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness

***Testing by the inhalation route is appropriate only if this constitutes the primary route of human exposure.***



5.2.3. In vitro genotoxicity testing

5.2.4. Cell culture study

5.2.5. Information on short-term toxicity and pathogenicity

***Testing shall be conducted via the oral route unless the primary route of exposure is expected to be inhalation. Testing shall be carried out via only a single exposure route.***

5.2.5.1. Health effects after repeated inhalatory exposure

***Testing by the inhalation route is appropriate only if this constitutes the primary route of human 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

***Testing may be waived if there is no evidence of specific toxicity in earlier studies.***

5.4. Genotoxicity — In vivo studies in somatic cells

***For new substances, it should be possible to assess the parameters of an in-vivo micronucleus test as part of a repeated exposure study.***

5.5. Genotoxicity — In vivo studies in germ cells

***Testing may be waived if there is no evidence of genotoxicity in somatic cell studies.***

END OF TIER II

- 5.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation
- 6. Residues in or on treated materials, food and feedingstuffs
  - 6.1. Persistence and likelihood of multiplication in or on treated materials, feedingstuffs or foodstuffs
  - 6.2. Further information required
    - 6.2.1. Non-viable residues
    - 6.2.2. Viable residues
  - 6.3. Summary and evaluation of residues in or on treated materials, food and feedingstuffs
- 7. Fate and behaviour in the environment
  - 7.1. Persistence and multiplication
    - 7.1.1. Soil
    - 7.1.2. Water
    - 7.1.3. Air
  - 7.2. Mobility
  - 7.3. Summary and evaluation of fate and behaviour in the environment
- 8. Effects on non-target organisms
  - 8.1. Effects on birds

*An avian dietary toxicity study in a single species may be proposed where a substance use profile indicates the potential for significant exposure to birds.*

*An avian reproduction study is not generally required, and is not appropriate if the dietary toxicity study shows that the LC50 is above 5 000 mg/kg.*
  - 8.2. Effects on aquatic organisms
    - 8.2.1. Effects on fish
    - 8.2.2. Effects on freshwater invertebrates
    - 8.2.3. Effects on algae growth
    - 8.2.4. Effects on plants other than algae
  - 8.3. Effects on bees
  - 8.4. Effects on arthropods other than bees
  - 8.5. Effects on earthworms

- 8.6. Effects on soil micro-organisms
- 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
- 9. Summary and evaluation of sections 1 to 8 including conclusions of the risk assessment and recommendations

## ANNEX III

### Data requirements for biocidal products

1. Dossiers on *biocidal products* shall contain the information needed to establish *that exposure is below the Threshold of Toxicological Concern (TTC)*, or where relevant, *to establish* Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL), Predicted Environmental Concentration (PEC), and Predicted No-Effect Concentration (PNEC).
2. *Whenever possible, the information should be derived from existing data in order to reduce the number of tests on animals. In particular, the provisions of Directive 1999/45/EC and Regulation (EC) No 1272/2008 shall apply.*
3. Information which is however not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied.
4. A detailed and full description of the studies conducted and of the methods used or a bibliographical reference to those methods shall be included.
5. The formats made available by the Commission must be used for submission of the dossiers. In addition, the special software package (IUCLID) made available by the Commission must be used for those parts of the dossiers to which IUCLID applies. Formats and further guidance on data requirements and dossier preparation are available on the Agency homepage.
6. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. *Methods listed in Annex I do not cover nanomaterials, except where specifically mentioned.* However, if a method is inappropriate or not described, other methods shall be used which are *scientifically satisfactory* and *the validity of which* must be justified in the application.
7. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Directive 86/609/EEC, and, in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency.
8. Where testing is done, a detailed description (specification) of the material used and its impurities must be provided. ■
9. Where test data exist that have been generated before ...\* by methods other than those laid down in Regulation (EC) No 440/2008, the adequacy of such data for the purposes of this Regulation and the need to conduct new tests according to the Regulation (EC) No 440/2008 must be decided by the competent authority of the Member State *concerned in agreement with the Agency*, on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrate animals.
10. All available relevant knowledge and information in literature should be provided.

