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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: Position of the Council at first reading with a view to the adoption of a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the making available on the market and use of biocidal products
- Adopted by the Council on 21 June 2011

REGULATION (EU) No …/2011
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of

concerning the making available on the market and use of biocidal products

(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[1],

Acting in accordance with the ordinary legislative procedure[2],

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1 OJ C 347, 18.12.2010, p. 62.

2 Position of the European Parliament of 22 September 2010 (not yet published in the *Official Journal*) and position of the Council at first reading of .... (not yet published in the *Official Journal*). Position of the European Parliament of… (not yet published in the *Official Journal*).

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 materials. 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 neither be made available on the market nor used unless authorised in accordance with this Regulation. Treated articles should not be placed on the market unless all active substances contained in the biocidal products with which they were treated or which they incorporate are approved in accordance with this Regulation.

(3) The purpose of this Regulation is to improve the free movement of biocidal products within the Union while ensuring 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, such as pregnant women and children. This Regulation should be underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or unacceptable effects on the environment. With a view to removing, as far as possible, obstacles to trade in biocidal products, rules should be laid down for the approval of active substances and the making available on the market and use of biocidal products, including rules on the mutual recognition of authorisations and on parallel trade.

(4) To ensure a high level of protection for human and animal health and the environment, this Regulation should apply without prejudice to EU legislation on safety in the workplace and environmental and consumer protection.

(5) Rules concerning the making available on the market of biocidal products within the Community were established through Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998[1]. It is necessary to adapt those rules in the light of experience and in particular the report on the first seven years of the implementation submitted by the Commission to the European Parliament and the Council, which analyses problems with and weaknesses of that Directive.

(6) Taking into account the main changes that should be made to the existing rules, a regulation is the appropriate legal instrument to replace Directive 98/8/EC to lay down clear, detailed and directly applicable rules. Moreover, a regulation ensures that legal requirements are implemented at the same time and in a harmonised manner throughout the Union.

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[1] OJ L 123, 24.04.1998, p. 1.

(7) A distinction should be drawn between existing active substances which were on the market in biocidal products on the transposition date set in Directive 98/8/EC and new active substances which were not yet on the market in biocidal products on that date. During the ongoing review of existing active substances, Member States should continue to allow biocidal products containing such substances to be made available on the market according to their national rules until a decision is taken on approval of those active substances. Following such a decision Member States, or, where appropriate, the Commission, should grant, cancel or modify authorisations as appropriate. New active substances should be reviewed before biocidal products containing them are placed on the market, so as to ensure that new products that are placed on the market comply with the requirements of this Regulation. However, to encourage the development of new active substances, the evaluation procedure for new active substances should not prevent Member States or the Commission from authorising, for a limited period of time, biocidal products containing an active substance before it is approved, provided that a full dossier has been submitted and it is believed that the active substance and the biocidal product satisfy the conditions set out in this Regulation.

(8) To ensure the equal treatment of persons placing active substances on the market, they should be required to hold a dossier, or have a letter of access to a dossier, or to relevant data in a dossier, for each of the active substances they manufacture or import for use in biocidal products. Biocidal products containing active substances for which the relevant person does not comply with that obligation should no longer be made available on the market. In such cases, there should be appropriate phase-out periods for disposal and use of existing stocks of biocidal products.

(9) This Regulation should apply to biocidal products that, in the form in which they are supplied to the user, consist of, contain or generate one or more active substances. It therefore should not apply to devices within industrial plants that generate biocidal products *in situ*.

(10) In order to ensure legal certainty, it is necessary to establish a Union list of active substances approved for use in biocidal products. A procedure should be laid down for assessing whether or not an active substance can be entered in that list. The information that interested parties should submit in support of an application for approval of an active substance and its inclusion in the list should be specified.

(11) This Regulation applies without prejudice to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency[1]. Under certain conditions, biocidal active substances are exempt from the relevant provisions of that Regulation.

(12) With a view to achieving a high level of protection of the environment and human and animal health, 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 approval is justified because of the negligible risk from exposure to the substance, public or animal health or environmental reasons or the disproportionate negative impact for society of non-approval. When deciding if such active substances may be approved, the availability of suitable and sufficient alternative substances or technologies should also be taken into account.

(13) 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 or treated articles does not meet the requirements of this Regulation, the Commission should be able to review the approval of the active substance.

[1] OJ L 396, 30.12.2006, p. 1.

(14) Active substances should be designated as candidates for substitution if they have certain intrinsic hazardous properties. In order to allow for a regular examination of substances identified as candidates for substitution, the approval period for those substances should not, even in the case of renewal, exceed seven years.

(15) In the course of granting or renewing the authorisation of a biocidal product that contains an active substance that is a candidate for substitution, it should be possible to compare the biocidal product with other authorised biocidal products, non-chemical means of control and prevention methods with regard to risks they pose and benefits from their use. As a result of such a comparative assessment, a biocidal product containing active substances identified as candidates for substitution should be prohibited or restricted where it is demonstrated that other authorised biocidal products or non-chemical control or prevention methods that present a significantly lower overall risk for human and animal health and the environment, are sufficiently effective and present no other significant economic or practical disadvantages. Appropriate phase-out periods should be provided for in such cases.

(16) In order to avoid unnecessary administrative and financial burdens for the industry and competent authorities, a full in-depth evaluation of an application to renew the approval of an active substance or the authorisation of a biocidal product should be carried out only if the competent authority that was responsible for the initial evaluation decides that this is necessary on basis of the available information.

(17) 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 ("the Agency") should carry out specified tasks with regard to the evaluation of active substances as well as the Union authorisation of certain categories of biocidal products and related tasks. Consequently, a Biocidal Products Committee should be established within the Agency to carry out certain tasks conferred on the Agency by this Regulation.

(18) Certain biocidal products and treated articles as defined in the Regulation are also regulated by other Union legislation. It is therefore necessary to draw clear borderlines in order to ensure legal certainty. A list of product types covered by this Regulation with an indicative set of descriptions within each type should be set out in an Annex to this Regulation.

(19) Biocidal products intended to be used not only for the purposes of this Regulation, but also in connection with medical devices, such as disinfectants used to disinfect surfaces in hospitals and medical devices, may pose risks other than those with which this Regulation is concerned. Therefore, such biocidal products should comply, in addition to the requirements laid down in this Regulation, with the relevant essential requirements set out in Annex I to 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[1], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[2] and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices[3].

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1 OJ L 189, 20.7.1990, p. 17.
2 OJ L 169, 12.7.1993, p. 1.
3 OJ L 331, 7.12.1998, p. 1.

(20) The safety of food and feed 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[1]. Therefore, the present Regulation should not apply to food and feed used for biocidal purposes.

(21) Processing aids are covered by existing Union legislation, in particular Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[2] and Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[3]. Therefore, it is appropriate to exclude them from the scope of this Regulation.

(22) As products used for the preservation of food or feed by the control of harmful organisms, previously covered by product type 20, are covered by Regulation (EC) No 1831/2003 and Regulation (EC) No 1333/2008, it is not appropriate to maintain that product type.

(23) 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.

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1 OJ L 31, 1.2.2002, p. 1.
2 OJ L 268, 18.10.2003, p. 29.
3 OJ L 354, 31.12.2008, p. 16.

(24) To avoid possible negative effects on the environment, biocidal products that can no longer lawfully be made available on the market should be dealt with in accordance with Union legislation on waste, in particular Directive 2008/98/EC, as well as national legislation implementing that legislation.

(25) To facilitate the making available on the market throughout the Union of certain biocidal products with similar conditions of use in all Member States, it is appropriate to provide for Union authorisation of those products. In order to allow some time for the Agency to build up the necessary capacity and to gain experience with this procedure, the possibility to apply for Union authorisation should be extended through a step-wise approach to further categories of biocidal products with similar conditions of use in all Member States.

(26) The Commission should review experience with the provisions on Union authorisations and report to the European Parliament and the Council by 31 December 2017, accompanying its report with proposals for changes if appropriate.

(27) To ensure that only biocidal products that comply with the relevant provisions of this Regulation are made available on the market, biocidal products should be subject to authorisation either by competent authorities, for making available on the market and use within the territory of a Member State, or part of it, or by the Commission for making available on the market and use within the Union.

(28) To encourage the use of products with a more favourable environmental or human health profile, it is appropriate to provide for simplified authorisation procedures for such biocidal products. Once authorised in at least one Member State, those products should be allowed to be made available on the market in all Member States without the need for mutual recognition, under certain conditions.

(29) To identify biocidal products which are eligible for simplified authorisation procedures, it is appropriate to establish a specific list of the active substances that those products may contain. That list should, initially, contain substances identified as presenting a low risk under Regulation (EC) No 1907/2006 or Directive 98/8/EC, substances identified as food additives, pheromones and other substances considered to have low toxicity, such as weak acids, alcohols and vegetable oils used in cosmetics and food.

(30) It is necessary to provide common principles for the evaluation and authorisation of biocidal products to ensure a harmonised approach by competent authorities.

(31) To evaluate the risks that would arise from proposed uses of biocidal products, it is appropriate that 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 applicants seeking authorisation and competent authorities carrying out an evaluation to decide on authorisation.

(32) In the light of the diversity of both active substances and biocidal products not subject to the simplified authorisation procedure, the data and test requirements should suit the individual circumstances and allow an overall risk assessment. Therefore, an applicant should be able to request the adaptation of the data requirements, as appropriate, including the waiving of data requirements which are not necessary or are impossible to submit in view of the nature or the proposed uses of the product. Applicants should provide appropriate technical and scientific justification to support their requests.

(33) In order to help applicants, and in particular small and medium-sized enterprises (SMEs), to comply with the requirements of this Regulation, Member States should provide advice, for example by establishing helpdesks. This advice should be in addition to the operational guidance documents and other advice and assistance provided by the Agency.

(34) In particular, to ensure that applicants can effectively exercise the right to request the adaptation of data requirements, Member States should provide advice on this possibility and the grounds on which such requests could be made.

(35) To facilitate access to the market it should be possible to authorise a group of biocidal products as a biocidal product family. Biocidal products within a biocidal product family should have similar uses and the same active substances. Variations in the composition or the replacement of non-active substances should be specified, but may not adversely affect the level of risk or significantly reduce the efficacy of the products.

(36) When authorising biocidal products 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, or, in the case of vertebrate animals, unnecessary suffering and pain. Furthermore, they may not have, in the light of current scientific and technical knowledge, any unacceptable effect on the environment or on human or animal health. Where appropriate, maximum residue limits for food and feed should be established with respect to active substances contained in a biocidal product to protect human and animal health. When these requirements are not met, biocidal products shall not be authorised unless their authorisation is justified because of the disproportionate negative impact for society of not authorising them when compared to the risks arising from their use.

(37) Where possible, the presence of harmful organisms should be avoided by means of suitable precautionary steps, such as proper warehousing of goods, compliance with relevant hygiene standards and immediate disposal of waste. As far as possible, biocidal products that pose lower risks for humans, animals and the environment should be used whenever they provide an effective remedy, and biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress should be used only as a last resort.

(38) Some authorised biocidal products may present certain risks if used by the general public. It is therefore appropriate to provide that certain biocidal products should not generally be authorised for making available on the market for use by the general public.

(39) To avoid duplication of the evaluation procedures and to ensure free movement of biocidal products within the Union, procedures should be established to ensure that product authorisations granted in one Member State are recognised in other Member States.

(40) To enable closer cooperation between Member States in the evaluation of biocidal products and to facilitate biocidal products' market access, it should be possible to launch the mutual recognition procedure when applying for the first national authorisation.

(41) It is appropriate to lay down procedures for the mutual recognition of national authorisations and, in particular, to resolve any disagreements without undue delay. If a competent authority refuses mutual recognition of an authorisation or proposes to restrict it, a co-ordination group should try to reach an agreement on the action to be taken. If the coordination group does not succeed in finding an agreement within a specified time, the Commission should be empowered to take a decision. In case of technical or scientific questions, the Commission may consult the Agency before preparing its decision.

(42) However, considerations related to public policy or public security, environmental and human and animal health protection, the protection of national treasures and the absence of the target organisms might justify, following agreement with the applicant, Member States' refusal to grant an authorisation or decision to adjust the terms and conditions of the authorisation to be granted. If no agreement with the applicant can be found, the Commission should be empowered to take a decision.

(43) The use of biocidal products of certain product-types might give rise to animal welfare concerns. Therefore, Member States should be allowed to derogate from the principle of mutual recognition for biocidal products falling under such product-types, 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.

(44) 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. To accomplish this, a Register for Biocidal Products should be established. Member States, the Commission and the Agency should use this Register to make available to each other the particulars and scientific documentation submitted in connection with applications for authorisation of biocidal products.

(45) If the use of a biocidal product is in the interests of a Member State, but there is no applicant interested in making available on the market such a product in the Member State, official or scientific bodies should be able to apply for an authorisation. If they are granted an authorisation, they should have the same rights and obligations as any other authorisation holder.

(46) To take account of scientific and technical developments as well as the needs of authorisation holders, it is appropriate to specify under which conditions authorisations can be cancelled, reviewed or amended. The notification and exchange of information which may affect authorisations is also necessary to enable competent authorities and the Commission to take appropriate action.

(47) 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 permit, for a limited period of time, the making available on the market of biocidal products which do not comply with the requirements of this Regulation.

(48) To encourage research and development in active substances and biocidal products, it is necessary to establish rules concerning the making available on the market and use of unauthorised biocidal products and non-approved active substances for the purposes of research and development.

(49) In view of the benefits for the internal market and for the consumer, it is desirable to establish harmonised rules for parallel trade in identical biocidal products authorised in different Member States.

(50) To determine, where necessary, the similarity of active substances, it is appropriate to lay down rules concerning technical equivalence.

(51) To protect human and animal health and the environment, and to avoid discrimination between treated articles originating in the Union and treated articles imported from third countries, all treated articles placed on the internal market should contain only approved active substances.

(52) To enable consumers to make informed choices, to facilitate enforcement and to provide an overview of their use, treated articles should be appropriately labelled.

(53) Applicants that have invested in supporting the approval of an active substance or the authorisation of a biocidal product in accordance with this Regulation or Directive 98/8/EC should be able to recover part of their investment by receiving equitable compensation whenever use of proprietary information which they submitted in support of such approval or authorisation is made for the benefit of subsequent applicants.

(54) With a view to ensuring that all proprietary information submitted in support of the approval of an active substance or the authorisation of a biocidal product is protected from the moment of its submission and to prevent situations where some information is without protection, the data protection periods should also apply to information submitted for the purposes of Directive 98/8/EC.

(55) 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 approval of such active substances or the authorisation of biocidal products containing them which is longer than the period of protection for information concerning existing active substances and biocidal products containing them.

(56) It is essential to minimise the number of tests on animals and for testing with biocidal products, or active substances contained in biocidal products, to be carried out only when the purpose and use of a product so requires. Applicants should share, and not duplicate, vertebrate animal studies in exchange for equitable compensation. In the absence of an agreement on sharing of 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 any decision on compensation made by national courts. Competent authorities and the Agency should have access to the contact details of the owners of such studies via a Union register so as to inform prospective applicants.

(57) The generation of information by alternative means not involving tests on animals which 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.

(58) To ensure that the requirements laid down with respect to the safety and quality of authorised biocidal products are satisfied when they are made available on the market, Member States should take measures for appropriate control and inspection arrangements and manufacturers should maintain a suitable and proportionate quality control system. To this end, it may be appropriate for Member States to take action together.

(59) Effective communication of information on risks resulting from biocidal products and risk management measures is 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 to the commercial interests of the person concerned, except where it is necessary for the protection of human health, safety or the environment or for other reasons of overriding public interest.

(60) To increase the efficiency of monitoring and control, and to provide information relevant for addressing the risks of biocidal products, authorisation holders should keep records of the products they place on the market.

(61) 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, they should be specified in this Regulation.

(62) The costs of the procedures associated with the operation of this Regulation need to be recovered from those making biocidal products available on the market and those seeking to do so in addition to those supporting the approval of active substances. To promote the smooth operation of the internal market, it is appropriate to establish certain common principles applicable both to fees payable to the Agency and to Member States' competent authorities, including the need to take into account, as appropriate, the specific needs of SMEs.

(63) 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 process appeals against decisions adopted by the Agency under this Regulation.

(64) There is scientific uncertainty about the safety of nanomaterials for human health and the environment. 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, if possible based on the work of appropriate international fora, and to specify that the approval of an active substance does not include the nanomaterial form unless explicitly mentioned. The Commission should regularly review the provisions on nanomaterials in the light of scientific progress.

(65) It is appropriate to provide for a deferred application of this Regulation so as to facilitate the smooth transition to the new systems for the approval of active substances and authorisation of biocidal products.

(66) The Agency should take over the coordination and facilitation tasks for new submissions for approval of active substances as of the date of applicability of this Regulation. However, in view of the high number of historical dossiers it is appropriate to allow some time for the Agency to prepare for the new tasks related to dossiers submitted under Directive 98/8/EC.

(67) 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 make such products available 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.

(68) Taking into consideration that some products were not covered by Community legislation on biocidal products, it is appropriate to provide for transitional periods for active substances generated *in situ* and treated articles.

(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. In particular, it should contribute to the fulfilment of the Strategic Approach to International Chemical Management adopted on 6 February 2006 in Dubai.

(70) In order to supplement or amend this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of certain non-essential elements of this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(71) The Commission should adopt immediately applicable delegated acts where, in duly justified cases relating to the restriction of an active substance in Annex I or to the removal of an active substance from that Annex, imperative grounds of urgency so require.

(72) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers[1].

[1] OJ L 55, 28.2.2011, p. 13.

(73) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the approval of an active substance or to the cancelling of an approval, imperative grounds of urgency so require.

(74) Since the objective of this Regulation, namely, to improve the functioning of the internal market for biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment cannot be sufficiently achieved by the Member States, and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

CHAPTER I
SCOPE AND DEFINITIONS

Article 1

Purpose and subject matter

1. The purpose of this Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment. The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, animals and the environment.

2. This Regulation lays down rules for:

   (a) the establishment at Union level of a list of active substances which may be used in biocidal products;

   (b) the authorisation of biocidal products;

   (c) the mutual recognition of authorisations within the Union;

   (d) the making available on the market and the use of biocidal products within one or more Member States or the Union;

   (e) the placing on the market of treated articles.

Article 2

Scope

1. This Regulation shall apply to biocidal products and treated articles. A list of the types of biocidal products covered by this Regulation and their descriptions is set out in Annex V.

2. Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall not apply to biocidal products or treated articles that are within the scope of the following instruments:

   (a) 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[1];

   (b) Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC;

[1] OJ L 92, 7.4.1990, p. 42.

(c) 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[1], 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[2] and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[3];

(d) Regulation (EC) No 1831/2003;

(e) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[4] and 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[5];

(f) Regulation (EC) No 1333/2008;

(g) Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods[6];

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1 OJ L 311, 28.11.2001, p. 1.
2 OJ L 311, 28.11.2001, p. 67.
3 OJ L 136, 30.4.2004, p. 1.
4 OJ L 139, 30.4.2004, p. 1.
5 OJ L 139, 30.4.2004, p. 55.
6 OJ L 354, 31.12.2008, p. 34.

(h) Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed[1];

(i) 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[2];

(j) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[3].

Notwithstanding point (i), this Regulation shall apply to biocidal products that are intended to be used both as biocidal products and plant protection products.

3. Subject to any explicit provision to the contrary in this Regulation or other Union legislation, 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[4];

(b) 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[5];

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1 OJ L 229, 1.9.2009, p. 1.
2 OJ L 309, 24.11.2009, p. 1.
3 OJ L 342, 22.12.2009, p. 59.
4 OJ 196, 16.8.1967, p. 1.
5 OJ L 183, 29.6.1989, p. 1.

(c) 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)[1];

(d) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption[2];

(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[3];

(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[4];

(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[5];

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1 OJ L 131, 5.5.1998, p. 11.
2 OJ L 330, 5.12.1998, p. 32.
3 OJ L 200, 30.7.1999, p. 1.
4 OJ L 262, 17.10.2000, p. 21.
5 OJ L 327, 22.12.2000, p. 1.

(h) Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work[1];

(i) Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants[2];

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

(k) Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising[3];

(l) 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[4];

(m) 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[5];

(n) 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[6];

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1 OJ L 158, 30.4.2004, p. 50.
2 OJ L 158, 30.4.2004, p. 7.
3 OJ L 376, 27.12.2006, p. 21.
4 OJ L 204, 31.7.2008, p. 1.
5 OJ L 353, 31.12.2008, p. 1.
6 OJ L 309, 24.11.2009, p. 71.

(o) Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer[1];

(p) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes[2];

(q) Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions[3].

4. Article 68 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

5. This Regulation shall not apply to:

(a) food or feed used as biocidal products;

(b) processing aids that are used as biocidal products.

6. Where a manufacturer intends a biocidal product 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 set out in Annex I to Directives 90/385/EEC, 93/42/EEC or 98/79/EC shall also be fulfilled with regard to that biocidal product.

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1 OJ L 286, 31.10.2009, p. 1.
2 OJ L 276, 20.10.2010, p. 33.
3 OJ L 334, 17.12.2010, p. 17.

7. Biocidal products which obtained final approval under the International Convention for the Control and Management of Ships' Ballast Water and Sediments shall be considered as authorised under Chapter VIII of this Regulation. Articles 46 and 67 shall apply accordingly.

8. Member States may allow for exemptions from this Regulation in specific cases for certain biocidal products, on their own or in a treated article, where necessary in the interests of defence.

9. The disposal of active substances and biocidal products shall be carried out in accordance with the Union and national waste legislation in force.

Article 3

Definitions

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

   (a) "biocidal product" means any substance, mixture or article, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the primary intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action;

(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 that has an action on or 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 the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of 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 present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, or

– a substance classified as hazardous according to Regulation (EC) No 1272/2008, and present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation;

(g) "harmful organism" means an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment;

(h) "residue" means a substance present in or on products of plant or animal origin, water resources, drinking water, food, feed or elsewhere in the environment and resulting from the use of a biocidal product, including such a substance's metabolites, breakdown or reaction products;

(i) "making available on the market" means any supply of a biocidal product or of a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge;

(j) "placing on the market" means the first making available on the market of a biocidal product or of a treated article;

(k) "use" means all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with a view to exporting the biocidal product or the treated article outside the Union;

(l) "treated article" means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products;

(m) "national authorisation" means an administrative act by which the competent authority of a Member State authorises the making available 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 making available 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, Union authorisation or authorisation in accordance with Article 25;

(p) "authorisation holder" means the person responsible for the making available on the market of a biocidal product in a particular Member State or in the Union and specified in the authorisation. If the person responsible for the placing on the market of the biocidal product is not established within the Union, the authorisation holder shall be a person established within the Union that the person responsible for placing on the market has designated by written mandate as the authorisation holder and who has accepted that designation in writing;

(q) "product-type" means one of the product-types specified in Annex V;

(r) "single biocidal product" means a biocidal product with no intended variations as to the percentage of the active or non-active substances it contains;

(s) "biocidal product family" means a group of biocidal products having similar uses, the active substances of which have the same specifications, and presenting specified variations in their composition which do not adversely affect the level of risk or significantly reduce the efficacy of the products;

(t) "letter of access" means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by competent authorities, the Agency, or the Commission for the purposes of this Regulation;

(u) "food" and "feed" mean food as defined in Article 2 of Regulation (EC) No 178/2002 and feed as defined in Article 3(4) of that Regulation;

(v) "food contact materials" means any material or article as referred to in Article 1(2) of 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[1];

(w) "processing aid" means any substance falling within the definition of point (b) of Article 3(2) of Regulation (EC) No 1333/2008 or point (h) of Article 2(2) of Regulation (EC) No 1831/2003;

(x) "technical equivalence" means similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out, as established in Article 53;

(y) "Agency" means the European Chemicals Agency established by Regulation (EC) No 1907/2006;

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[1] OJ L 338, 13.11.2004, p. 4.

(z) "advertisement" means a means of promoting the sale or use of biocidal products by printed, electronic or other media;

(aa) "nanomaterial" means nanomaterial as defined in Commission Recommendation 20../…/EC of … … … concerning the definition of nanomaterials;

(ab) "administrative change" means an amendment of an existing authorisation of a purely administrative nature involving no change to the properties or efficacy of the biocidal product or biocidal product family;

(ac) "minor change" means an amendment of an existing authorisation that is not of a purely administrative nature and requires only a limited re-assessment of the properties or efficacy of the biocidal product or biocidal product family;

(ad) "major change" means an amendment of an existing authorisation which is neither an administrative change nor a minor change;

(ae) "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, when subject to high exposure to biocidal products over the long term, workers and residents;

(af) "small and medium-sized enterprises" or "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[1].

[1] OJ L 124, 20.5.2003, p. 36.

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".

3. The Commission may, at the request of a Member State, decide, by means of implementing acts, whether a specific product or group of products is a biocidal product or a treated article or neither. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

CHAPTER II
APPROVAL OF ACTIVE SUBSTANCES

Article 4

Conditions for approval

1. An active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in point (b) of Article 18(1) taking into account the factors set out in Article 18(2) and (5).

2. The approval of an active substance shall be restricted to those product-types for which relevant data have been submitted in accordance with Article 6.

3. The approval shall specify the following conditions, as appropriate:

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

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

   (c) the product-type;

   (d) manner and area of use including, where relevant, use in treated articles;

   (e) designation of categories of users;

(f) where relevant, 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.

4. The approval of an active substance shall not cover nanomaterials except where explicitly mentioned.

Article 5

Exclusion criteria

1. Subject to paragraph 2, the following active substances shall not be approved:

(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 identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties;

(e) active substances which fulfil the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) according to Annex XIII to Regulation (EC) No 1907/2006.

2. Without prejudice to Article 4(1), active substances referred to in paragraph 1 of this Article may be approved if it is shown that at least one of the following conditions is met:

(a) the risk to humans or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or strictly controlled conditions;

(b) the active substance is essential to prevent or to control a serious danger to public or animal health or the environment; or

(c) not approving the active substance would cause disproportionate negative impacts for society when compared with the risk to human health or the environment arising from the use of the substance.

When deciding whether an active substance may be approved in accordance with the first subparagraph, the availability of suitable and sufficient alternative substances or technologies shall also be taken into account.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 82 specifying scientific criteria for the determination of endocrine disrupting properties.

Pending the adoption of those criteria, active substances that are classified in accordance with the provisions of Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as, carcinogen category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties.

Substances such as those that are classified in accordance with the provisions of Regulation (EC) No 1272/2008 as, or that meet the criteria to be classified as, toxic for reproduction category 2 and that have toxic effects on the endocrine organs, may be considered as having endocrine-disrupting properties.

Article 6

Data requirements for an application

1. An application for approval of an active substance shall contain at least the following elements:

(a) a dossier for the active substance satisfying the requirements set out in Annex II;

(b) a dossier satisfying the requirements set out in Annex III for at least one representative biocidal product that contains the active substance; and

(c) if the active substance meets at least one of the exclusion criteria listed in Article 5(1), evidence that Article 5(2) is applicable.

2. Notwithstanding paragraph 1, the applicant need not provide data as part of the dossiers required under points (a) and (b) of paragraph 1 where any of the following applies:

(a) the data are not necessary owing to the exposure associated with the proposed uses;

(b) it is not scientifically necessary to supply the data; or

(c) it is not technically possible to generate the data.

However, sufficient data shall be provided in order to make it possible to determine whether an active substance meets the criteria referred to in Article 5(1) or 10(1), if required by the evaluating competent authority under Article 8(2).

3. An applicant may propose to adapt the data as part of the dossiers required under points (a) and (b) of 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.

4. In order to establish uniform conditions for the application of point (a) of paragraph 2, the Commission shall, by means of implementing acts, specify in which circumstances the exposure associated with the proposed uses would justify adapting the data requirements of points (a) and (b) of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

Article 7

Submission and validation of applications

1. The applicant shall submit an application for approval of an active substance, or for making subsequent amendments to the conditions of approval of an active substance, to the Agency, informing it of the name of the competent authority of the Member State that it proposes should evaluate the application and providing written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

2. The Agency shall, after checking that the application has been submitted in the correct format, notify the evaluating competent authority without delay that the application is available via the Register for Biocidal Products.

   The Agency shall inform the applicant of the fees payable under Article 79(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable under Article 79(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the exact date of the acceptance of the application and its unique identification code.

3. Within 30 days of the Agency accepting an application, the evaluating competent authority shall validate the application if the data required in accordance with points (a) and (b) and, where relevant, point (c) of Article 6(1), and any justifications for the adaptation of data requirements, have been submitted.

In the context of the validation referred to in the first subparagraph, the evaluating competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

4. Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The evaluating competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirement laid down in paragraph 3.

The evaluating 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 Agency accordingly. In such cases, part of the fee paid in accordance with Article 79 shall be reimbursed.

5. On validating an application in accordance with paragraph 3 or 4, the evaluating competent authority shall without delay inform the applicant, the Agency and other competent authorities accordingly and indicate the exact date of the validation.

6. An appeal may be brought, in accordance with Article 76, against decisions of the Agency under paragraph 2 of this Article.

Article 8

Evaluation of applications

1. The evaluating competent authority shall, within 365 days of the validation of an application, evaluate it in accordance with Articles 4 and 5, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3), and send an assessment report and the conclusions of its evaluation to the Agency.

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall give the applicant the opportunity to provide written comments on the assessment report and on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

2. Where 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 accordingly. As specified in the second subparagraph of Article 6(2), the evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to permit a determination of whether an active substance meets the criteria referred to in Article 5(1) or 10(1). The 365-day period referred to in paragraph 1 of this Article shall be suspended from the date of issue of the request until the date the information is received. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances.

3. Where 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, 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 270 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the approval of the active substance having regard to the conclusions of the evaluating competent authority.

Article 9

Approval of an active substance

1. The Commission shall, on receipt of the opinion of the Agency referred to in Article 8(4), either:

   (a) adopt an implementing Regulation providing that an active substance is approved, and under which conditions, including the dates of approval and of expiry of the approval; or

   (b) in cases where the requirements of Article 4(1) or, where applicable, Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, adopt an implementing decision that an active substance is not approved.

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

2. Approved active substances shall be included in a Union list of authorised active substances. The Commission shall keep the list up to date and make it electronically available to the public.

Article 10

Active substances which are candidates for substitution

1. An active substance shall be considered a candidate for substitution if any of the following conditions are met:

   (a) it meets at least one of the exclusion criteria listed in Article 5(1) but may be approved in accordance with Article 5(2);

   (b) its acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario;

   (c) 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;

   (d) there are reasons for concern linked to the nature of the critical 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;

   (e) it contains a significant proportion of non-active isomers or impurities.

2. When preparing its opinion on the approval or renewal of the approval of an active substance, the Agency shall examine whether the active substance fulfils any of the criteria listed in paragraph 1 and address the matter in its opinion.

3. Prior to submitting its opinion on the approval or renewal of the approval of an active substance to the Commission, the Agency shall make publicly available, without prejudice to Articles 65 and 66, information on potential candidates for substitution during a period of no more than 60 days, during which time interested third parties may submit relevant information, including information on available substitutes. The Agency shall take due account of the information received when finalising its opinion.

4. By way of derogation from Articles 4(1) and 12(3), the approval of an active substance that is considered as a candidate for substitution and each renewal shall be 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 the relevant Regulation adopted in accordance with Article 9.

Article 11

Technical guidance notes

The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter, in particular Articles 5(2) and 10(1).

CHAPTER III
RENEWAL AND REVIEW OF APPROVAL OF AN ACTIVE SUBSTANCE

Article 12

Conditions for renewal

1. The Commission shall renew the approval of an active substance if the active substance still meets the condition laid down in Article 4(1) and, where relevant, the conditions set out in Article 5(2).

2. In the light of scientific and technical progress, the conditions specified for the active substance referred to in Article 4(3) shall be reviewed and, where appropriate, amended.

3. Unless otherwise specified in the decision to renew the approval of an active substance, the renewal shall be for fifteen years for all product-types to which the approval applies.

Article 13

Submission and acceptance of applications

1. Applicants wishing to seek renewal of the approval of an active substance for one or more product-types shall submit an application to the Agency at least 550 days before the expiry of the approval. Where there are different expiry dates for different product-types, the application shall be submitted at least 550 days before the earliest expiry date.

2. When applying for the renewal of the approval of the active substance, the applicant shall submit:

   (a) a list of all relevant data that it has generated since the initial approval or, as appropriate, since the previous renewal; and

   (b) its assessment of whether the conclusions of the initial or previous assessment of the active substance remain valid and any supporting information.

3. The applicant shall also submit the name of the competent authority of the Member State that it proposes should evaluate the application for renewal and provide written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

The Agency shall, after checking that it has been submitted in the correct format, notify the evaluating competent authority without delay that the application is available via the Register for Biocidal Products.

The Agency shall inform the applicant of the fees payable under Article 79(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable under Article 79(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the exact date of the acceptance.

4. An appeal may be brought, in accordance with Article 76, against decisions of the Agency under paragraph 3 of this Article.

Article 14

Evaluation of applications for renewal

1. On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for approval or, as appropriate, the previous renewal, the evaluating competent authority shall, within 90 days of the Agency accepting an application in accordance with Article 13(3), decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product-types for which renewal is requested.

The evaluating competent authority may at any time require the applicant to submit the data referred to in Article 13(2)(a).

2. Where 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, 2 and 3 of Article 8.

Where the evaluating competent authority decides that a full evaluation of the application is not necessary, it shall, within 180 days of the Agency accepting the application in accordance with Article 13(3), prepare and submit to the Agency a recommendation on the renewal of the approval of the active substance. It shall provide the applicant with a copy of its recommendation.

3. Within 270 days of receipt of a recommendation from the evaluating competent authority, if it has carried out a full evaluation of the application, or 90 days otherwise, the Agency shall prepare and submit to the Commission an opinion on renewal of the approval of the active substance.

4. The Commission shall, on receipt of the opinion of the Agency, adopt:

(a) an implementing Regulation providing that the approval of an active substance is renewed for one or more product-types, and under which conditions; or

(b) an implementing decision that the approval of an active substance is not renewed.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

Article 9(2) shall apply.

5. Where, for reasons beyond the control of the applicant, the approval of the active substance is likely to expire before a decision has been taken on its renewal, the Commission shall, by means of implementing acts, adopt a decision postponing the expiry date of approval for a period sufficient to enable it to examine the application. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 81(2).

6. Where the Commission decides not to renew the approval of an active substance for one or more product-types it may grant a period of grace for the disposal, making available on the market and use of existing stocks of biocidal products of the product-type(s) concerned containing that active substance.

The period of grace shall not exceed 180 days for making available on the market and an additional maximum of 180 days for disposal and use of existing stocks of biocidal products of the product-type(s) concerned containing that active substance.

Article 15

Review of approval of an active substance

1. The Commission may review the approval of an active substance for one or more product-types at any time where there are serious indications that the conditions laid down in Article 4(1) or, where relevant, Article 5(2) are no longer met. The Commission may also review the approval of an active substance for one or more product-types at the request of a Member State if there are indications that the use of the active substance in biocidal products or treated articles raises serious concerns about the safety of such biocidal products or treated articles.

   Where those indications are confirmed the Commission shall adopt an implementing Regulation amending the conditions of approval of an active substance or cancelling its approval. That implementing Regulation shall be adopted in accordance with the examination procedure referred to in Article 81(3). Article 9(2) shall apply. The Commission shall inform the initial applicant(s) for the approval accordingly.

   On duly justified imperative grounds of urgency the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 81(4).

2. The Commission may consult the Agency on any questions of a scientific or technical nature related to the review of approval of an active substance. The Agency shall, within 270 days of the request, prepare an opinion and submit it to the Commission.

3. Where the Commission cancels the approval of an active substance, it may grant a period of grace for the disposal, making available on the market and use of existing stocks of biocidal products containing that active substance.

The period of grace shall not exceed 180 days for making available on the market and an additional maximum of 180 days for disposal and use of existing stocks of biocidal products containing that active substance.

Article 16

Implementing measures

The Commission may adopt, by means of implementing acts, detailed measures for the implementation of Articles 12 to 15, further specifying the procedures for the renewal and review of the approval of an active substance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

CHAPTER IV
GENERAL PRINCIPLES CONCERNING THE AUTHORISATION OF BIOCIDAL PRODUCTS

Article 17
Making available on the market and use of biocidal products

1. Biocidal products shall not be made available on the market or used unless authorised in accordance with this Regulation.

2. Applications for authorisation shall be made by, or on behalf of, the prospective authorisation holder.

   Applications for national authorisation in a Member State shall be submitted to the competent authority of that Member State ("the receiving competent authority").