### TITLE 1 – Chemical products

#### Dossier requirements

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\* Date of entry into force of this Regulation.

The following data will be required to support submissions.

1. 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))
2. 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, ***taking account of the concentrations referred to in Article 16(4)***
  - 2.3. Physical state and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution
3. 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

***Storage stability and shelf life will be generally determined based on the stability of the active substance. In the case of readily decomposable active substances, the storage stability and the shelf life may be determined by other valid scientific means, such as extrapolating the analytical data of the active substance from product aging experiments until reaching the efficacy threshold.***
  - 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
4. 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 Annex II, Section 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:
  - 4.2.1. Soil
  - 4.2.2. Air
  - 4.2.3. Water (including drinking water)
  - 4.2.4. Animal and human body fluids and tissues
  - 4.2.5. Treated food or feedingstuffs
5. 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 Annex II, Section 5.4
  - 5.9. User: industrial, professional, general public (non-professional)
  - 5.10. The proposed label claims for the product
  - 5.11. Efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate
  - 5.12. Any other known limitations on efficacy including resistance
6. Toxicological studies
  - 6.1. Acute toxicity

For studies of Sections 6.1.1 to 6.1.2, *without prejudice to Articles 6 and 9 of regulation (EC) No 1272/2008, classification by calculation may be the default approach. Only in exceptional cases should additional in-vivo testing be*

*considered, and in such cases, only the single most relevant exposure route should be tested.* Gases and volatile liquids should be administered by the inhalation route

6.1.1. Oral



6.1.2. Inhalation

*Testing by the inhalation route is appropriate only if:*

*(i) classification by calculation is not feasible; and*

*(ii) this constitutes the primary route of human exposure, taking into account the vapour pressure of the substance and the possibility of exposure to aerosols, particles or droplets of an inhalable size.*

*The Acute Toxic Class Method is the first-choice method for in-vivo testing. Only in exceptional circumstances should the classic “lethal concentration” (LC50) test be used. Justification for the use of another test shall be provided.*



6.2. Skin and eye irritation<sup>1</sup>

*Classification by calculation may be the default approach.*

6.3. Skin sensitisation

*Classification by calculation may be the default approach.*

6.4. Information on *in-vitro* 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 Annex II, shall be required for the toxicologically relevant non-active substances of the preparation

7. 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 ecotoxicological relevant non-active substances (i.e. substances of concern), such as information from safety

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<sup>1</sup> Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

data sheets

8. 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 Annex II, Title1, point 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:
    - 8.6.1. Air
    - 8.6.2. Water, including drinking water
    - 8.6.3. 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
9. Where relevant, the following additional data shall also be provided
  - 9.1. Further human health-related studies
    - 9.1.1. Food and feedingstuffs studies
      - 9.1.1.1. 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
      - 9.1.1.2. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product
    - 9.1.2. Other test(s) related to the exposure to humans  
Suitable test(s) and a reasoned case will be required for the biocidal product
  - 9.2. Further studies on fate and behaviour in the environment
    - 9.2.1. Where relevant all the information required in Annex II, Section 12



9.2.2. Testing for distribution and dissipation in the following:

9.2.2.1. Soil

9.2.2.2. Water

9.2.2.3. Air

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

9.3. Further Ecotoxicological studies

9.3.1. Effects on birds

■

9.3.2. Effects on aquatic organisms

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

9.3.2.1.1. Particular studies with fish and other aquatic organisms

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

9.3.2.1.3. The studies referred to in Annex II, Section 13.2.1, 2.2, 2.3 and 2.4 may be required for relevant components of the biocidal product

9.3.2.1.4. 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

9.3.3. Effects on other non-target organisms

■

9.3.3.1. Acute toxicity to honeybees

9.3.3.2. Effects on beneficial arthropods other than bees

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

9.3.3.4. Effects on soil non-target micro-organisms

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

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

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

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

10. Classification, packaging and labelling
  - Proposals for safety-data sheets, where appropriate
  - Hazard symbol(s)
  - Indications of danger
  - Hazard statements
  - Precautionary statements
  - Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials to be included
11. Summary and evaluation of Sections 2 to 10

## TITLE 2 – Micro-organisms

### Dossier requirements

The following data will be required to support submissions.

1. Applicant
  - 1.1. Name and address, etc.
  - 1.2. Formulator of the biocidal product and the micro-organism(s) (names, addresses, including location of plant(s))
2. Identity of the biocidal products
  - 2.1. Trade name or proposed trade name, and manufacturer's development code number of the biocidal product
  - 2.2. Detailed quantitative and qualitative information on the composition of the biocidal product
  - 2.3. Physical state and nature of the biocidal product
  - 2.4. Function
3. Physical, chemical and technical properties of the biocidal product
  - 3.1. Appearance (colour and odour)
  - 3.2. Storage stability and shelf-life
    - 3.2.1. Effects of light, temperature and humidity on technical characteristics of the biocidal product
    - 3.2.2. Other factors affecting stability
  - 3.3. Explosivity and oxidising properties
  - 3.4. Flash point and other indications of flammability or spontaneous ignition

- 3.5. Acidity, alkalinity and pH value
- 3.6. Viscosity and surface tension
- 3.7. Technical characteristics of the biocidal product
  - 3.7.1. Wettability
  - 3.7.2. Persistent foaming
  - 3.7.3. Suspensibility and suspension stability
  - 3.7.4. Dry sieve test and wet sieve test
  - 3.7.5. Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)
  - 3.7.6. Emulsifiability, re-emulsifiability, emulsion stability
  - 3.7.7. Flowability, pourability (rinsability) and dustability
- 3.8. Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered
  - 3.8.1. Physical compatibility
  - 3.8.2. Chemical compatibility
  - 3.8.3. Biological compatibility
- 3.9. Summary and evaluation of physical, chemical and technical properties of the biocidal product
4. Analytical methods
  - 4.1. Methods for the analysis of the biocidal product
  - 4.2. Methods to determine and quantify residues
5. Intended use and efficacy
  - 5.1. Field of use envisaged
  - 5.2. Mode of action
  - 5.3. Details of intended use
  - 5.4. Application rate
  - 5.5. Content of micro-organism in material used (e.g. in the application device or bait)
  - 5.6. Method of application
  - 5.7. Number and timing of applications and duration of protection
  - 5.8. Necessary waiting periods or other precautions to avoid adverse effects to human and

animal health and the environment

- 5.9. Proposed instructions for use
- 5.10. Category of users
- 5.11. Information on the possible occurrence of the development of resistance
- 5.12. Effects on the materials or products treated with the biocidal product

6. Effects on human health

6.1. Basic acute toxicity studies

6.1.1. Acute oral toxicity

***Without prejudice to Articles 6 and 9 of Regulation (EC) No 1272/2008, classification by calculation may be the default approach. Only in exceptional cases should additional in-vivo testing be considered, and in such cases, only the single most relevant exposure route should be tested.***