   Applications for Union authorisation shall be submitted to the Agency.

3. An authorisation for a biocidal product may be granted for a single biocidal product or a biocidal product family.

4. An authorisation shall be granted for a maximum period of 10 years.

5. Biocidal products shall be used in compliance with the terms and conditions of the authorisation stipulated in accordance with Article 21(1) and the labelling and packaging requirements laid down in Article 68.

Proper use shall 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 and appropriate precautionary steps are taken.

Member States shall take necessary measures to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use.

6. The authorisation holder shall notify each competent authority that has granted a national authorisation for a biocidal product family of each product within the biocidal product family before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission.

Article 18

Conditions for granting an authorisation

1. A biocidal product other than those eligible for the simplified authorisation procedure in accordance with Article 24 shall be authorised provided the following conditions are met:

   (a) the active substances are approved for the relevant product-type and any conditions specified for those active substances are met;

   (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 of this Article, fulfils the following criteria:

      (i) the biocidal product is sufficiently effective;

      (ii) the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;

(iii) the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on human or animal health, including that of vulnerable groups directly or through drinking water, food, feed, air, or through other indirect effects;

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

– the fate and distribution of the biocidal product 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;

– the impact of the biocidal product on non-target organisms;

– the impact of the biocidal product on biodiversity and the ecosystem;

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

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

(e) where appropriate, maximum residue limits for food and feed have been established with respect to active substances contained in a biocidal product in accordance with Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[1], Regulation (EC) No 1935/2004, 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[2], Regulation (EC) No 470/2009 of the European Parliament and of 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[3] and Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[4].

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

(a) realistic worst case conditions under which the biocidal product may be used;

(b) the way in which treated articles treated with the biocidal product or containing the biocidal product may be used;

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1 OJ L 37, 13.2.1993, p. 1
2 OJ L 70, 16.3.2005, p. 1.
3 OJ L 152, 16.6.2009, p. 11.
4 OJ L 140, 30.5.2002, p. 10.

(c) the consequences of use and disposal of the biocidal product;

(d) cumulative and synergistic effects.

3. A biocidal product shall only be authorised for uses for which relevant information has been submitted in accordance with Article 19.

4. A biocidal product shall not be authorised for making available on the market for use by the general public where:

(a) it fulfils the criteria according to Directive 1999/45/EC for classification as:

– toxic or very toxic;

– a category 1 or 2 carcinogen;

– a category 1 or 2 mutagen; or

– toxic for reproduction category 1 or 2;

(b) it fulfils the criteria according to Regulation (EC) No 1272/2008 for classification as:

– acute oral toxicity category 1 or 2 or 3;

– acute dermal toxicity category 1 or 2 or 3;

– acute inhalation toxicity (gases and dust/mist) category 1 or 2 or 3;

– acute inhalation toxicity (vapours) category 1 or 2;

– a category 1A or 1B carcinogen;

– a category 1A or 1B mutagen; or

– toxic for reproduction category 1A or 1B;

(c) it fulfils the criteria for being PBT or vPvB in accordance with Annex XIII to Regulation (EC) No 1907/2006;

(d) it has endocrine-disrupting properties; or

(e) it has developmental neurotoxic or immunotoxic effects.

5. Notwithstanding paragraphs 1 and 4, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met, or may be authorised for making available on the market for use by the general public when the criteria referred to in paragraph 4(c) are met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human or animal health or to the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

6. In the case of a biocidal product family, a reduction in the percentage of one or more active substances may be allowed, and/or a variation in percentage of one or more non-active substances, and/or the replacement of one or more non-active substances by other specified substances presenting the same or lower risk. The classification, hazard and precautionary statements for each product within the biocidal product family shall be the same (with the exception of a biocidal product family comprising a concentrate for professional use and ready-for-use products obtained through dilution of that concentrate).

A biocidal product family shall be authorised only if all the biocidal products within it, taking into account the permitted variations referred to in the first subparagraph, are expected to comply with the conditions set out in paragraph 1.

7. Where appropriate, the prospective authorisation holder or its representative shall apply for the establishment of maximum residue limits with respect to active substances contained in a biocidal product in accordance with Regulation (EEC) No 315/93, Regulation (EC) No 1935/2004, Regulation (EC) No 396/2005, Regulation (EC) No 470/2009 and Directive 2002/32/EC.

8. Where a biocidal product is intended for direct application to the external parts of the human body (epidermis, hair system, nails, lips and external genital organs), or to the teeth and the mucous membranes of the oral cavity, it shall not contain any non-active substance that may not be included in a cosmetic product pursuant to Regulation (EC) No 1223/2009.

Article 19

Requirements for applications for authorisation

1. The applicant for an authorisation shall submit the following documents together with the application:

(a) for biocidal products other than biocidal products meeting the conditions laid down in Article 24:

(i) a dossier or letter of access for the biocidal product satisfying the requirements set out in Annex III;

(ii) a summary of the characteristics of the biocidal product including the information referred to in points (a), (b) and (e) to (m) of Article 21(2), as applicable;

(iii) a dossier or a letter of access for the biocidal product satisfying the requirements set out in Annex II for each active substance in the biocidal product;

(b) for biocidal products that the applicant considers meet the conditions laid down in Article 24:

(i) a summary of the characteristics of the biocidal product as referred to in point (a)(ii) of this paragraph;

(ii) efficacy data; and

(iii) any other relevant information in support of the conclusion that the biocidal product meets the conditions laid down in Article 24.

2. The receiving competent authority may require that applications for national authorisation be submitted in one or more of the official languages of the Member State where that competent authority is situated.

3. If the application concerns a biocidal product that is intended by its manufacturer to be used also for the purposes referred to in Article 2(6), it shall be accompanied by a declaration of conformity regarding compliance with the relevant essential requirements of Directives 90/385/EEC, 93/42/EEC or 98/79/EC.

Article 20

Waiving of data requirements

1. By way of derogation from Article 19, the applicant need not provide data required under that Article where any of the following applies:

   (a) the data are not necessary owing to the exposure associated with the proposed uses;

   (b) it is not scientifically necessary to supply the data; or

   (c) it is not technically possible to generate the data.

2. The applicant may propose to adapt the data requirements of Article 19 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.

3. In order to ensure the harmonised application of paragraph 1(a) of this Article, the Commission shall be empowered to adopt delegated acts in accordance with Article 82 specifying criteria for defining when the exposure associated with the proposed uses would justify adapting the data requirements of Article 19.

Article 21

Content of authorisation

1. An authorisation shall stipulate the terms and conditions relating to the making available on the market and use of the single biocidal product or the biocidal product family and include a summary of the biocidal product characteristics.

2. Without prejudice to Articles 65 and 66, the summary of the biocidal product characteristics for a single biocidal product or, in the case of a biocidal product family, the biocidal products within that biocidal product family, shall include 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 of the biocidal product, together with, in the case of a biocidal product family, the suffixes to apply to individual biocidal products within the biocidal product family;

(e) qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge of which is essential for proper use of biocidal products; and in the case of a biocidal product family, the quantitative composition shall indicate a minimum and maximum percentage for each active and non-active substance, where the minimum percentage indicated for certain substances may be 0 %;

(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) type of formulation of the biocidal product;

(i) hazard and precautionary statements;

(j) product-type and, where relevant, an exact description of the authorised use;

(k) target harmful organisms;

(l) application doses and instructions for use;

(m) categories of users;

(n) particulars of likely direct or indirect adverse effects and first aid instructions and emergency measures to protect the environment;

(o) instructions for safe disposal of the product and its packaging;

(p) conditions of storage and shelf-life of the biocidal product under normal conditions of storage;

(q) in the case of a biocidal product that is intended by its manufacturer to be used also for the purposes referred to in Article 2(6), any specific use conditions 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;

(r) where relevant, other information about the biocidal product.

Article 22

Comparative assessment of biocidal products

1. The receiving competent authority or, in the case of an 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 authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1).

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 making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment in accordance with Annex VI ("comparative assessment") demonstrates that both of the following criteria are met:

   (a) for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human and animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages;

   (b) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.

4. By way of derogation from paragraph 1, a biocidal product containing an active substance that is a candidate for substitution may be authorised for a period of up to four years without comparative assessment in exceptional cases where it is necessary to acquire experience first through using that product in practice.

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 that decision by means of implementing acts in accordance with the examination procedure referred to in Article 81(3).

The Commission shall be empowered to adopt delegated acts in accordance with Article 82 specifying when comparative assessments involve questions better addressed at Union level and the procedures for such comparative assessments.

6. Notwithstanding Article 17(4), and without prejudice to paragraph 4 of this Article, an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted for a period not exceeding five years and renewed for a period not exceeding five years.

7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or amendment of the authorisation shall take effect five years after that decision. However, where the approval of the active substance which is a candidate for substitution expires on an earlier date, the cancellation of the authorisation shall take effect on that earlier date.

Article 23

Technical guidance notes

The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter and, in particular, Articles 21(2) and 22(3).

CHAPTER V

SIMPLIFIED AUTHORISATION PROCEDURE

Article 24

Eligibility for the simplified authorisation procedure

For eligible biocidal products, an application for authorisation may be made under a simplified authorisation procedure. A biocidal product shall be eligible if all the following conditions are met:

(a) all the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex;

(b) the biocidal product does not contain any substance of concern;

(c) the biocidal product is sufficiently effective; and

(d) the handling of the biocidal product and its intended use do not require personal protective equipment.

Article 25

Applicable procedure

1. Applicants seeking the authorisation of a biocidal product meeting the conditions of Article 24 shall submit an application to the Agency, informing it of the name of the competent authority of the Member State that it proposes should evaluate the application and providing written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

2. The Agency shall, after checking that it has been submitted in the correct format, notify the evaluating competent authority without delay that the application is available via the Register for Biocidal Products.

   The evaluating competent authority shall inform the applicant of the fees payable under Article 79 and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

   Upon receipt of the fees payable under Article 79, the evaluating competent authority shall accept the application and inform the applicant accordingly.

3. Within 90 days of accepting an application, the evaluating competent authority shall authorise the biocidal product if satisfied that the product meets the conditions laid down in Article 24.

4. Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The evaluating competent authority shall, within 90 days of receipt of the additional information, authorise the biocidal product if satisfied, on the basis of the additional information submitted, that the product meets the conditions laid down in Article 24.

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, part of the fee paid in accordance with Article 79 shall be reimbursed.

5. On authorising the biocidal product in accordance with paragraph 3 or 4, the evaluating competent authority shall without delay inform the applicant, the Agency and other competent authorities accordingly via the Register for Biocidal Products indicating the exact date of the authorisation.

6. An appeal may be brought, in accordance with Article 76, against decisions of the Agency under paragraph 2 of this Article.

Article 26

Making available on the market of biocidal products authorised in accordance with the simplified authorisation procedure

1. A biocidal product authorised in accordance with Article 25 may be made available on the market in all Member States without the need for mutual recognition. However, the authorisation holder shall notify each Member State before placing the biocidal product on the market within the territory of that Member State and shall use the official language or languages of that Member State in the product's labelling, unless that Member State provides otherwise.

2. Where a Member State other than that of the evaluating competent authority considers that a biocidal product authorised in accordance with Article 25 has not been notified or labelled in accordance with paragraph 1 of this Article or does not meet the requirements of Article 24, it may refer that matter to the coordination group established in accordance with Article 34(1). Article 34(3) and Article 35 shall apply *mutatis mutandis*.

Where a Member State has valid reasons to consider that a biocidal product authorised in accordance with Article 25 does not meet the criteria laid down in Article 24 and a decision pursuant to Articles 34 and 35 has not yet been taken, that Member State may provisionally restrict or prohibit the use or sale of that product on its territory.

Article 27

Amendment of Annex I

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 82 amending Annex I, after receiving the opinion of the Agency, in order to include active substances provided that there is evidence that they do not give rise to concern according to paragraph 2.

2. Active substances give rise to concern where:

   (a) they fulfil the criteria for classification according to Regulation (EC) No 1272/2008 as:

   – explosive/highly flammable;

   – organic peroxide;

   – acutely toxic of category 1, 2 or 3;

   – corrosive of category IA, IB or IC;

   – respiratory sensitizer;

   – skin sensitizer;

   – germ cell mutagen of category 1 or 2;

   – carcinogen of category 1 or 2;

– human reproductive toxicant of category 1 or 2 or with effects on or via lactation;

– specific target organ toxicant by single or repeated exposure; or

– toxic to aquatic life of acute category 1;

(b) they fulfil any of the substitution criteria set out in Article 10(1); or

(c) they have neurotoxic or immunotoxic properties.

Active substances also give rise to concern, even if none of the specific criteria in points (a) to (c) are met, where a level of concern equivalent to that arising from points (a) to (c) can be reasonably demonstrated based on reliable information.

3. The Commission shall also be empowered to adopt delegated acts in accordance with Article 82 amending Annex I, after receiving the opinion of the Agency, in order to restrict or to remove the entry for an active substance if there is evidence that biocidal products containing that substance do not, in certain circumstances, satisfy the conditions set out in paragraph 1 of this Article or in Article 24. Where imperative grounds of urgency so require, the procedure provided for in Article 83 shall apply to delegated acts adopted pursuant to this paragraph.

4. The Commission shall apply paragraph 1 or 2 at its own initiative or at the request of an economic operator or a Member State providing the necessary evidence as referred to in those paragraphs.

Whenever the Commission amends Annex I it shall adopt a separate delegated act in respect of each substance.

CHAPTER VI
NATIONAL AUTHORISATIONS OF BIOCIDAL PRODUCTS

Article 28

Submission and validation of applications

1. Applicants wishing to apply for a national authorisation in accordance with Article 17 shall submit an application to the receiving competent authority. The receiving competent authority shall inform the applicant of the fees payable under Article 79, and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly. Upon receipt of the fees payable under Article 79, the receiving competent authority shall accept the application and inform the applicant indicating the exact date of the acceptance.

2. Within 30 days of acceptance, the receiving competent authority shall validate the application if it complies with the following requirements:

(a) the relevant information referred to in Article 19 has been submitted; and

(b) the applicant states that it has not applied to any other competent authority for a national authorisation for the same biocidal product for the same use(s).

In the context of the validation referred to in the first subparagraph, the receiving competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

3. Where the receiving competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The receiving competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirements laid down in paragraph 1.

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

4. Where the Register for Biocidal Products shows that a competent authority other than the receiving competent authority is examining an application relating to the same biocidal product or has already authorised the same biocidal product, the receiving competent authority shall decline to evaluate the application. In that event, the receiving competent authority shall inform the applicant of the possibility of seeking mutual recognition in accordance with Article 32 or 33.

5. If paragraph 3 does not apply and the receiving competent authority considers that the application is complete, it shall validate the application and without delay inform the applicant accordingly and indicate the date of the validation.

Article 29

Evaluation of applications

1. The receiving competent authority shall, within 365 days of the validation of an application in accordance with Article 28, decide whether to grant an authorisation in accordance with Article 18. It shall take into account the results of the comparative assessment carried out in accordance with Article 22, if applicable.

2. Where it appears that additional information is necessary to carry out the evaluation, the receiving competent authority shall ask the applicant to submit such information within a specified time limit. The 365-day period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances.

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

3. Within the 365-day period referred to in paragraph 1, the receiving competent authority shall:

(a) draft a report summarising the conclusions of its assessment and the reasons for authorising the biocidal product or for refusing to grant an authorisation (the "assessment report");

(b) send an electronic copy of the draft assessment report to the applicant and provide it with the opportunity to submit comments within 30 days; and

(c) take due account of those comments when finalising its assessment.

4. Where the receiving competent authority decides to grant an authorisation it shall enter the following information in the Register for Biocidal Products:

(a) the summary of biocidal product characteristics referred to in Article 21(2);

(b) the final assessment report;

(c) any terms or conditions imposed on the making available on the market or use of the biocidal product.

Where the receiving competent authority decides not to grant an authorisation it shall enter the final assessment report in the Register for Biocidal Products.

In either case, it shall notify the applicant of its decision together with an electronic copy of the final assessment report.

Article 30

Renewal of a national authorisation

1. An application by or on behalf of an authorisation holder wishing to seek the renewal of a national authorisation for one or more product-types shall be submitted to the receiving competent authority at least 550 days before the expiry date of the authorisation. Where renewal is sought for more than one product-type, the application shall be submitted at least 550 days before the earliest expiry date.

2. The receiving competent authority shall renew the national authorisation, provided that the conditions set out in Article 18 are still satisfied. It shall take into account the results of the comparative assessment carried out in accordance with Article 22, if applicable.

3. When applying for renewal, the applicant shall submit:

   (a) a list of all relevant data that it has generated since the initial authorisation or, as appropriate, previous renewal; and

   (b) its assessment of whether the conclusions of the initial or previous assessment of the biocidal product remain valid and any supporting information.

4. The receiving competent authority shall inform the applicant of the fees payable under Article 79 and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

Upon receipt of the fees payable under Article 79, the receiving competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

5. On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for authorisation or, as appropriate, the previous renewal, the receiving competent authority shall, within 90 days of accepting an application in accordance with paragraph 4, decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product types for which renewal is requested.

The receiving competent authority may at any time require the applicant to submit the data from the list referred to in point (a) of paragraph 3.

6. Where the receiving competent authority decides that a full evaluation of the application is necessary, it shall decide on the renewal of the authorisation after carrying out an evaluation of the application in accordance with paragraphs 1, 2 and 3 of Article 29.

Where the receiving competent authority decides that a full evaluation of the application is not necessary, it shall decide on the renewal of the authorisation within 180 days of accepting the application in accordance with paragraph 4 of this Article.

7. Where, for reasons beyond the control of the holder of a national authorisation, no decision is taken on the renewal of that authorisation before its expiry, the receiving competent authority shall grant a renewal for the period necessary to complete the evaluation.

8. As soon as the receiving competent authority has taken a decision on whether to grant a renewal of a national authorisation, it shall update the information referred to in Article 29(4) in the Register for Biocidal Products. It shall notify the applicant of its decision together with an electronic copy of the final assessment report.

CHAPTER VII
MUTUAL RECOGNITION PROCEDURES

Article 31

Authorisation through mutual recognition

1. Applications for mutual recognition of a national authorisation shall be made in accordance with the procedures set out in Article 32 (mutual recognition in sequence) or Article 33 (mutual recognition in parallel).

2. Without prejudice to Article 36, all Member States receiving applications for mutual recognition of a national authorisation for a biocidal product shall, in accordance with and subject to the procedures set out in this Chapter, authorise the biocidal product under the same terms and conditions.

Article 32

Mutual recognition in sequence

1. Applicants wishing to seek the mutual recognition in sequence in one or more Member States ("the Member States concerned") of the national authorisation of a biocidal product already granted in another Member State in accordance with Article 17 ("the reference Member State") shall submit an application to each of the competent authorities of the Member States concerned containing, in each case:

   (a) a translation of the national authorisation granted by the reference Member State, into such official languages of the Member State concerned as it may require; and

   (b) a summary in electronic form of the dossier satisfying the requirements set out in Annex III or, at the request of the competent authority of the Member State concerned, the actual information submitted to the competent authority of the reference Member State in accordance with Article 19.

The competent authorities of the Member States concerned shall inform the applicant of the fees payable under Article 79 and shall reject the application if the applicant fails to pay the fees within 30 days. They shall inform the applicant and the other competent authorities accordingly. Upon receipt of the fees payable under Article 79, the competent authority of the Member States concerned shall accept the application and inform the applicant indicating the date of acceptance.

2. Within 30 days of acceptance referred to in paragraph 1, the Member States concerned shall validate the application and inform the applicant accordingly, indicating the date of the validation.

Within 90 days of validating the application, and subject to Articles 34, 35 and 36, the Member States concerned shall agree on the summary of biocidal product characteristics and shall record their agreement in the Register for Biocidal Products.

3. The procedure shall be closed after all the Member States concerned have agreed on the summary of biocidal product characteristics and recorded their agreement in the Register for Biocidal Products.

4. Within 30 days of closure of the procedure, each of the Member States concerned shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics.

Article 33

Mutual recognition in parallel

1. Applicants wishing to seek the mutual recognition in parallel of a biocidal product which has not yet been authorised in accordance with Article 17 in any Member State shall submit to the competent authority of the Member State of its choice ("the reference Member State") an application containing:

   (a) the information referred to in Article 19;

   (b) a list of all other Member States where a national authorisation is sought ("the Member States concerned").

   The reference Member State shall be responsible for the evaluation of the application.

2. The applicant shall, at the same time as submitting the application to the reference Member State in accordance with paragraph 1, submit to the competent authorities of each of the Member States concerned an application for mutual recognition of the authorisation for which it has applied to the reference Member State. This application shall contain:

   (a) a summary in electronic form of the dossier as required in Annex III or, at the request of any of the competent authorities of the Member States concerned, the actual information submitted to the competent authority of the reference Member State in accordance with Article 19;

(b) the names of the reference Member State and of the Member States concerned;

(c) the summary of biocidal product characteristics referred to in Article 19(1)(a)(ii) in such official languages of the Member States concerned as they may require.

3. The competent authorities of the reference Member State and of the Member States concerned shall inform the applicant of the fees payable in accordance with Article 79 and shall reject the application if the applicant fails to pay the fees within 30 days. They shall inform the applicant and the other competent authorities accordingly. Upon receipt of the fees payable under Article 79, the competent authorities of the reference Member State and of the Member States concerned shall accept the application and inform the applicant accordingly indicating the date of acceptance.

4. The reference Member State shall validate the application in accordance with Article 28(2) and (3) and inform the applicant and the Member States concerned accordingly.

Within 365 days of validating an application, the reference Member State shall evaluate the application and draft an assessment report in accordance with Article 29(3) and shall send its assessment report and the summary of biocidal product characteristics to the Member States concerned and to the applicant.

5. Within 90 days of receipt of the documents referred to in paragraph 4, and subject to Articles 34, 35 and 36, the Member States concerned shall agree on the summary of biocidal product characteristics, and shall record their agreement in the Register for Biocidal Products. The reference Member State shall enter the agreed summary of biocidal product characteristics and the final assessment report in the Register for Biocidal Products, together with any agreed terms or conditions imposed on the making available on the market or use of the biocidal product.

6. The procedure shall be closed after all the Member States concerned have agreed the summary of biocidal product characteristics and recorded their agreement in the Register for Biocidal Products.

7. Within 30 days of closure of the procedure, the reference Member State and each of the Member States concerned shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics.

Article 34

Referral of objections to the coordination group

1. A coordination group shall be set up to examine any question, other than matters referred to in Article 36, relating to whether a biocidal product for which an application for mutual recognition has been made in accordance with Article 32 or Article 33 meets the conditions for granting an authorisation laid down in Article 18.

   All Member States and the Commission shall be entitled to participate in the work of the coordination group. The Agency shall provide the secretariat of the coordination group.

The coordination group shall establish its rules of procedure.

2. If, within the 90-day period laid down in Articles 32(2) and 33(5), any of the Member States concerned considers that a biocidal product authorised by the reference Member State does not meet the conditions laid down in Article 18, it shall send a detailed explanation of the points of disagreement and the reasons for its position to the reference Member State, the other Member States concerned, the applicant, and, where applicable, to the authorisation holder. The points of disagreement shall be referred without delay to the coordination group.

3. Within the coordination group, all Member States referred to in paragraph 2 of this Article shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known. Where they reach agreement within 60 days of the referral of the points of disagreement referred to in paragraph 2 of this Article, the reference Member State shall record the agreement in the Register for Biocidal Products. The procedure shall then be considered to be closed and the reference Member State and each of the Member States concerned shall authorise the biocidal product in accordance with Article 32(4) or 33(7) as appropriate.

Article 35

Referral of unresolved objections to the Commission

1. If the Member States referred to in Article 34(2) fail to reach agreement within the 60-day period laid down in Article 34(3), the reference Member State shall immediately inform the Commission, and provide it with a detailed statement of the matters on which Member States have been unable to reach agreement and the reasons for their disagreement. A copy of that statement shall be forwarded to the Member States concerned, the applicant and, where applicable, the authorisation holder.

2. The Commission may ask the Agency for an opinion on scientific or technical questions raised by Member States. Where the Commission does not ask the Agency for an opinion it shall provide the applicant and, where applicable, the authorisation holder with the opportunity to provide written comments within 30 days.

3. The Commission shall adopt, by means of implementing acts, a decision on the matter referred to it. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

4. The decision referred to in paragraph 3 shall be addressed to all Member States and reported for information to the applicant and, where applicable, the authorisation holder. The Member States concerned and the reference Member State shall, within 30 days of notification of the decision, either grant, refuse to grant or revoke the authorisation, or vary its terms and conditions as necessary to comply with the decision.

Article 36

Derogations from mutual recognition

1. By way of derogation from Article 31(2), any of the Member States concerned may propose to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of:

   (a) the protection of the environment;

   (b) public policy or public security;

   (c) the protection of health and life of humans, animals or plants;

   (d) the protection of national treasures possessing artistic, historic or archaeological value; or

   (e) the target organisms not being present in harmful quantities.

   Any of the Member States concerned may, in particular, propose in accordance with the first subparagraph to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or 10(1) applies.

2. The Member State concerned shall communicate to the applicant a detailed statement of the grounds for seeking a derogation pursuant to paragraph 1 and shall seek to reach an agreement with the applicant on the proposed derogation.

If the Member State concerned is unable to reach agreement with the applicant or receives no reply from the applicant within 60 days of that communication it shall inform the Commission. In that case, the Commission:

(a) may ask the Agency for an opinion on scientific or technical questions raised by the applicant or the Member State concerned;

(b) shall adopt a decision on the derogation in accordance with the examination procedure referred to in Article 81(3).

The Commission's decision shall be addressed to the Member State concerned and the Commission shall inform the applicant thereof.

The Member State concerned shall take necessary measures to comply with the Commission's decision within 30 days of its notification.

3. By way of derogation from Article 31(2), a Member State may refuse to grant authorisations for product-types 15, 17 and 20 on grounds of animal welfare. Member States shall without delay inform other Member States and the Commission of any decision taken in this respect and its justification.

Article 37

Opinion of the Agency

1. If so requested by the Commission pursuant to Article 35(2) or 36(2), the Agency shall issue an opinion within 120 days from the date on which the matter in question was referred to it.

2. Before issuing its opinion, the Agency shall provide the applicant and, where applicable, the authorisation holder with an opportunity to provide written comments within a specified time limit not exceeding 30 days.

   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 38

Application for mutual recognition by official or scientific 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 the protection of public health may apply, under the mutual recognition procedure provided for in Article 32 and with the consent of the authorisation holder in that other Member State, for a national authorisation for the same biocidal product, with the same use and the same conditions for use as in that Member State.

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 79.

2. Where the competent authority of the Member State concerned considers that the biocidal product fulfils the conditions referred to in Article 18 and the conditions under this Article are met, the competent authority shall authorise the making available on the market and use of the biocidal product. In that case, the body that made the application shall have the same rights and obligations as other authorisation holders.

Article 39

Detailed rules and technical guidance notes

The Commission shall be empowered to adopt delegated acts in accordance with Article 82 specifying detailed rules for the renewal of authorisations subject to mutual recognition.

The Commission shall also draw up technical guidance notes to facilitate the implementation of this Chapter and, in particular, Articles 36 and 38.

CHAPTER VIII
UNION AUTHORISATIONS OF BIOCIDAL PRODUCTS

SECTION 1
GRANTING OF UNION AUTHORISATIONS

Article 40

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 Member State as a national authorisation. For those categories of biocidal products referred to in Article 41(1), the applicant may apply for Union authorisation as an alternative to applying for a national authorisation and mutual recognition.

Article 41

Biocidal products for which Union authorisation may be granted

1. Applicants may apply for Union authorisation for biocidal products which have similar conditions of use across the Union and which fall within the following categories of biocidal products:

   (a) biocidal products of product-types 6, 7, 9, 10, 12, 13 and 22; and

(b) with effect from 1 January 2020, all other biocidal products except for those of product-types 14, 15, 17, 20 and 21.

2. The Commission shall report to the European Parliament and the Council on the application of this Article by 31 December 2017. It shall, if appropriate, accompany its report with relevant proposals for adoption in accordance with the ordinary legislative procedure.

Article 42

Submission and validation of applications

1. Applicants wishing to apply for Union authorisation in accordance with Article 41(1) shall submit an application to the Agency, including a confirmation that the biocidal product would have similar conditions of use across the Union, informing the Agency of the name of the competent authority of the Member State that they propose should evaluate the application and providing written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

2. The Agency shall, after checking that the application has been submitted in the correct format, notify the evaluating competent authority without delay that the application is available via the Register for Biocidal Products.

The Agency shall inform the applicant of the fees payable under Article 79(1), and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable under Article 79(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly.

3. Within 30 days of the Agency accepting an application, the evaluating competent authority shall validate the application if the relevant information referred to in Article 19 has been submitted.

In the context of the validation referred to in the first subparagraph, the evaluating competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

4. Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant what additional information is required for the evaluation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The evaluating competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirement laid down in paragraph 3.

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, part of the fee paid in accordance with Article 79 shall be reimbursed.

5. On validating the application in accordance with paragraph 3 or 4, the evaluating competent authority shall, without delay, inform the applicant, the Agency and other competent authorities accordingly and indicate the exact date of the validation.

6. An appeal may be brought, in accordance with Article 76, against decisions of the Agency under paragraph 2 of this Article.

Article 43

Evaluation of applications

1. The evaluating competent authority shall, within 365 days of the validation of an application, evaluate it in accordance with Article 18, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 20(2), and send an assessment report and the conclusions of its evaluation to the Agency.

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall provide the applicant with the opportunity to provide written comments on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

2. Where 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 accordingly. The 365-day period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received. However, the suspension shall not exceed 180 days in total other than in exceptional cases and where justified by the nature of the data requested.

3. Within 180 days of 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 laid down in Article 18(1) are fulfilled, and a draft summary of biocidal product characteristics, as referred to in Article 21(2);

(b) where relevant, details of any terms or conditions which should be imposed on the making available 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, by means of implementing acts, a decision on the Union authorisation of the biocidal product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3). As soon as the Commission has taken a decision to grant a Union authorisation, it shall enter the information referred to in Article 29(4) in the Register for Biocidal Products.

The Commission may, at the request of a Member State, decide to adjust certain conditions of a Union authorisation specifically for the territory of that Member State or decide that a Union authorisation shall not apply in the territory of that Member State, provided that such a request can be justified on one or more of the grounds referred to in Article 36(1).

SECTION 2

RENEWAL OF UNION AUTHORISATIONS

Article 44

Submission and acceptance of applications

1. An application by or on behalf of an authorisation holder wishing to seek the renewal of a Union authorisation shall be submitted to the Agency at least 550 days before the expiry date of the authorisation.

The application shall be accompanied by the fees payable under Article 79(1).

2. When applying for renewal, the applicant shall submit:

(a) a list of all relevant data that it has generated since the initial authorisation or, as appropriate, previous renewal; and

(b) its assessment of whether the conclusions of the initial or previous assessment of the biocidal product remain valid and any supporting information.

3. The applicant shall also submit the name of the competent authority of the Member State that it proposes should evaluate the application for renewal and provide written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

The Agency shall, after checking that the application has been submitted in the correct format, notify the evaluating competent authority without delay that the application is available via the Register for Biocidal Products.

The Agency shall inform the applicant of the fees payable to it under Article 79(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable to it under Article 79(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly.

4. An appeal may be brought, in accordance with Article 76, against decisions of the Agency under paragraph 3 of this Article.

Article 45

Evaluation of applications for renewal

1. On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for Union authorisation or, as appropriate, the previous renewal, the evaluating competent authority shall, within 30 days of the Agency accepting the application in accordance with Article 44(3), decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary.

   The evaluating competent authority may at any time require the applicant to submit the data from the list referred to in Article 44(2)(a).

2. Where 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 and 2 of Article 43.

   Where the evaluating competent authority decides that a full evaluation of the application is not necessary, it shall, within 180 days of the Agency accepting the application, prepare and submit to the Agency a recommendation on the renewal of the authorisation. It shall provide the applicant with a copy of its recommendation.

3. Within 180 days of receipt of a recommendation from the evaluating competent authority, the Agency shall prepare and submit to the Commission an opinion on the renewal of the Union authorisation.

4. 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 examination procedure referred to in Article 81(3). As soon as the Commission has taken a decision, it shall update the information referred to in Article 29(4) in the Register for Biocidal Products.

   The Commission shall renew a Union authorisation, provided that the conditions set out in Article 18 are still satisfied.

5. 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 by means of implementing acts. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 81(2).

CHAPTER IX
CANCELLATION, REVIEW AND AMENDMENT OF AUTHORISATIONS

Article 46

Obligation for notification of unexpected or adverse effects

1. On becoming aware of information concerning the authorised biocidal product, or the active substance(s) it contains, which may affect the authorisation, the holder of an authorisation 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 data or information on the adverse effects of the active substance or biocidal product for humans, in particular vulnerable groups, or the environment;

   (b) any data indicating the potential of the active substance for the development of resistance;

   (c) new data or information indicating that the biocidal product is not sufficiently effective.

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 47.

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 data or information it receives.

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 47.

Article 47

Cancellation or amendment of an authorisation

1. Without prejudice to Article 22, the competent authority of a Member State or, in the case of a Union authorisation, the Commission, shall at any time cancel or amend an authorisation it has granted where it considers that:

(a) the conditions referred to in Article 18 are not satisfied;

(b) the authorisation was granted on the basis of false or misleading information; or

(c) the authorisation holder has failed to comply with its obligations under the authorisation or this Regulation.

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 it the opportunity to submit comments or additional information within a specified time limit. The evaluating competent authority or, in the case of a Union authorisation, the Commission, shall take due account of those 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 that have issued authorisations under the mutual recognition procedure for biocidal products for which the authorisation has been cancelled or amended shall, within 120 days of the notification, cancel or amend the authorisations and shall notify the Commission accordingly.

In the case of disagreement between competent authorities of certain Member States concerning national authorisations subject to mutual recognition the procedures laid down in Articles 34 and 35 shall apply *mutatis mutandis*.

4. As soon as the competent authority or, in the case of a Union authorisation, the Commission, has taken a decision to cancel or amend an authorisation, it shall update the information referred to in Article 29(4) relating to the biocidal product concerned in the Register for Biocidal Products.

Article 48

Cancellation of an authorisation

at the request of the authorisation holder

At the reasoned request of an authorisation holder, the competent authority that granted the national authorisation or, in the case of Union authorisation, the Commission, shall cancel the authorisation. Where such a request concerns a Union authorisation, it shall be submitted to the Agency.

As soon as the competent authority or, in the case of a Union authorisation, the Commission, has taken a decision to cancel an authorisation, it shall update the information referred to in Article 29(4) relating to the biocidal product concerned in the Register for Biocidal Products.

Article 49

Amendment of an authorisation

at the request of the authorisation holder

1. Amendments to the terms and conditions of an authorisation shall be made only by the competent authority that authorised the biocidal product concerned, or in the case of a Union authorisation, by the Commission.

2. An authorisation holder seeking to change any of the information submitted in relation to the initial application for authorisation of the product shall apply to the competent authorities of relevant Member States having authorised the biocidal product concerned, or in the case of a Union authorisation, the Agency. Those competent authorities shall decide, or, in the case of a Union authorisation, the Agency shall examine and the Commission decide whether the conditions of Article 18 are still met and whether the terms and conditions of the authorisation need to be amended.

   The application shall be accompanied by the fees payable under Article 79.

Article 50

Detailed rules

In order to ensure a harmonised approach to the cancellation and amendment of authorisations, the Commission shall lay down detailed rules for the application of Articles 46 to 49 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

The rules referred to in the first paragraph of this Article shall be based*, inter alia,* on the following principles:

(a) a simplified notification procedure shall be applied for administrative changes;

(b) a reduced evaluation period shall be established for minor changes;

(c) in the case of major changes, the evaluation period shall be proportionate to the extent of the proposed change.

Article 51

Period of grace

Notwithstanding Article 88, 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, making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health or the environment.

The period of grace shall not exceed 180 days for the making available on the market and an additional maximum period of 180 days for the disposal and use of existing stocks of the biocidal products concerned.

CHAPTER X
PARALLEL TRADE

Article 52

Parallel trade

1. A competent authority of a Member State ("Member State of introduction") shall, at the request of the applicant, grant a parallel trade permit for a biocidal product that is authorised in another Member State ("Member State of origin") to be made available on the market and used in the Member State of introduction, if it determines in accordance with paragraph 3 that the biocidal product is identical to a biocidal product already authorised in the Member State of introduction ("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 the information referred to in paragraph 4 and all other information necessary to demonstrate that the biocidal product is identical to the reference product as defined in paragraph 3.