6.1.2. Acute inhalation toxicity

***Testing by the inhalation route is appropriate only if this constitutes the primary route of human exposure.***

6.1.3. Acute percutaneous toxicity

6.2. Additional acute toxicity studies

6.2.1. Skin irritation

***Classification by calculation may be the default approach.***

6.2.2. Eye irritation

***Classification by calculation may be the default approach.***

6.2.3. Skin sensitisation

***Classification by calculation may be the default approach.***

6.3. Data on exposure

6.4. Available toxicological data relating to non-active substances

6.5. Supplementary studies for combinations of biocidal products

6.6. Summary and evaluation of effects on human health

7. Residues in or on treated materials, food and feedingstuffs

8. Fate and behaviour in the environment

9. Effects on non-target organisms

- 9.1. Effects on birds
- 9.2. Effects on aquatic organisms
- 9.3. Effects on bees
- 9.4. Effects on arthropods other than bees
- 9.5. Effects on earthworms
- 9.6. Effects on soil micro-organisms
- 9.7. Additional studies on additional species or higher tier studies such as studies on selected non-target organisms
  - 9.7.1. Terrestrial plants
  - 9.7.2. Mammals
  - 9.7.3. Other relevant species and processes
- 9.8. Summary and evaluation of effects on non-target organisms
10. Classification, packaging and labelling

As established in point b of Article 18(1), proposals including justification for the hazard and precautionary statements in accordance with the provisions set in Regulation (EC) No 1272/2008 and Directive 1999/45/EC must be submitted. The classification comprises of the description of the category/categories of danger and qualifying hazard statements for all dangerous properties.

- 10.1. Packaging and compatibility of the biocidal product with proposed packaging materials
- 10.2. Procedures for cleaning application equipment
- 10.3. Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment
- 10.4. Recommended methods and precautions concerning: handling, storage, transport or fire
- 10.5. Measures in the case of an accident
- 10.6. Procedures for destruction or decontamination of the biocidal product and its packaging
  - 10.6.1. Controlled incineration
  - 10.6.2. Others
- 10.7. 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

- 10.8. Indication on the need for biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC
11. Summary and evaluation of Sections 1 to 10 including conclusions of the risk assessment and recommendations

## ANNEX IV

### GENERAL RULES FOR THE ADAPTATION OF THE DATA REQUIREMENTS

The applicant may propose to adapt the data requirements set out in Annexes II and III according to the general rules set out in this Annex. The reasons for such adaptations to the data requirements must be clearly stated under the appropriate heading of the dossier referring to the specific rule(s) of this Annex ***and must be based on sufficient scientific grounds and be confirmed by the competent authority.***

#### 1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY

##### 1.1. Use of existing data

##### 1.1.1. Data on physical-chemical properties from experiments not carried out according to GLP or the relevant test methods.

Data shall be considered to be equivalent to data generated by the corresponding test methods if the following conditions are met:

- (1) adequacy for the purpose of classification and labelling and risk assessment;
- (2) sufficient documentation is provided to assess the adequacy of the study; and
- (3) the data are valid for the endpoint being investigated and the study is performed using an acceptable level of quality assurance.

##### 1.1.2. Data on human health and environmental properties from experiments not carried out according to GLP or the relevant test methods.

Data shall be considered to be equivalent to data generated by the corresponding test methods if the following conditions are met:

- (1) adequacy for the purpose of classification and labelling and risk assessment;
- (2) adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods;
- (3) exposure duration comparable to or longer than the corresponding test methods if exposure duration is a relevant parameter; and
- (4) adequate and reliable documentation of the study is provided.

##### 1.1.3. Historical human data

Historical human data, such as epidemiological studies on exposed populations, accidental or occupational exposure data, biomonitoring studies, clinical studies and human volunteer studies performed in accordance with internationally accepted ethical standards shall be considered. The strength of the data for a specific human health effect depends, among other things, on the type of analysis and on the parameters covered and on the magnitude and specificity of the response and consequently the predictability of the effect. Criteria for assessing the adequacy of the data include:

- (1) the proper selection and characterisation of the exposed and control groups;
- (2) adequate characterisation of exposure;

- (3) sufficient length of follow-up for disease occurrence;
- (4) valid method for observing an effect;
- (5) proper consideration of bias and confounding factors; and
- (6) a reasonable statistical reliability to justify the conclusion.

In all cases adequate and reliable documentation shall be provided.