2. Where the competent authority of the Member State of introduction determines that a biocidal product is identical to the reference product, it shall grant a parallel trade permit within 60 days of receipt of the fees payable under Article 79. 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 30 days of receiving the request.

3. A biocidal product shall be considered as identical to the reference product only if all the following conditions are met:

(a) they have been manufactured by the same company, by an associated undertaking or under license in accordance with the same manufacturing process;

(b) they are identical in specification and content in respect of the active substances and the type of formulation;

(c) they are the same in respect of the non-active substances present; and

(d) they are either the same or equivalent in 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) name and address of the competent authority of the Member State of origin;

(c) name and address of the authorisation holder in the Member State of origin;

(d) 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;

(e) name and address of the applicant;

(f) name to be given to the biocidal product to be distributed in the Member State of introduction;

(g) a draft label for the biocidal product intended to be made available on the market in the Member State of introduction in the official language or languages of the Member State of introduction, unless that Member State provides otherwise;

(h) a sample of the biocidal product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;

(i) 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 (d).

5. The parallel trade permit shall prescribe the same conditions for making available 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 48 and the requirements of Article 18 are still fulfilled, the validity of the parallel trade permit shall expire on the date on which the authorisation of the reference product would normally have expired.

7. Without prejudice to specific provisions in this Article, Articles 46 to 49 and Chapter XV shall apply *mutatis mutandis* to biocidal products made available 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 29(4) in the Register for Biocidal Products.

CHAPTER XI
TECHNICAL EQUIVALENCE

Article 53

Assessment of technical equivalence

1. Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence ("the applicant") shall submit an application to the Agency and pay the applicable fee.

2. The applicant shall submit all data necessary to assess technical equivalence.

3. After giving the applicant the opportunity to submit comments, the Agency shall take a decision within 90 days of receipt of the application and shall communicate it to Member States and to the applicant.

4. Where appropriate, the Agency may consult the competent authority of the Member State which acted as the evaluating competent authority for the evaluation of the active substance.

5. An appeal may be brought, in accordance with Article 76, against decisions of the Agency under paragraph 3 of this Article.

6. The Commission may draw up technical guidance notes to facilitate the implementation of this Article.

CHAPTER XII
DEROGATIONS

Article 54

Derogation from the requirements

1. By way of derogation from Articles 17 and 18, a competent authority may permit, for a period not exceeding 270 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use, if such a measure is necessary because of a danger to public health or the environment which cannot be contained by other means.

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 the revocation of such action.

On receipt of a reasoned request from the competent authority, the Commission shall, without delay and by means of implementing acts, decide whether, and under what conditions, the action taken by that competent authority may be extended, for a period not exceeding 550 days. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

2. By way of derogation from point (a) of Article 18(1) and until an active substance is approved, competent authorities and the Commission may authorise, for a period not exceeding three years, a biocidal product containing a new active substance.

Such a provisional authorisation may be issued only if, after dossiers have been evaluated in accordance with Article 8, the evaluating competent authority has submitted a recommendation for approval of the new active substance and the competent authorities which received the application for the provisional authorisation or, in the case of a provisional Union authorisation, the Agency, consider that the biocidal product may be expected to comply with points (b), (c) and (d) of Article 18(1) taking into account the factors set out in Article 18(2).

The competent authorities or the Commission shall enter the information referred to in Article 29(4) in the Register for Biocidal Products.

If the Commission decides not to approve the new active substance, the competent authorities which granted the provisional authorisation or the Commission shall cancel that authorisation.

Where a decision on the approval of the new active substance has not yet been adopted by the Commission when the period of three years expires, the competent authorities which granted the provisional authorisation, or the Commission, may extend the provisional authorisation for a period not exceeding one year, provided that there are good reasons to believe that the active substance will satisfy the requirements of Article 4(1) or, where applicable, Article 5(2). Competent authorities which extend the provisional authorisation shall inform the other competent authorities and the Commission of such action.

3. By way of derogation from point (a) of Article 18(1), the Commission may, by means of implementing acts, allow a Member State to authorise a biocidal product containing a non-approved active substance if it is satisfied that that active substance is essential for the protection of cultural heritage and that no appropriate alternatives are available. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 81(2). A Member State wishing to obtain such a derogation shall apply to the Commission, providing due justification.

Article 55

Research and development

1. By way of derogation from Article 17, an experiment or a test for the purposes of research or development involving an unauthorised biocidal product or a non-approved active substance intended exclusively for use in a biocidal product ("experiment" or "test") may take place only under the conditions laid down in this Article.

   Persons carrying out an experiment or test 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. They shall make this information available to the competent authority on request.

2. Any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the relevant competent authority of the Member State where the experiment or test will occur. The notification shall include the information listed in the second subparagraph of paragraph 1.

   In the absence of an opinion from the competent authority within 45 days of the notification referred to in the first subparagraph, the notified experiment or test may take place.

3. If the experiments or tests could have harmful effects, whether immediate or delayed, on human or animal health, in particular on vulnerable groups, or any unacceptable adverse effect on the environment, humans or animals, the relevant 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 of its decision.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 82 specifying detailed rules for the application of this Article.

Article 56

Exemption from registration

under Regulation (EC) No 1907/2006

In addition to the active substances referred to in Article 17(2) of Regulation (EC) No 1907/2006, active substances manufactured or imported for use in biocidal products authorised for placing on the market in accordance with Article 26, Article 54 or Article 55 shall be regarded as being registered and the registration as completed for manufacture or import for use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5, Title II of Regulation (EC) No 1907/2006.

CHAPTER XIII
TREATED ARTICLES

Article 57

Placing on the market of treated articles

1. This Article shall apply exclusively to treated articles within the meaning of Article 3(1)(l) that are not biocidal products within the meaning of Article 3(1)(a). It shall not apply to treated articles where the sole treatment undertaken was the fumigation or disinfection of premises or containers used for storage or transport and where no residues are expected to remain from such treatment.

2. A treated article shall not be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2), for the relevant product-type and use, or in Annex I, and any conditions or restrictions specified therein are met.

3. Where the release of the active substances contained in the biocidal products with which a treated article was treated or which it incorporates, is intended or expected under normal or reasonably foreseeable conditions of use, the person responsible for the placing on the market of that treated article shall ensure that the label provides the following information:

   (a) a statement that the treated article incorporates biocidal products;

(b) where substantiated, the biocidal property attributed to the treated article;

(c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;

(d) any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates.

4. Where the release of the active substances contained in the biocidal products with which a treated article was treated or which it incorporates, is not intended or expected under normal or reasonably foreseeable conditions of use, the person responsible for the placing on the market of the treated article shall ensure that the label provides the following information:

(a) a statement that the treated article was treated with biocidal products; and

(b) the address of a website containing the name of all active substances used for the treatment, without prejudice to Article 24 of Regulation (EC) No 1272/2008.

The label of such a treated article shall not lay claim to any biocidal property.

5. The labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty.

6. The Commission may adopt implementing acts for the application of paragraph 2 of this Article, including appropriate notification procedures, possibly involving the Agency, and further specifying the labelling requirements under paragraph 3, 4 and 5 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

7. Where there are serious indications that an active substance contained in a biocidal product with which a treated article is treated or which it incorporates does not meet the conditions laid down in Article 4(1), 5(2) or 24, the Commission shall review the approval of that active substance or its inclusion in Annex I in accordance with Article 15(1) or 27(2).

CHAPTER XIV
DATA PROTECTION AND DATA-SHARING

Article 58

Protection of data held by competent authorities or the Agency

1. Without prejudice to Articles 61 and 62, data 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 where:

   (a) the subsequent applicant has a letter of access; or

(b) the relevant time limit for data protection has expired.

2. When submitting data to a competent authority or to the Agency for the purposes of this Regulation the applicant shall, where relevant, indicate the name and contact details of the data owner for all data submitted. The applicant shall also specify whether it is the data owner or holds a letter of access.

3. The applicant shall, without delay, inform the competent authority or the Agency about any changes to the ownership of the data.

4. 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[1] shall also have access to the data referred to in paragraph 1 of this Article.

Article 59

Data protection periods

1. Data 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 the data shall start when they are submitted for the first time.

[1] OJ L 66, 4.3.2004, p. 45.

Data protected under Directive 98/8/EC or under this Article or for which the protection period expired under Directive 98/8/EC or under this Article shall not be protected again.

2. The protection period for data submitted with a view to the approval of an existing active substance shall end 10 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

The protection period for data submitted with a view to the approval of a new active substance shall end 15 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

The protection period for new data submitted with a view to the renewal or review of the approval of an active substance shall end 5 years from the first day of the month following the date of the adoption of a decision in accordance with Article 14(4) concerning the renewal or the review.

3. The protection period for data submitted with a view to the authorisation of a biocidal product containing only existing active substances shall end 10 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 29(4), Article 33(7) or Article 43(4).

The protection period for data submitted with a view to the authorisation of a biocidal product containing a new active substance shall end 15 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 29(4), 33(7) or 43(4).

The protection period for new data submitted with a view to the renewal or amendment of the authorisation of a biocidal product shall end 5 years from the first day of the month following the decision concerning the renewal or amendment of the authorisation.

Article 60

Letter of access

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

   (a) the name and contact details of the data owner and the beneficiary;

   (b) the name of the active substance or biocidal product for which access to the data is authorised;

   (c) the date on which the letter of access takes effect;

   (d) a list of the submitted data to which the letter of access grants citation rights.

2. Revocation of a letter of access shall not affect the validity of the authorisation issued on the basis of the letter of access in question.

Article 61

Data sharing

1. In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. 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 ("the prospective applicant") shall ask the Agency whether such tests or studies have already been submitted in connection with a previous application under this Regulation or Directive 98/8/EC. The competent authority or the Agency shall verify whether such tests or studies have already been submitted.

   Where such tests or studies have already been submitted in connection with a previous application, under this Regulation or Directive 98/8/EC, the competent authority or the Agency shall, without delay, communicate the name and contact details of the data owner to the prospective applicant.

   Where the data acquired under those tests or studies are still protected under Article 59, the prospective applicant:

   (a) shall, in the case of data involving tests on vertebrate animals, request from the data owner the right to refer to those tests or studies; and

   (b) may, in the case of data not involving tests on vertebrate animals, request from the data owner the right to refer to those tests or studies.

Article 62

Compensation for data sharing

1. Where a request has been made in accordance with Article 61(2), the prospective applicant and the data owner 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 data owner shall make the data available to the prospective applicant and shall give the prospective applicant permission to refer to the data owner's tests or studies.

3. Where no such agreement is reached within 60 days of a request made according to Article 61(2) with respect to data involving tests on vertebrate animals, the prospective applicant shall, without delay, inform the Agency, competent authority and the data owner accordingly. Within 60 days of being informed about the failure to reach an agreement, the Agency shall give the prospective applicant the right to refer to those tests or studies. Where the prospective applicant and data owner cannot agree, national courts shall decide on the proportionate share of the cost that the prospective applicant shall pay to the data owner.

4. Compensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner, having regard to the guidance established by the Agency[1]. The prospective applicant shall be required to share only in the costs of information that it is required to submit for the purposes of this Regulation.

5. An appeal may be brought, in accordance with Article 76, against decisions of the Agency under paragraph 3 of this Article.

Article 63

Use of data for subsequent applications

1. Where the relevant data protection period according to Article 59 has expired in relation to an active substance, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the active substance is technically equivalent to the active substance for which the data protection period has expired, including the degree of purity and the nature of any relevant impurities.

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[1] Chapter 7 of the guidance on data sharing established in accordance with Regulation (EC) No 1907/2006.

Where the relevant data protection period according to Article 59 has expired in relation to a biocidal product, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the biocidal product is the same as the one already authorised, or the differences between them are not significant in relation to the risk assessment and the active substance(s) in the biocidal product are technically equivalent to those in the biocidal product already authorised, including the degree of purity and the nature of any impurities.

An appeal may be brought, in accordance with Article 76, against decisions of the Agency under the first and second subparagraphs of this paragraph.

2. Notwithstanding paragraph 1, subsequent applicants shall provide the following data accordingly to the receiving competent authority or the Agency, as applicable:

(a) all necessary data for the identification of the biocidal product, including its composition;

(b) the data needed to identify the active substance and to establish technical equivalence of the active substance;

(c) the data needed to demonstrate the comparability of the risk from and efficacy of the biocidal product to that of the authorised biocidal product.

CHAPTER XV
INFORMATION AND COMMUNICATION

SECTION 1
MONITORING AND REPORTING

Article 64

Compliance with requirements

1. Member States shall make the necessary arrangements for the monitoring of biocidal products and treated articles which have been placed on the market 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[1] shall apply accordingly.

2. Member States shall make the necessary arrangements for official controls to be carried out in order to enforce compliance with this Regulation.

   In order to facilitate such enforcement, manufacturers of biocidal products placed on the Union market shall maintain a suitable system of quality control of the manufacturing process without causing disproportionate administrative burden to economic operators and Member States.

[1] OJ L 218, 13.8.2008, p. 30.

3. Every three years, from …*, Member States shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The report shall include:

(a) information on the results of official controls carried out in accordance with paragraph 2;

(b) information on any poisonings and, where available, occupational diseases involving biocidal products.

Reports shall cover the period up to 30 June of the year preceding their submission.

The Commission shall, within one year of receipt of the reports referred to in the first subparagraph, prepare and publish a composite report.

4. The Commission shall draw up a report on the implementation of this Regulation, in particular Article 57, by 1 January 2020. The Commission shall submit the report to the European Parliament and to the Council.

* OJ: Insert the date- two years after the day of the application of this Regulation.

Article 65

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[1] and the rules of the Management Board of the Agency, adopted in accordance with Article 118(3) of Regulation (EC) No 1907/2006, shall apply to documents held by the Agency for the purposes of this Regulation.

2. The Agency and the competent authorities shall refuse access to information where disclosure would undermine the protection of the commercial interests or the privacy or safety of the persons concerned.

   Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or the privacy or safety of the persons concerned:

   (a) details of the full composition of a biocidal product;

   (b) the precise tonnage of the active substance or biocidal product manufactured or made available on the market;

   (c) 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;

[1] OJ L 145, 31.5.2001, p. 43.

(d) names and addresses of persons involved in testing on vertebrate animals.

However, where urgent action is essential to protect human health, safety or the environment or for other reasons of overriding public interest, the Agency or the competent authorities shall disclose the information referred to in this paragraph.

3. Notwithstanding paragraph 2, after the authorisation has been granted, access to the following information shall not in any case be refused:

(a) the name and address of the authorisation holder;

(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 methods for rendering the active substance or biocidal product harmless;

(g) a summary of the results of the tests required pursuant to Article 19 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, transport and use as well as from fire or other hazards;

(i) safety data sheets;

(j) methods of analysis referred to in Article 18(1)(c);

(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. Any person submitting 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 66(2) shall not be made available, including a justification as to why the disclosure of the information could be harmful for their commercial interests or those of any other party concerned.

Article 66

Electronic public access

1. The following information held by the Agency or the Commission on active substances shall be made publicly and easily available free of charge:

(a) without prejudice to paragraph 2 (e), where available, the ISO name and the name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature;

(b) if applicable, the name as given in European Inventory of Existing Commercial Chemical Substances;

(c) the classification and labelling, including whether the active substance meets any of the criteria set out in Article 5(1);

(d) physicochemical data and data on pathways and environmental fate and behaviour;

(e) the result of each toxicological and ecotoxicological study;

(f) acceptable exposure level or predicted no-effect concentration established in accordance with Annex VI;

(g) the guidance on safe use provided in accordance with Annex II and Annex III;

(h) analytical methods if requested in accordance with Annex II which make it possible to detect an active substance or its residues 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 an active substance that was not previously approved or included in Annex I, it shall be made publicly available from the date on which the approval or inclusion 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 65(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) of this Article;

(c) information, other than that listed in paragraph 1 of this Article, 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 paragraph 1(a) of this Article 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.

If the information listed in the first subparagraph of this paragraph concerns an active substance that was not previously approved or included in Annex I, it shall be made publicly available from the date on which the approval or inclusion becomes effective.

Article 67

Record-keeping and reporting

1. Authorisation holders shall keep records of the biocidal products they place on the market for at least ten years after placing on the market, or ten years after the date on which the authorisation was cancelled or expired, whichever is the earlier. They shall make available the relevant information contained in these records to the competent authority on request.

2. To ensure the uniform application of paragraph 1 of this Article, the Commission shall adopt implementing acts to specify the form and content of the information in records. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 81(2).

SECTION 2

INFORMATION ABOUT BIOCIDAL PRODUCTS

Article 68

Classification, packaging and labelling of biocidal products

1. Authorisation holders shall ensure that biocidal products are classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 21(2), and with Directive 1999/45/EC and, where applicable, Regulation (EC) No 1272/2008.

   In addition, products which may be mistaken for food, including drink, or feed 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 and, in particular, shall not be attractive to children.

2. In addition to compliance with paragraph 1, authorisation holders shall ensure that labels are not misleading in respect of the risks from the product to human health or the environment or its efficacy and, in any case, do not mention the indications "low-risk biocidal product", "non-toxic", "harmless", "natural", "environmentally friendly", "animal friendly" or similar indications. 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 or the Commission;

(c) the name and address of the authorisation holder;

(d) the type of formulation;

(e) the uses for which the biocidal product is authorised;

(f) directions for use, frequency of application and dose rate, expressed in metric units, in a 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" and, where applicable, warnings for vulnerable groups;

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

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

(k) where applicable, 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 and transport;

(l) where applicable, the categories of users to which the biocidal product is restricted;

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

(n) 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), (i), (j), (k) and (m) may be indicated on the packaging or on an accompanying leaflet integral to the packaging.

3. Member States may require:

(a) the provision of models or drafts of the packaging, labelling and leaflets;

(b) that biocidal products made available on the market in their territories be labelled in their official language or languages.

Article 69

Safety Data Sheets

Safety data sheets for active substances and biocidal products shall be prepared and made available in accordance with Article 31 of Regulation (EC) No 1907/2006, where applicable.

Article 70

Register for Biocidal Products

1. The Agency shall establish and maintain an information system which shall be referred to as the Register for Biocidal Products.