#### **1.1.4. Calculation methods for the evaluation of health hazards of preparations**

*Data requirements for preparations may generally be waived consistent with Annex II to Directive 1999/45/EC and/or Annex I to Regulation (EC) No 1272/2008, which takes into consideration all the health hazards of substances contained in the preparation. Guidance is specifically provided for the following categories of adverse health effects:*

- *acute lethal effects*
- *non-lethal irreversible effects after a single exposure*
- *severe effects after repeated or prolonged exposure*
- *corrosive or irritant effects*
- *sensitising effects*
- *carcinogenic effects*
- *mutagenic effects*
- *reprotoxic effects.*

#### **1.2. Weight of evidence**

There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion. There may be sufficient weight of evidence from the use of newly developed test methods, not yet included in the relevant test methods or from an international test method recognised by the Commission as being equivalent, leading to the conclusion that a substance has or has not a particular dangerous property.

Where sufficient weight of evidence for the presence or absence of a particular dangerous property is available:

- further testing on vertebrate animals for that property shall be omitted,
- further testing not involving vertebrate animals may be omitted.

In all cases adequate and reliable documentation shall be provided.

#### **1.3. Qualitative or Quantitative structure-activity relationship ((Q)SAR)**



Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence or absence of a certain dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:

- results are derived from a (Q)SAR model whose scientific validity has been established,
- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and risk assessment, and
- adequate and reliable documentation of the applied method is provided.

#### 1.4. In vitro methods

Results obtained from suitable in vitro methods may indicate the presence of a certain dangerous property or may be important in relation to a mechanistic understanding, which may be important for the assessment. In this context, ‘suitable’ means sufficiently well developed according to internationally agreed test development criteria.

Such confirmation may be waived, if the following conditions are met:

- (1) results are derived from an in vitro method whose scientific validity has been established by a validation study, according to internationally agreed validation principles;
- (2) results are adequate for the purpose of classification and labelling *and/or* risk assessment; and
- (3) adequate and reliable documentation of the applied method is provided.

#### 1.5. Grouping of substances and read-across approach

Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or ‘category’ of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint. The similarities may be based on:

- (1) a common functional group;
- (2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or
- (3) a constant pattern in the changing of the potency of the properties across the category.

If the group concept is applied, substances shall be classified and labelled on this basis.

In all cases results should:

- be adequate for the purpose of classification and labelling and risk assessment,
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method,
- cover an exposure duration comparable to or longer than the corresponding test method if exposure duration is a relevant parameter, and
- adequate and reliable documentation of the applied method shall be provided.

## 2. TESTING IS TECHNICALLY NOT POSSIBLE

Testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible. The guidance given in the relevant test methods, more specifically on the technical limitations of a specific method, shall always be respected.

## 3. PRODUCT-TAILORED EXPOSURE-DRIVEN TESTING

- 3.1. Testing in accordance with sections 6 and 7 of Annexes II and III may be omitted based on exposure considerations.
- 3.2. In all cases, adequate justification and documentation shall be provided. The justification shall be based on an exposure assessment in accordance with the Technical Notes for Guidance.

ANNEX V  
BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN  
ARTICLE 2(1)

These product-types exclude products where they are covered by the Directives mentioned in Article 2(2) for the purposes of those Directives.

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 feedingstuffs contact in private, public and industrial areas, including hospitals, as well as products used as algacides.

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, feedingstuffs 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.

***These include products which inhibit surface build-ups of microorganisms (e.g. pathogenic or odour-generating germs) and thus curb or prevent the creation of odours and/or have other uses.***

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: -

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.

ANNEX VI  
COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL  
PRODUCTS

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 Annex lays down principles to ensure that evaluations made and decisions taken by a competent authority or the Agency, or the Commission, where relevant, 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 point (b) of Article 16(1).
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, ***taking due account of cumulative, combination and synergistic effects.***
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 the inclusion of the active substance into Annex I. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation, *taking due account of cumulative, combination and synergistic effects*. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.

4. In order to carry out a risk assessment data are required. These data are detailed in Annexes 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. Competent authorities or the Agency should take due consideration of the requirements of Article 6 and Article 19 of this Regulation 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 (EC) No 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 Annex I to this Regulation. Data may also be required on a substance of concern present in a biocidal product.
5. 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.
6. When making evaluations and taking decisions concerning the authorisation of a biocidal product the competent authorities or the Agency 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.
7. 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.
8. 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 Annex, are subject to a simplified procedure as detailed in Article 16(5) of this Regulation.
9. The application of these common principles shall lead to the competent authorities or the Commission deciding whether or not a biocidal product can be authorised, such authorisation may include restrictions on use or other conditions. In certain cases the competent authorities may conclude that more data are required before an authorisation decision can be made.
10. During the process of evaluation and decision-making, applicants and the competent authorities 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 Article 16 and of this Annex. 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.

11. The judgments made by the competent authorities 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

12. The data submitted in support of an application for authorisation of a biocidal product shall be examined for overall scientific value by the receiving competent authorities. After acceptance of these data the competent authorities shall utilise them by carrying out a risk assessment based on the proposed use of the biocidal product.
13. 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 ***all available data*** shall be ***included in the dossier for authorisation of a biocidal product*** for each of these. The ***data*** 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.
14. 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, ***taking due account of cumulative, combination and synergistic effects***.
15. 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.
16. 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.
17. 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

18. 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.
19. 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,
  - *immunotoxicity*,
  - any other special properties of the active substance or substance of concern,
  - other effects due to physico-chemical properties.
20. The populations previously mentioned are:
  - professional users,
  - non-professional users,
  - humans exposed indirectly via the environment.
21. 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 Article 58 then dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation shall be required.
22. ***In order to reduce the number of tests on animals, adverse effects should, whenever possible, be studied on the basis of the information on the active substance and existing information on the substances that give cause for concern which the biocidal product contains. In particular, the provisions of Directive 1999/45/EC or Regulation (EC) No 1272/2008 shall be applied for the purpose of ascertaining adverse effects of the biocidal product.***
23. 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.

24. The competent authorities shall apply points 25 to 28 when carrying out a dose (concentration) - response (effect) assessment on an active substance or a substance of concern present in a biocidal product.
25. 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.
26. 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 this Regulation. 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.
27. 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 point 25.
28. 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.
29. 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.
30. 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.
31. The exposure assessment shall be based on the information in the technical dossier provided in conformity with Article 6 and Article 19 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.

32. 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.

33. Where, for any of the effects set out in point 19 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

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

Effects on the environment

35. 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.

36. 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 this Regulation then dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation shall be required.

37. 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.

38. 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.

39. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Article 6 and Article 18. 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)).

40. 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 point 3.3.1 of Annex I to Regulation (EC) No. 1907/2006.

41. 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.

42. 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.
43. 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.
44. 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 point 32. 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.
45. 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.
46. 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

47. Data shall be submitted to and evaluated by the competent authorities to assess whether the biocidal product does not cause unnecessary suffering *and pain* 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. *These findings shall for each authorised biocidal product be made publicly available on the Agency website.*

48. The competent authorities shall, where relevant, evaluate the possibility of the development of resistance to an active substance in the biocidal product by the target organism.
49. If there are indications that any other unacceptable effects may occur the competent authorities 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

50. 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 competent authorities or the Agency 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.
51. Testing should be carried out according to Union 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 competent authorities or the Agency)
  - individual producer standard method (accepted by competent authorities or the Agency)
  - data from the actual development of the biocidal product (accepted by competent authorities or the Agency).

#### Summary

52. In each of the areas where risk assessments have been carried out, i.e. effects on man, animals, and the environment, the competent authorities 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.
53. 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

54. Subject to point 90, the competent authorities or the Commission 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.

55. In making a decision concerning authorisation, the competent authorities or the Commission 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.
56. If the conclusion arrived at by the competent authorities or the Commission 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.
57. The competent authorities or the Commission 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 Union level to be used in such biocidal products.
58. The competent authorities or the Commission 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.
59. In the decision-making process the competent authorities or the Commission 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, *taking due account of cumulative, combination and synergistic effects*,
  - 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.