2. The Register for Biocidal Products shall be used for the exchange of information between competent authorities, the Agency and the Commission and between applicants and competent authorities, the Agency and the Commission.

3. Applicants shall use the Register for Biocidal Products to generate and submit the application form for all procedures relating to the approval of active substances and the authorisation of biocidal products, mutual recognition, the granting of parallel trade permits and the renewal, the cancellation and amendment of authorisations. Once the relevant competent authority has validated an application in accordance with Article 7, 28 or 42, or accepted an application in accordance with Article 13, 19 or 44, it shall be made available via the Register for Biocidal Products to all other competent authorities and to the Agency.

4. Competent authorities shall update the information in the Register for Biocidal Products 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. The Commission may adopt implementing acts laying down detailed rules on the types of information to be entered in the Register for Biocidal Products. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 81(2).

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 82 specifying the procedures for the use of the register.

Article 71

Advertising

1. Any advertisement for biocidal products shall, in addition to complying with Regulation (EC) No 1272/2008, include the sentences "Use biocides safely. Always read the label and product information before use.". The sentences shall be clearly distinguishable and legible 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 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 or its efficacy. In any case, the advertising of a biocidal product shall not mention "low-risk biocidal product", "non-toxic", "harmless", "natural", "environmentally friendly", "animal friendly" or any similar indication.

Article 72

Poison control

Article 45 of Regulation (EC) No 1272/2008 shall apply for the purposes of this Regulation.

CHAPTER XVI
THE AGENCY

Article 73

Role of the Agency

1. The Agency shall carry out the tasks conferred on it by this Regulation.

2. 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.

Article 74

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 approval and renewal of approval of active substances;

   (b) review of approval of active substances;

   (c) applications for inclusion in Annex I of active substances meeting the conditions laid down in Article 27 and review of the inclusion of such active substances in Annex I;

(d) identification of active substances which are candidates for substitution;

(e) applications for Union authorisation of biocidal products and for renewal, cancellation and amendments of Union authorisations, except where the applications are for administrative changes;

(f) scientific and technical matters concerning mutual recognition in accordance with Article 37;

(g) at the request of the Commission or of Member States' competent authorities, any other questions that arise from the operation of this Regulation relating to risks to human or animal health or the environment or technical guidance.

2. Each Member State shall be entitled to appoint a member of the Biocidal Products Committee. Member States may also appoint an alternate member.

In order to facilitate its work, the Committee may, by a decision of the Management Board of the Agency in agreement with the Commission, be divided into two or more parallel committees. Each parallel committee shall be responsible for the tasks of the Biocidal Products Committee assigned to it. Each Member State shall be entitled to appoint one Member for each of the parallel committees. The same person may be appointed to more than one parallel committee.

3. Committee members shall be appointed on the basis of their experience relevant to performing the tasks specified in paragraph 1 and may work within a competent authority. They shall be supported by the scientific and technical resources available to Member States. To this end, Member States shall provide adequate scientific and technical resources to Committee members that they have nominated.

4. Article 85, paragraphs 4, 5, 8 and 9, and Articles 87 and 88 of Regulation (EC) No 1907/2006 shall apply *mutatis mutandis* to the Biocidal Products Committee.

Article 75

Secretariat of the Agency

1. 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 Register for Biocidal Products;

   (b) performing the tasks relating to the validation of the applications referred to in Articles 7(3) and (4), 13(3), 42(3) and (4), and 44(3) of this Regulation;

   (c) establishing technical equivalence;

(d) providing technical and scientific guidance and tools for the application of this Regulation by the Commission and Member States' competent authorities and providing support to national helpdesks;

(e) providing advice and assistance to applicants, in particular to SMEs, for the approval of an active substance or its inclusion in Annex I to this Regulation or for a Union authorisation;

(f) preparing explanatory information on this Regulation;

(g) establishing and maintaining database(s) with information on active substances and biocidal products;

(h) at the request of the Commission, providing technical and scientific support to improve cooperation between the Union competent authorities, international organisations and third countries on scientific and technical issues relating to biocidal products;

(i) notification of decisions taken by the Agency;

(j) specification of formats and software packages for the submission of information to the Agency.

2. The Secretariat shall make the information identified in Article 66(1) and (2) publicly available, free of charge, over the internet, except where a request made under Article 65(4) is considered justified. The Agency shall make other information available on request in accordance with Article 65.

Article 76

Appeal

1. Appeals against decisions of the Agency taken pursuant to Articles 7(2), 13(3), 25(2), 42(2), 44(3), 53 (3), 62(3) and 63(1) shall lie with the Board of Appeal set up in accordance with Regulation (EC) No 1907/2006.

   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, in accordance with Article 79(1) of this Regulation, by the person bringing an appeal.

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

Article 77

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 to the Agency in accordance with this Regulation;

   (c) any charges paid to the Agency for services that it provides under this Regulation;

   (d) any voluntary contributions from Member States.

2. Revenue and expenditure for activities related to this Regulation and to Regulation (EC) No 1907/2006 shall be dealt with separately in the Agency's budget and shall have 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. Revenue of the Agency referred to in paragraph 1 of this Article shall not be used for carrying out tasks under Regulation (EC) No 1907/2006.

Article 78

Formats and software for submission of information to the Agency

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

The technical dossier referred to in Articles 6(1) and 19 shall be submitted using the IUCLID software package.

CHAPTER XVII
FINAL PROVISIONS

Article 79

Fees and charges

1. The Commission shall adopt, on the basis of the principles set out in paragraph 3, an implementing Regulation specifying:

   (a) the fees payable to the Agency, including an annual fee;

(b) the rules defining conditions for reduced fees, fee waivers and the reimbursement of the member of the Biocidal Products Committee who acts as a rapporteur; and

(c) conditions of payment.

That implementing Regulation shall be adopted in accordance with the examination procedure referred to in Article 81(3). It shall apply only with respect to fees paid to the Agency.

The Agency may collect charges for other services it provides.

The fees payable to the Agency shall be set at such a 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.

2. Member States shall directly charge applicants fees for services that they provide with respect to the procedures under this Regulation, including the services undertaken by Member States' competent authorities when acting as evaluating competent authority.

Based on the principles set out in paragraph 3, the Commission may issue guidance concerning a harmonised structure of fees.

Member States may levy annual fees with respect to biocidal products made available on their markets.

Member States may collect charges for other services they provide.

Member States shall set and publish the amount of fees payable to their competent authorities.

3. Both the implementing Regulation referred to in paragraph 1 and Member States' own rules concerning fees shall respect the following principles:

(a) fees shall be set at such a level as to ensure that the revenue derived from the fees is, in principle, sufficient to cover the cost of the services delivered and shall not exceed what is necessary to cover those costs;

(b) partial reimbursement of the fee if the applicant fails to submit the information requested within the specified time limit;

(c) the specific needs of SMEs shall be taken into account, as appropriate;

(d) the structure and amount of fees shall take into account whether information has been submitted jointly or separately;

(e) in duly justified circumstances, and where it is accepted by the Agency or the competent authority, the whole fee or a part of it may be waived; and

(f) as regards Member States' rules only, the deadlines for the payment of fees to competent authorities shall be fixed taking due account of the deadlines of the procedures provided for in this Regulation.

Article 80

Competent authorities

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

   Member States shall ensure that competent authorities have a sufficient number of suitably qualified and experienced staff so that the obligations laid down in this Regulation can be carried out efficiently and effectively.

2. Competent authorities shall provide advice to applicants, in particular to SMEs, and to any other interested parties on their respective responsibilities and obligations under this Regulation. That shall include the provision of advice about the possibility of adapting the data requirements of Articles 6 and 19, the grounds on which such an adaptation can be made, and on how to prepare a proposal. It shall be in addition to the advice and assistance that the Secretariat of the Agency shall provide in accordance with Article 75(1)(d).

   Competent authorities may in particular provide advice by establishing helpdesks. Helpdesks already established under Regulation (EC) No 1907/2006 may act as helpdesks under this Regulation.

3. Member States shall inform the Commission of the names and addresses of the designated competent authorities and, where they exist, helpdesks by …[*]. Member States shall, without undue delay, inform the Commission of any changes to the names and addresses of the competent authorities or helpdesks.

The Commission shall make publicly available a list of competent authorities and helpdesks.

Article 81

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Biocidal Products ("the committee"). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011 shall apply.

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[*] OJ: Insert the date - the day of the application of this Regulation.

Article 82

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Articles 5(3), 20(3), 22(5), 27(1) and (3), Article 39, Articles 55(4), 70(6), Article 84 and Article 88(1) shall be conferred on the Commission for a period of five years from…[*] . The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of powers referred to in Articles 5(3), 20(3), 22(5), 27(1) and (3), Article 39, Articles 55(4), 70(6), Article 84 and Article 88(1) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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[*] OJ: the date of the entry into force of this Regulation.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Articles 5(3), 20(3), 22(5), 27(1) and (3), Article 39, Articles 55(4), 70(6), Article 84 and Article 88(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.

Article 83

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 82(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

Article 84

Adaptation to scientific and technical progress

In order to allow the provisions of this Regulation to be adapted to scientific and technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 82 concerning the adaptation of Annexes II, III and IV to such scientific and technical progress.

Article 85

Active substances included in Annex I to Directive 98/8/EC

The active substances included in Annex I to Directive 98/8/EC shall be deemed to have been approved under this Regulation and shall be included in the list referred to in Article 9(2).

Article 86

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 …* and shall notify the Commission without delay of any subsequent amendment affecting them.

* OJ: Insert the date -the day of application of this Regulation.

Article 87

Safeguard clause

Where, on the basis of new evidence, a Member State has justifiable grounds to consider that a biocidal product, although authorised in accordance with this Regulation, constitutes a serious immediate or long-term risk to human or animal health, in particular to vulnerable groups, or to the environment, it may take appropriate provisional measures. The Member State shall, without delay, inform the Commission and the other Member States accordingly and give reasons for its decision based on the new evidence.

The Commission shall, by means of implementing acts, either permit the provisional measure for a time period defined in the decision or require the Member State to revoke the provisional measure. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

Article 88

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 with the aim of achieving it by 14 May 2014. To that end, the Commission shall be empowered to adopt delegated acts in accordance with Article 82 concerning the carrying out of the work programme and specification of the related rights and obligations of the competent authorities and the participants in the programme.

Depending upon the progress of the work programme, the Commission shall be empowered to adopt delegated acts in accordance with Article 82 concerning the extension of the duration of the work programme for a determined period.

In order to facilitate a smooth transition from Directive 98/8/EC to this Regulation, during the work programme the Commission shall adopt either implementing regulations providing that an active substance is approved, and under which conditions, or, in cases where the requirements of Article 4(1) or, where applicable, 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, implementing decisions stating that an active substance is not approved. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3). Regulations approving an active substance shall specify the date of approval. Article 9(2) shall apply.

2. By way of derogation from Articles 17(1), 18(1) and 19(1) of this Regulation, and without prejudice to paragraphs 1 and 3 of this Article, a Member State may continue to apply its current system or practice of making a given biocidal product available on the market until two years after the date of approval of the last of the active substances in that biocidal product. It may, according to its national rules, authorise the making available on the market in its territory only of a biocidal product containing existing active substances which have been or are being 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[1], but which have not yet been approved for that product-type.

[1] OJ L 325, 11.12.2007, p. 3.

By way of derogation from the first subparagraph, in the case of a decision not to approve an active substance, a Member State may continue to apply its current system or practice of making biocidal products available on the market for up to twelve months after the date of the decision not to approve an active substance in accordance with the third subparagraph of paragraph 1.

3. Following a decision to approve a particular active substance for a specific product-type Member States shall ensure that authorisations for biocidal products of that product-type and containing that active substance are granted, modified or cancelled as appropriate in accordance with this Regulation within two years of the date of approval.

To that effect, those wishing to apply for the authorisation or mutual recognition in parallel of biocidal products of that product-type containing no active substances other than existing active substances shall submit applications for authorisation or mutual recognition in parallel to Member States' competent authorities no later than the date of approval of the active substance(s). In the case of biocidal products containing more than one active substance, applications for authorisation shall be submitted no later than the date of approval of the last active substance for that product-type.

Where no application for authorisation or mutual recognition in parallel has been submitted in accordance with the second subparagraph:

(a) the biocidal product shall no longer be made available on the market with effect from 180 days after the date of approval of the active substance(s); and

(b) disposal and use of existing stocks of the biocidal product may continue until 365 days after the date of approval of the active substance(s).

4. Where a Member State's competent authority rejects the application for authorisation of a biocidal product submitted under paragraph 3 or decides not to grant authorisation, that biocidal product shall no longer be made available on the market 180 days after the date of such rejection or decision. Disposal and use of existing stocks of such biocidal products may continue until 365 days after the date of such rejection or decision.

Article 89

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

1. The Agency shall be responsible for coordinating the process of evaluation of dossiers submitted after …* and shall facilitate the evaluation by providing organisational and technical support to the Member States and the Commission.

* OJ: Insert the date -one year before the day of application of this Regulation.

2. Dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by …[*] 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 …* and shall facilitate the preparation of the evaluation by providing organisational and technical support to the Member States and the Commission from …[**].

Article 90

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 that Directive. The provisions of Directive 98/8/EC shall apply to these products until the expiry of the registration. The registration shall not be renewable.

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[*] OJ: Insert the date - the day of application of this Regulation.

[**] OJ: Insert the date -one year after the day of application of this Regulation.

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 of inclusion in Annex IA to that Directive of the active substance(s) in the low-risk biocidal product.

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 of this paragraph may continue to be made available on the market until the date of the decision granting the registration. In the case of refusal to grant a registration to make such a low-risk biocidal product available on the market, the biocidal product shall no longer be made available on the market 180 days after the date of the 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 of this paragraph may continue to be made available on the market until 180 days after the date referred to in first subparagraph of this paragraph.

Disposal and use of existing stocks of low-risk biocidal products which are not registered for the relevant use by the competent authority may continue until 365 days 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 from the date of the expiry of the registration referred to in paragraph 1.

Article 91

Transitional measures concerning biocidal products authorised under Directive 98/8/EC

1. Biocidal products for which an authorisation in accordance with Articles 3, 4, 15 or 17 of Directive 98/8/EC was granted before the date of entry into force of this Regulation can continue to be made available on the market and used subject, where applicable, to any conditions of authorisation stipulated under that Directive until the expiry date of the authorisation or its cancellation.

2. This Regulation shall apply to biocidal products referred to in paragraph 1 from the date of the expiry of the authorisation or its cancellation.

Article 92

Transitional measures concerning active substances generated in situ

1. Applications for authorisation of substances, mixtures and articles considered as biocidal products because they generate active substances *in situ* and which were available on the market on...[*] shall be submitted at the latest by …[**].

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[*] OJ: Insert the date of the entry into force of this Regulation.

[**] OJ: Insert the date - four years after the day of the application of this Regulation.

2. By way of derogation from Article 17(1), substances, mixtures and articles referred to in paragraph 1 of this Article which were available on the market on …* and for which an application was submitted in accordance with paragraph 1 of this Article may continue to be made available on the market until the date of the decision granting the authorisation. In the case of a decision refusing to grant the authorisation, the biocidal product shall no longer be made available on the market 180 days after such a decision.

By way of derogation from Article 17(1), substances, mixtures and articles referred to in paragraph 1 of this Article which were available on the market on...* and for which an application was not submitted in accordance with paragraph 1of this Article may continue to be made available on the market until 180 days after the date referred to in paragraph 1 of this Article.

Disposal and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission may continue until 365 days after the date of the decision referred to in the first subparagraph or twelve months after the date referred to in the second subparagraph, whichever is the later.

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* OJ: Insert the date of the entry into force of this Regulation.

Article 93

Transitional measures concerning treated articles

1. By way of derogation from Article 57 and without prejudice to Article 88, treated articles that were available on the market on …[*] may, until the date of a decision concerning the approval for the relevant product type of the active substance(s) contained in the biocidal products with which the treated articles were treated or which they incorporate, continue to be placed on the market if the application for the approval of the active substance(s) for the relevant product type is submitted at the latest by …[**].

2. In the case of a decision not to approve an active substance for the relevant product type, treated articles which were treated with, or which incorporate, biocidal product(s) containing that active substance shall no longer be placed on the market 180 days after such a decision or as of …[**], whichever is the later, unless an application for the approval has been submitted in accordance with paragraph 1.

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[*] OJ: Insert the date - the day of the entry into force of this Regulation.

[**] OJ: Insert the date - three years after the day of application of this Regulation.

Article 94

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 by 1 January 2017.

By way of derogation from Article 17(1), biocidal products which are food contact materials and which were available on the market on …* for which an application was submitted in accordance with the first subparagraph of this paragraph may continue to be made available on the market until the date of the decision granting the authorisation. In case of a refusal to grant an authorisation, such biocidal products shall no longer be made available on the market within 180 days after such decision.

By way of derogation from Article 17(1), biocidal products which are food contact materials and which were available on the market on …[*] for which an application was not submitted in accordance with the first subparagraph of this paragraph may continue to be made available on the market until 180 days after the date referred to in the first subparagraph of this paragraph.

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[*] OJ: Insert the date - the day of the entry into force of this Regulation.

2. Disposal and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission may continue until 365 days after the date of the decision referred to in the second subparagraph of paragraph 1 or twelve months after the date referred to in the third subparagraph of paragraph 1, whichever is the later.

Article 95

Transitional measures concerning access to the active substance dossier

1. As of …*, any person wishing to place active substance(s) on the Union market on its own or in biocidal products (the "relevant person") shall, for every active substance that they manufacture or import for use in biocidal products, submit to the Agency:

(a) a dossier complying with the requirements of Annex II; or

(b) a letter of access to a dossier complying with the requirements of Annex II; or

(c) a reference to a dossier complying with the requirements of Annex II and for which all data protection periods have expired.

If the relevant person is not a natural or legal person established within the Union, the importer of the biocidal product containing such active substance(s) shall submit the information required under the first subparagraph.

* OJ: Insert the date - the day of the application of this Regulation.

For the purposes of this paragraph and for existing active substances listed in Annex II to Regulation (EC) No 1451/2007, the provisions on mandatory data sharing, as laid down in Articles 61 and 62 of this Regulation, shall apply to all toxicological and ecotoxicological studies included in the dossier. The relevant person shall be required to apply for data sharing only for those data that it does not already possess.

The relevant person to whom a letter of access to the dossier on the active substance has been issued shall be entitled to allow applicants for the authorisation of a biocidal product containing that active substance to make reference to that letter of access for the purposes of Article 19(1).