60. The competent authorities or the Commission 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.
61. The competent authorities or the Commission 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.

#### Effects on humans

62. The competent authorities or the Commission 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.
63. The competent authorities or the Commission 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.
64. The competent authorities or the Commission 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.
65. The competent authorities or the Commission 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.
66. 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.
67. The competent authorities or the Commission 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.
68. 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.
69. If the relationship between the exposure and the effect cannot be reduced to an acceptable level then no authorisation can be given by the competent authorities or the Commission for the biocidal product.

#### Effects on animals



70. The competent authorities or the Commission 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.
71. Using the same relevant criteria as described in the section dealing with effects on humans, the competent authorities or the Commission shall consider the risks posed to animals from the biocidal product when making an authorisation decision.

#### Effects on the environment

72. The competent authorities or the Commission 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 competent authorities or the Commission shall, when coming to a final decision in accordance with point 90, take into account the criteria in points 75 to 85.

73. 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.

74. 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 competent authorities or the Commission 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 point 37.

#### Water

75. The competent authorities or the Commission 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.
76. The competent authorities or the Commission 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:
- the maximum permissible concentration laid down by Council Directive

80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption<sup>1</sup>, or

- the maximum concentration as laid down following the procedure for including the active substance in Annex I to this Regulation, 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.

77. The competent authorities or the Commission 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 **groundwater** **or** 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
  - Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States<sup>2</sup>,
  - Directive 80/778/EEC or
- has an impact deemed unacceptable on non-target species
- **risks a non-achievement of the objectives or standards fixed by:**
  - **Directive 98/83/EC, or**
  - **Directive 2000/60/EC or**
  - **Directive 2006/118/EC or**
  - **Directives 2008/56/EC, or**
  - **Directive 2008/105/EC, or**
  - **international agreements containing important obligations on the protection of marine waters from pollution.**

78. 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

79. Where unacceptable contamination of soil is likely to occur, the competent authorities or the Commission 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

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<sup>1</sup> OJ L 229, 30.8.1980, p. 11.

<sup>2</sup> OJ L 194, 25.7.1975, p. 26.

- 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

80. The competent authorities or the Commission 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

81. The competent authorities or the Commission 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.
82. The competent authorities or the Commission 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.
83. The competent authorities or the Commission 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

84. If the development of resistance to the active substance in the biocidal product is likely the competent authorities or the Commission 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.
85. 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

86. Competent authorities or the Commission 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.
87. 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 or, where appropriate, in the Union, except where the biocidal product is intended for use in specific circumstances. Competent authorities 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

88. In each of the areas where risk assessments have been carried out, i.e. effects on humans, animals, and the environment, the competent authorities or the Commission 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

89. The competent authorities or the Commission 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.
90. The competent authorities or the Commission 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.
91. The competent authorities or the Commission 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 Annex and this Regulation.

ANNEX VII<sup>1</sup>  
CORRELATION TABLE

This Regulation	Directive 98/8/EC
Article 1	Article 1.1
Article 2	
2.1	Article 1.2
2.2	Article 1.2
2.3	Article 1.3
2.4	Article 1.4
2.5	
2.6	
Article 3	
3.1	Article 2.1
3.2	Article 2.2
Article 4	
4.1	Article 10.1
4.2	Article 10.3
4.3	Article 10.2
4.4	Article 10.2
Article 5	
Article 6	
6.1	Article 11.1.a
6.2	Article 11.1.a.i and ii
6.3	
Article 7	
7.1	Article 11.1.a
7.2	
7.3	
7.4	
7.5	
7.6	
Article 8	
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8.2	Article 11.2 2 <sup>nd</sup> subparagraph
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<sup>1</sup> The correlation table has not yet been changed to reflect Parliament's position. It will be updated once an agreement between Parliament and Council has been reached.

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