By way of derogation from Article 59 of this Regulation, all data protection periods for substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but not yet approved under this Regulation shall end on 31 December 2025.

2. The Agency shall make publicly available the list of persons that have made a submission in accordance with paragraph 1 or for whom it has taken a decision in accordance with Article 62(3). The list shall also contain the names of persons who are participants in the work programme established under the first subparagraph of Article 88(1) or have taken over the role of the participant.

3. As of …*, biocidal products containing an active substance, for which no relevant person is included in the list referred to in paragraph 2, shall not be made available on the market.

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* OJ: Insert the date - two years after the day of the application of this Regulation.

Without prejudice to Articles 51 and 88, disposal and use of existing stocks of biocidal products containing an active substance, for which no relevant person is included in the list referred to in paragraph 2, may continue until …[*].

4. This Article shall not apply to active substances listed in Annex I in categories 1 to 5 and 7 or to biocidal products containing only such active substances.

Article 96

Repeal

Without prejudice to Articles 85, 88, 89, 90 and 91 of this Regulation, Directive 98/8/EC is hereby repealed with effect from ...[**].

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

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[*] OJ: Insert the date - three years after the day of the application of this Regulation.

[**] OJ: Insert the date - date of application of this Regulation.

Article 97

Entry into force

This Regulation shall enter into force on the twentieth 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 Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

LIST OF ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 24

EC number	Name/group	Restriction	Comment
Category 1 - Substances authorised as food additives according to Regulation (EC) No 1333/2008			
200-018-0	Lactic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008.	E 270
204-823-8	Sodium acetate	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008.	E 262
208-534-8	Sodium benzoate	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008.	E 211
201-766-0	(+)-Tartaric acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008.	E 334
Category 2 - Substances included in Annex IV to Regulation (EC) No 1907/2006			
200-066-2	Ascorbic acid		
232-278-6	Linseed oil		

EC number	Name/group	Restriction	Comment
Category 3 - Weak acids			
200-580-7	Acetic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008.	
201-176-3	Propionic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008.	
Category 4 - Traditionally used substances of natural origin			
Natural oil	Lavender oil		CAS 8000-28-0
Natural oil	Peppermint oil		CAS 8006-90-4
Category 5 – Pheromones			
222-226-0	Oct-1-en-3-ol		
Mixture	Webbing clothes moths pheromone		
Category 6 – Substances included in Annex I or IA to Directive 98/8/EC			
204-696-9	Carbon dioxide	Only for use in ready-for-use gas canisters functioning together with a trapping device	
231-783-9	Nitrogen	Only for use in limited quantities in ready-for-use canisters	
250-753-6	(Z,E)-Tetradec-9,12-dienyl acetate		
Category 7 – Other			
	Baculovirus		
215-108-5	Bentonite		
203-376-6	Citronellal		
231-753-5	Iron sulphate		

ANNEX II

INFORMATION REQUIREMENTS FOR ACTIVE SUBSTANCES

1. This Annex sets out the information requirements for the preparation of the dossier referred to in point (a) of Article 6(1).

2. The data elements set down in this Annex comprise a Core Data Set (CDS) and an Additional Data Set (ADS). The data elements belonging to the CDS are considered as the basic data which should, in principle, be provided for all active substances. However, in some cases the physical or chemical properties of the substance may mean that it is impossible or unnecessary to provide specific data elements belonging to the CDS.

   With regard to the ADS, the data elements to be provided for a specific active substance shall be determined by considering each of the ADS data elements indicated in this Annex taking into account, inter alia, the physical and chemical properties of the substance, existing data, information which is part of the CDS and the types of products in which the active substance will be used and the exposure patterns related to these uses.

Specific indications for the inclusion of some data elements are provided in column 1 of the Annex II table. The general considerations regarding adaptation of information requirements as set out in Annex IV shall also apply. In light of the importance of reducing testing on vertebrate animals, column 3 of the Annex II table gives specific indications for the adaptation of some of the data elements which might require the use of such tests on vertebrate animals. The information submitted shall, in any case, be sufficient to support a risk assessment demonstrating that the criteria referred to in Article 4(1) are met.

The applicant should consult the detailed technical guidance regarding the application of this Annex and the preparation of the dossier referred to in point (a) of Article 6 (1), which is available on the web-site of the Agency.

The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set down in Article 61(2), applicants may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrate animals that the applicant proposes to carry out.

Additional information may need to be submitted if it is necessary to carry out the evaluation as indicated in Article 8(2).

3. A detailed and full description of the studies conducted or referred to and of the methods used shall be included. It is important to ensure that the data available is relevant and is of sufficient quality to fulfil the requirements. Evidence should also be provided to demonstrate that the active substance upon which the tests have been carried out is the same as the substance for which the application has been submitted.

4. The formats made available by the Agency must be used for submission of the dossiers. In addition, IUCLID 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 website of the Agency.

5. 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 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[1]. However, if a method is inappropriate or not described, other methods shall be used which are, whenever possible, internationally recognised and must be justified in the application.

[1] OJ L 142, 31.5.2008, p. 1.

6. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Directive 2010/63/EU of the European Parliament and the Council of 22 September 2010 on the protection of animals used for scientific purposes[1] 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[2] or other international standards recognised as being equivalent by the Commission or the Agency. Tests on physico-chemical properties and safety-relevant substance data should be performed at least according to international standards.

7. Where testing is done, a detailed description (specification) of the active substance used and its impurities must be provided. Testing should be performed with the active substance as manufactured or, in the case of some of the physical and chemical properties (see indications given in column I of the table), with a purified form of the active substance.

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1 OJ L 276, 20.10.2010, p. 33.
2 OJ L 50, 20.2.2004, p. 44.

8. 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, on a case-by-case basis, taking into account, among other factors, the need to minimise testing on vertebrate animals.

9. New tests involving vertebrate animals shall be conducted as the last available option to comply with the data requirements set out in this Annex when all the other data sources have been exhausted. *In-vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall also be avoided.

* OJ: please insert the date referred to in the first paragraph of Article 97.

TITLE 1

CHEMICAL SUBSTANCES

CORE DATA SET AND ADDITIONAL DATA SET FOR ACTIVE SUBSTANCES

Information required to support the approval of an active substance is listed in the table below.

Conditions for not requiring a specific test that are set out in the appropriate test methods in the Regulation (EC) No 440/2008 and are not repeated in column 3, also apply.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
1. APPLICANT		
1.1. Name and address		
1.2. Contact person		
1.3. Active substance manufacturer (name, address and location of manufacturing plant(s))		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
2. IDENTITY OF THE ACTIVE SUBSTANCE For the active substance, the information given in this section shall be sufficient to enable the active substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.		
2.1. Common name proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)		
2.2. Chemical name (IUPAC and CA nomenclature or other international chemical name(s))		
2.3. Manufacturer's development code number(s)		
2.4. CAS number plus EC, INDEX and CIPAC numbers		
2.5. Molecular and structural formula (including SMILES notation, if available and appropriate)		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
2.6. Information on optical activity and full details of any isomeric composition (if applicable and appropriate)		
2.7. Molar mass		
2.8. Method of manufacture (syntheses pathway) of active substance including information on starting materials and solvents including suppliers, specifications and commercial availability		
2.9. Specification of purity of the active substance as manufactured in g/kg, g/l or %w/w (v/v) as appropriate, providing inclusively the upper and lower limit		
2.10. The identity of any impurities and additives including by-products of synthesis, optical isomers, degradation products (if the substance is unstable) un-reacted and end-groups etc of polymers and un-reacted starting materials of UVC-substances		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
2.11. Analytical profile of at least five representative batches (g/kg active substance) including information on content of the impurities referred to in 2.10.		
2.12. The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower		
3. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE		
3.1. Appearance[1]		
3.1.1. Aggregate state (at 20°C and 101.3 kPa)		
3.1.2. Physical state (i.e. viscous, crystalline, powder) (at 20°C and 101.3 kPa)		
3.1.3. Colour (at 20°C and 101.3 kPa)		
3.1.4. Odour (at 20°C and 101.3 kPa)		
3.2. Melting/freezing point[2]		
3.3. Acidity, alkalinity		
3.4. Boiling point[2]		
3.5. Relative Density[2]		

[1] The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

[2] The information being provided is for the purified active substance of stated specification.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
3.6. Absorption spectra data (UV/VIS, IR, NMR) and a mass spectrum, molar extinction coefficient at relevant wavelengths, where relevant[1]		
3.7. Vapour pressure[1]		
3.7.1. Henry's law constant must always be stated for solids and liquids if it can be calculated.		
3.8. Surface tension[1]		
3.9. Water solubility[1]		
3.10. Partition coefficient (n-octanol/water) and its pH dependency[1]		
3.11. Thermal stability, identity of breakdown products[1]		
3.12. Reactivity towards container material		
3.13. Dissociation constant	ADS	
3.14. Granulometry		
3.15. Viscosity	ADS	
3.16. Solubility in organic solvents, including effect of temperature on solubility[1]	ADS	
3.17. Stability in organic solvents used in biocidal products and identity of relevant breakdown products[2]	ADS	

[1] The information being provided is for the purified active substance of stated specification.

[2] The information provided should be for the purified active substance of stated specification or for the active substance as manufactured, if different.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS		
4.1. Explosives		
4.2. Flammable gases		
4.3. Flammable aerosols		
4.4. Oxidising gases		
4.5. Gases under pressure		
4.6. Flammable liquids		
4.7. Flammable solids		
4.8. Self-reactive substances and mixtures		
4.9. Pyrophoric liquids		
4.10. Pyrophoric solids		
4.11. Self-heating substances and mixtures		
4.12. Substances and mixtures which in contact with water emit flammable gases		
4.13. Oxidising liquids		
4.14. Oxidising solids		
4.15. Organic peroxides		
4.16. Corrosive to metals		
4.17. Additional physical indicators for hazards		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
4.17.1. Auto-ignition temperature (liquids and gases),		
4.17.2. Relative self ignition temperature for solids		
4.17.3. Dust explosion hazard		
5. METHODS OF DETECTION AND IDENTIFICATION		
5.1. Analytical methods including validation parameters for the determination of active substance as manufactured and where appropriate, for relevant residues, isomers and impurities of the active substance and additives (e.g. stabilisers). For impurities other than relevant impurities this only applies if they are present at ≥ 1g/kg.		
5.2. Analytical methods for monitoring purposes including recovery rates and the limits of quantification and detection for the active substance, and for residues thereof in/on the following where relevant		
5.2.1. Soil		
5.2.2. Air		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
5.2.3. Water (Surface, drinking etc) and sediment		
5.2.4. Animal and human body fluids and tissues		
5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (not necessary if neither the active substance nor articles treated with it come into contact with food producing animals, food of plant or animal origin or feeding stuffs).	ADS	
6. EFFECTIVENESS AGAINST TARGET ORGANISMS		
6.1. Function, e.g. fungicide, rodenticide, insecticide, bactericide and mode of control e.g. attracting, killing, inhibiting		
6.2. Representative organism(s) to be controlled and products, organisms or objects to be protected		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
6.3. Effects on representative target organism(s)		
6.4. Likely concentration at which the active substance will be used in products and, where appropriate, in treated articles		
6.5. Mode of action (including time delay)		
6.6. Efficacy data to support these claims on biocidal products and, where label claims are made, on treated articles, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate		
6.7. Any known limitations on efficacy		
6.7.1. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
6.7.2. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
7. INTENDED USES AND EXPOSURE		
7.1. Field of use(s) envisaged for biocidal products and, where appropriate, treated articles		
7.2. Product type(s)		
7.3. Detailed description of the intended use pattern(s) including in treated articles		
7.4. Users e.g. industrial, trained professional, professional or general public (non-professional)		
7.5. Likely tonnage to be placed on the market per year		
7.6. Exposure data in conformity with Annex VI to Regulation XXXX/20YY		
7.6.1. Information on human exposure associated with the intended uses and disposal of the active substance		
7.6.2. Information on environmental exposure associated with the intended uses and disposal of the active substance		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
7.6.3. Information on exposure of food-producing animals and food and feeding stuffs associated with the intended uses of the active substance		
7.6.4. Information on exposure from treated articles including leaching data (either laboratory studies or model data)		
8. TOXICOLOGICAL PROFILE FOR HUMAN AND ANIMAL INCLUDING METABOLISM		
8.1. Skin irritation or skin corrosion The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal irritation and corrosion set out in the Appendix to Test Guideline B.4. Acute Toxicity-Dermal Irritation/Corrosion (Annex B.4. to Regulation (EC) No 440/2008)		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.2. Eye irritation The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5.Acute Toxicity: Eye Irritation/Corrosion (Annex B.5. to Regulation (EC) No 440/2008)		
8.3. Skin 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 Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for *in vivo* testing. If another skin sensitisation test is used justification shall be provided.		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)

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.4. Respiratory sensitisation	ADS	
8.5. Mutagenicity The assessment of this endpoint shall comprise the following consecutive steps: - an assessment of the available *in vivo* genotoxicity data - an *in vitro* test for gene mutations in bacteria, an *in vitro* cytogenicity test in mammalian cells and an *in vitro* gene mutation test in mammalian cells are required - appropriate *in vivo* genotoxicity studies shall be considered in case of a positive result in any of the *in vitro* genotoxicity studies		
8.5.1. *In vitro* gene mutation study in bacteria		
8.5.2. *In vitro* cytogenicity study in mammalian cells		
8.5.3. *In vitro* gene mutation study in mammalian cells		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.6. *In vivo* genotoxicity study The assessment of this endpoint shall comprise the following consecutive steps: - If there is a positive result in any of the *in vitro* genotoxicity studies and there are no results available from an *in vivo* study already, an appropriate *in vivo* somatic cell genotoxicity study shall be proposed / conducted by the applicant. - If either of the *in vitro* gene mutation tests is positive, an *in vivo* test to investigate unscheduled DNA synthesis shall be conducted. - A second *in vivo* somatic cell test may be necessary, depending on the results, quality and relevance of all the available data	ADS	The study/ies do(es) not generally need to be conducted if: - the results are negative for the three *in vitro* tests and if no metabolites of concern are formed in mammals or - valid *in vivo* micronucleus data is generated within a repeat dose study and the *in vivo* micronucleus test is the appropriate test to be conducted to address this information requirement - the substance is known to be carcinogenic category 1A or 1B or mutagenic category 1A, 1B or 2.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
- 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 to demonstrate that the substance reached the tested organ. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.		
8.7. Acute toxicity In addition to the oral route of administration (8.7.1), for substances other than gases, the information mentioned under 8.7.2 to 8.7.3 shall be provided for at least one other route of administration. - The choice for the second route will depend on the nature of the substance and the likely route of human exposure. - Gases and volatile liquids should be administered by the inhalation route		The study/ies do(es) not generally need to be conducted if: - the substance is classified as corrosive to the skin.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
- If the only route of exposure is the oral route, then information for only that route need be provided. If either the dermal or inhalation route is the only route of exposure to humans then an oral test may be considered - There may be specific circumstances where all routes of administration are deemed necessary.		
8.7.1. By oral route The Acute Toxic Class Method is the preferred method for the determination of this end-point.		The study need not be conducted if: - the substance is a gas or a highly volatile substance

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8.7.2. By inhalation Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account: - the vapour pressure of the substance (a volatile substance has vapour pressure > 1 x 10^{-2} Pa at 20°C) and/or - the active substance is a powder containing a significant proportion (e.g. 1% on a weight basis) of particles with particle size MMAD < 50 micrometers or - the active substance is included in products that are powders or are applied in a manner that generates exposure to aerosols, particles or droplets of an inhalable size (MMAD <50 micrometers). - The Acute Toxic Class Method is the preferred method for the determination of this end-point.		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.7.3. By dermal route Testing by the dermal route is appropriate if: - inhalation of the substance is unlikely; or - skin contact in production and/or use is likely; or - the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.		
8.8. Toxicokinetics and metabolism studies in mammals The toxicokinetics and metabolism studies should provide basic data about the rate and extent of absorption, the tissue distribution and the relevant metabolic pathway including the degree of metabolism, the routes and rate of excretion and the relevant metabolites.		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.8.1. Further toxicokinetic and metabolism studies in mammals Additional studies might be required based on the outcome of the toxicokinetic and metabolism study conducted in rat. These further studies shall be required if: - there is evidence that metabolism in the rat is not relevant for human exposure - route-to-route extrapolation from oral to dermal/inhalation exposure is not feasible. - Where it is considered appropriate to obtain information on dermal absorption, the assessment of this endpoint shall proceed using a tiered approach for assessment of dermal absorption.	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.9. Repeated dose toxicity In general, only one route of administration is necessary and the oral route is the preferred route. However, in some cases it may be necessary to evaluate more than one route of exposure. For the evaluation of the safety of consumers in relation to active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route. Testing by the dermal route shall be considered if: - skin contact in production and/or use is likely; and - inhalation of the substance is unlikely; and - one of the following conditions is met: (i) toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test; or		The repeated dose toxicity study (28 or 90 days) does not need to be conducted if: - a substance undergoes immediate disintegration and there are sufficient data on the cleavage products for systemic and local effects and no synergistic effects are expected; or - relevant human exposure can be excluded in accordance with section 3 of Annex IV

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
(ii) information or test data indicate dermal absorption is comparable or higher than oral absorption; or (iii) dermal toxicity is recognised for structurally related substances and for example is observed at lower doses than in the oral toxicity test or dermal absorption is comparable or higher than oral absorption. Testing by the inhalation route shall be considered if: - exposure of humans via inhalation is likely taking into account the vapour pressure of the substance (volatile substances and gases have vapour pressure > 1 x 10-2 Pa at 20°C) and/or - There is the possibility of exposure to aerosols, particles or droplets of an inhalable size (MMAD <50 micrometers).		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.9.1. Short-term repeated dose toxicity study (28 days), preferred species is rat		The short-term toxicity study (28 days) does not need to be conducted if: (i) a reliable sub-chronic (90 day) study is available, provided that the most appropriate species, dosage, solvent and route of administration were used, (ii) the frequency and duration of human exposure indicates that a longer term study is appropriate and one of the following conditions is met: - other available data indicate that the substance may have a dangerous property that cannot be detected in a short-term toxicity study; or

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		- appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short term toxicity study but which are liable to result in adverse effects after prolonged exposure.

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8.9.2. Sub-chronic repeated dose toxicity study (90-day), preferred species is rat		The sub-chronic toxicity study (90 days) does not need to be conducted if: - a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as H372 and H373 (Regulation (EC) No 1272/2008), for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor allows the extrapolation towards the NOAEL-90 days for the same route of exposure and; - a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used; or

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
		- the substance is unreactive, insoluble, not bioaccumulative 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.
8.9.3. Long-term repeated dose toxicity (≥ 12 months)		The long-term toxicity study (≥ 12 months) does not need to be conducted if: - Long-term exposure can be excluded and no effects have been seen at the limit dose in the 90-day study or - a combined long-term repeated dose/carcinogencity study (8.11.1) is undertaken.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.9.4. Further repeat dose studies Further repeat dose studies including testing on a second species (non-rodent), studies of longer duration or through a different route of administration shall be undertaken in case of: - no other information on toxicity for a second non-rodent species is provided for; or - failure to identify a no observed adverse effect level (NOAEL) in the 28 or the 90 day study, unless the reason is that no effects have been observed at the limit dose; or - substances bearing positive structural alerts for effects for which the rat or mouse is an inappropriate or insensitive model, or	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
- toxicity of particular concern (e.g. serious/severe effects); or - indications of an effect for which the available data is inadequate for toxicological 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, hormonal activity); or - concern regarding local effects for which a risk characterisation cannot be performed by route-to route extrapolation, or - particular concern regarding exposure (e.g. use in biocidal products leading to exposure levels which are close to the toxicologically relevant dose levels); or		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
- effects shown in substances with a clear relationship in molecular structure with the substance being studied were not detected in the 28 or the 90 days study or - the route of administration used in the initial repeated dose study was inappropriate in relation to the expected route of human exposure and route-to-route extrapolation cannot be made		
8.10. Reproductive toxicity For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.		The studies need not be conducted if: - the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented including measures related to reproductive toxicity; or - the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented including measures related to reproductive toxicity; or

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
		- the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available provided that the dataset is sufficiently comprehensive and informative), 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 the pattern of use indicates there is no or no significant human exposure.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
		- If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Reproductive toxicity 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. - If a substance is known to cause developmental toxicity, meeting the criteria for classification as Reproductive toxicity 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.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.10.1. Pre-natal developmental toxicity study, preferred species is rabbit; oral route of administration is the preferred route. The study shall be initially performed on one species. A decision on the need to perform additional studies on a second species (rat) or mechanistic studies should be based on the outcome of the first test and all other relevant available data.		
8.10.2. Two-generation reproductive toxicity study, rat, oral route of administration is the preferred route. If another reproductive toxicity test is used justification shall be provided.		
8.10.3. Further pre-natal developmental toxicity study, preferred species is rat, oral route of administration.	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.11. Carcinogenicity See 8.11.1 for new study requirements		A carcinogenicity study does not need to be conducted if: - 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.
8.11.1. Combined carcinogenicity study and long-term repeated dose toxicity Rat, oral route of administration is the preferred route, if an alternative route is proposed a justification must be provided For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.11.2. Carcinogenicity testing in a second species - A second carcinogenicity study should normally be conducted using the mouse as test species. - For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.		
8.12. Relevant health data, observations and treatments Justification should be provided if data is not available		
8.12.1. Medical surveillance data on manufacturing plant personnel		
8.12.2. Direct observation, e.g. clinical cases, poisoning incidents		
8.12.3. Health records, both from industry and any other available sources		
8.12.4. Epidemiological studies on the general population		
8.12.5. Diagnosis of poisoning including specific signs of poisoning and clinical tests		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.12.6. Sensitisation/allergenicity observations		
8.12.7. Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known		
8.12.8. Prognosis following poisoning		
8.13. Additional studies Additional data which may be required depending on the characteristics and intended use of the active substance.	ADS	
8.13.1. Phototoxicity	ADS	
8.13.2. Neurotoxicity including developmental neurotoxicity - The preferred test species is the rat unless another test species is justified to be more appropriate. - For delayed neurotoxicity tests the preferred species will be the adult hen. - If anticholine esterase activity is detected a test for response to reactivating agents should be considered	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
If the active substance is an organophosphorus compound or if there is any evidence e.g. knowledge of the mechanism of action or from repeat dose studies that the active substance may have neurotoxic or developmental neurotoxic properties then additional information or specific studies will be required. For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.		
8.13.3. Endocrine disruption If there is any evidence from *in vitro*, repeat dose or reproduction toxicity studies, that the active substance may have endocrine disrupting properties then additional information or specific studies shall be required: - to elucidate the mode/mechanism of action - provide sufficient evidence for relevant adverse effects	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.		
8.13.4. Immunotoxicity including developmental immunotoxicity If there is any evidence, from skin sensitisation, repeat dose or reproduction toxicity studies, that the active substance may have immunotoxic properties then additional information or specific studies shall be required: - to elucidate the mode/mechanism of action - provide sufficient evidence for relevant adverse effects in humans For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.	ADS	
8.13.5. Mechanistic data - any studies necessary to clarify effects reported in toxicity studies.	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.14. Studies related to the exposure of humans to the active substance.	ADS	
8.15. Toxic effects on livestock and pets.	ADS	
8.16. Food and feeding stuffs studies including for food- producing animals and their products (milk, eggs and honey) Additional information related to the exposure of humans to the active substance contained in biocidal products.	ADS	
8.16.1. Proposed acceptable residue levels i.e. maximum residue limits (MRL) and the justification of their acceptability	ADS	
8.16.2. Behaviour of the residue of the active substance on the treated or contaminated food or feeding stuffs including the kinetics of disappearance. Residue definitions should be provided where relevant. It is also important to compare residues found in toxicity studies with residues formed in food-producing animals, their product as well as food and feed.	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.16.3. Overall material balance for the active substance. Sufficient residue data from supervised trials on food producing species and their products as well as food and feed to demonstrate that residues likely to arise from the proposed use would not be of concern for human or animal health	ADS	
8.16.4. Estimation of potential or actual exposure of humans to the active substance and residues through diet and other means	ADS	
8.16.5. If residues of the active substance occur on feeding stuffs for a significant period of time or also residues found in food of animal origin after treatment on or around food-producing animals (e.g. direct treatment on animals or indirect treatment of animal houses or surroundings) then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.16.6. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the active substance	ADS	
8.16.7. Any other available information that is relevant It may be applicable to include information on migration into food, especially in the case of treatment of food contact materials	ADS	
8.16.8. Summary and evaluation of data submitted under 8.16.1 to 8.16.8 It is important to investigate if the same metabolites are found in food (from animals or plants) as the ones tested in toxicity studies. Otherwise values for risk assessment (e.g. ADI) are not valid for the residues found.	ADS	
8.17. If the active substance is to be used in products for action against plants including algae then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.18. Summary of mammalian toxicology Provide overall evaluation and conclusion with regard to all toxicological data and any other information concerning the active substances including NOAEL		
9. ECOTOXICOLOGICAL STUDIES		
9.1. Toxicity to Aquatic Organisms		
9.1.1. Short-term toxicity testing on fish When short-term fish toxicity data is required the threshold approach (tiered strategy) should be applied		The study does not need to be conducted if: - a valid long-term aquatic toxicity study on fish is available.
9.1.2. Short-term toxicity testing on aquatic invertebrates		
9.1.2.1. Daphnia magna		
9.1.2.2. Other species	ADS	
9.1.3. Growth inhibition study on algae		
9.1.3.1. Effects on growth rate of green algae		
9.1.3.2. Effects on growth rate of the cyanobacteria or of a diatom		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
9.1.4. Bioconcentration 9.1.4.1. Estimation methods 9.1.4.2. Experimental determination		The experimental determination may not need to be carried out if: - it can be demonstrated on the basis of physico-chemical properties (e.g. log Kow < 3) or other evidence that the substance has a low potential for bioconcentration
9.1.5. Inhibition of microbial activity 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		
9.1.6. Further Toxicity Studies on Aquatic Organisms If the results of the ecotoxicological studies, studies on fate and behaviour and/or the intended use(s) of the active substance indicate a risk for the aquatic environment or if long-term exposure is expected then one or more of the tests described in this section shall be conducted.	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
9.1.6.1. Long term toxicity testing on Fish (a) Fish Early Life Stage (FELS) Test (b) Fish short term toxicity test on embryo and sack fry stages (c) Fish juvenile growth test (d) Fish full life cycle test	ADS	
9.1.6.2. Long term toxicity testing on invertebrates (a) Daphnia growth and reproduction study (b) Other species reproduction and growth (e.g. Mysid) (c) Other species development and emergence (e.g. Chironomus)	ADS	
9.1.7. Bioaccumulation in an appropriate aquatic species	ADS	
9.1.8. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk	ADS	
9.1.9. Studies on sediment dwelling organisms	ADS	
9.1.10. Effects on aquatic macrophytes	ADS	
9.1.11. Amphibian metamorphosis assay	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
9.2. Terrestrial toxicity, initial tests 9.2.1. Effects on soil microorganisms 9.2.2. Effects on earthworms or other soil- dwelling non-target invertebrates 9.2.3. Acute toxicity to plants	ADS	
9.3. Terrestrial tests, long term 9.3.1. Reproduction study with earthworms or other soil-dwelling non-target invertebrates	ADS	
9.4. Effects on birds 9.4.1. Acute oral toxicity 9.4.2. Short-term toxicity – eight-day dietary study in at least one species (other than chickens, ducks and geese) 9.4.3. Effects on reproduction	ADS	For endpoint 9.4.3 the study does not need to be conducted if: - the dietary toxicity study shows that the LC_{50} is above 2000 mg/kg
9.5. Effects on arthropods 9.5.1. Effects on honeybees 9.5.2. Other non-target terrestrial arthropods, e.g. predators	ADS	
9.6. Bioconcentration, terrestrial	ADS	
9.7. Bioaccumulation, terrestrial	ADS	
9.8. Effects on other non-target, non-aquatic organisms	ADS	
9.9. Effects on mammals 9.9.1. Acute oral toxicity 9.9.2. Short term toxicity 9.9.3. Long term toxicity 9.9.4. Effects on reproduction	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
9.10. Identification of endocrine activity	ADS	
10. ENVIRONMENTAL FATE AND BEHAVIOUR		
10.1. Fate and behaviour in water and sediment		
10.1.1. Degradation, initial studies If the assessment performed indicates the need to investigate further the degradation of the substance and its degradation products or the active substance has an overall low or absent abiotic degradation, then the tests described in 10.1.3 and 10.3.2 and where appropriate - in 10.4 shall be required. The choice of the appropriate test(s) depends on the results of the initial assessment performed.		
10.1.1.1 Abiotic		
(a) Hydrolysis as a function of pH and identification of breakdown products - The identification of breakdown products is required when the breakdown products at any sampling time are present at ≥10%		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
(b) Phototransformation in water, including identification of transformation products		
10.1.1.2. Biotic		
(a) Ready biodegradability		
(b) Inherent biodegradability (where appropriate)		
10.1.2. Adsorption/desorption		
10.1.3. Rate and route of degradation including identification of metabolites and degradation products		
10.1.3.1. Biological sewage treatment		
(a) Aerobic biodegradation	ADS	
(b) Anaerobic biodegradation	ADS	
(c) STP simulation test	ADS	
10.1.3.2. Biodegradation in freshwater		
(a) Aerobic aquatic degradation study	ADS	
(b) Water/sediment degradation test	ADS	
10.1.3.3 Biodegradation in sea water	ADS	
10.1.3.4 Biodegradation during manure storage	ADS	
10.1.4. Adsorption and desorption in water/aquatic sediment systems and, where relevant, adsorption and desorption of metabolites and degradation products	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
10.1.5. Field study on accumulation in sediment	ADS	
10.1.6. Inorganic substances: information on fate and behaviour in water	ADS	
10.2. Fate and behaviour in soil	ADS	
10.2.1. Laboratory study on rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in one soil type (unless pH dependent route) under appropriate conditions Laboratory studies on rate of degradation in three additional soil types	ADS	
10.2.2. Field studies, two soil types	ADS	
10.2.3 Soil accumulation studies	ADS	
10.2.4. Adsorption and desorption in at least three soil types and, where relevant, adsorption and desorption of metabolites and degradation products	ADS	
10.2.5. Further studies on sorption		
10.2.6. Mobility in at least three soil types and where relevant mobility of metabolites and degradation products	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
10.2.6.1. Column leaching studies		
10.2.6.2. Lysimeter studies		
10.2.6.3. Field leaching studies		
10.2.7. Extent and nature of bound residues The determination and characteristics of bound residues is recommended to be combined with a soil simulation study.	ADS	
10.2.8. Other soil degradation studies	ADS	
10.2.9. Inorganic substances: information on fate and behaviour in soil		
10.3. Fate and behaviour in air		
10.3.1. Phototransformation in air (estimation method) Identification of transformation products		
10.3.2. Fate and behaviour in air, further studies	ADS	
10.4. Additional studies on fate and behaviour in the environment	ADS	
10.5. Definition of the residue 10.5.1. Definition of the residue for risk assessment	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
10.5.2. Definition of the residue for monitoring		
10.6. Monitoring data	ADS	
10.6.1. Identification of all degradation products (>10%) must be included in the studies on degradation in soil, water and sediments		
11. MEASURES NECESSARY TO PROTECT HUMAN HEALTH, ANIMALS AND THE ENVIRONMENT		
11.1. Recommended methods and precautions concerning handling, use, storage, transport or fire		
11.2. In case of fire, nature of reaction products, combustion gases etc.		
11.3. Emergency measures in case of accident		
11.4. Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
11.5. Procedures for waste management of the active substance for industry or professional users		
11.6. Possibility of reuse or recycling		
11.7. Possibility of neutralisation of effects		
11.8. Conditions for controlled discharge including leachate qualities on disposal		
11.9. Conditions for controlled incineration		
11.10. Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances[1], of Annex I and II to Directive 2006/118/EC on the protection of groundwater against pollution and deterioration[2], of Annex I to Directive 2008/105/EC on environmental quality standards in the field of water policy[3], of Annex I Part B to Directive 98/83/EC or Annex VIII and X to Directive 2000/60/EC.		

[1] OJ L 20, 26.1.1980, p. 43.
[2] OJ L 372, 27.12.2006, p. 19.
[3] OJ L 348, 24.12.2008, p. 84.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
12. CLASSIFICATION, LABELLING AND PACKAGING		
12.1. State any existing classification and labelling.		
12.2. The hazard classification of the substance resulting from the application of the Regulation (EC) No 1272/2008 In addition, for each entry, the reasons why no classification is given for an endpoint should be provided		
12.2.1. Hazard Classification		
12.2.2. Hazard pictogram		
12.2.3. Signal word		
12.2.4. Hazard statements		
12.2.5. Precautionary statements including prevention, response, storage and disposal		
12.3. Specific concentration limits, where applicable, resulting from the application of Regulation (EC) No 1272/2008		
13. SUMMARY AND EVALUATION The key information identified from the endpoints in each sub-section (2-12) is summarised, evaluated and a draft risk assessment is performed.		

TITLE 2

MICRO-ORGANISMS

CORE DATA SET AND ADDITIONAL DATA SET FOR ACTIVE SUBSTANCES

Information required to support the approval of an active substance is listed in the table below.

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 3, also apply.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
1. APPLICANT		
1.1. Name and address		
1.2. Contact person		
1.3. Manufacturer (name, address and location of manufacturing plant)		
2. IDENTITY OF THE MICROORGANISM		
2.1. Common name of the micro-organism (including alternative and superseded names)		
2.2. Taxonomic name and strain		
2.3. Collection and culture reference number where the culture is deposited		
2.4. Methods, procedures and criteria used to establish the presence and identity of the micro-organism		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
2.5. Specification of the technical grade active ingredient		
2.6. Method of production and quality control		
2.7. Content of the micro-organism		
2.8. Identity and content of impurities, additives, contaminating micro-organisms		
2.9. Analytical profile of batches		
3. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM		
3.1. General information on the microorganism		
3.1.1. Historical background		
3.1.2. Historical uses		
3.1.3. Origin, natural occurrence and geographical distribution		
3.2. Development stages/life cycle of the micro-organism		
3.3. Relationships to known plant or animal or human pathogens		
3.4. Genetic stability and factors affecting it		
3.5. Information on the production of metabolites (especially toxins)		
3.6. Production and resistance to antibiotics and other anti-microbial agents		
3.7. Robustness to environmental factors		
3.8. Further information on the micro-organism		
4. METHODS OF DETECTION AND IDENTIFICATION		
4.1. Analytical methods for the analysis of the microorganism as manufactured		

Column 1 Information required:		Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
4.2.	Methods used for monitoring purposes to determine and quantify residues (viable or non-viable)		
5.	EFFECTIVENESS AGAINST TARGET ORGANISM		
5.1.	Function and mode of control e.g. attracting, killing, inhibiting		
5.2.	Infectiveness, dispersal and colonisation ability		
5.3.	Representative organism(s) controlled and products, organisms or objects to be protected		
5.4.	Effects on representative target organism(s) Effects on materials, substances and products		
5.5.	Likely concentration at which the micro-organism will be used		
5.6.	Mode of action (including time delay)		
5.7.	Efficacy data		
5.8.	Any known limitations on efficacy		
5.8.1.	Information on the occurrence or possible occurrence of the development of resistance of the target organism(s) and appropriate management strategies		
5.8.2.	Observations on undesirable or unintended side effects.		
5.8.3.	Host specificity, range and effects on species other than the target organism		
5.9.	Methods to prevent loss of virulence of seed stock of the micro-organism		

Column 1 Information required:		Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
6.	INTENDED USES AND EXPOSURE		
6.1.	Field of use(s) envisaged		
6.2.	Product type(s)		
6.3.	Detailed description of the use pattern(s)		
6.4.	Category of users for which the micro-organism should be approved		
6.5.	Exposure data applying, as appropriate, the methodologies described in section 5 of Annex I to Regulation (EC) No 1907/2006		
6.5.1.	Information on human exposure associated with the intended uses and disposal of the active substance		
6.5.2.	Information on environmental exposure associated with the intended uses and disposal of the active substance		
6.5.3.	Information on exposure of food producing animals and food and feeding stuffs associated with the intended uses of the active substance		
7.	EFFECT ON HUMAN AND ANIMAL HEALTH		
7.1.	Basic information		
7.1.1.	Medical data		
7.1.2.	Medical surveillance on manufacturing plant personnel		
7.1.3.	Sensitisation/allergenicity observations		
7.1.4.	Direct observation, e.g. clinical cases Any pathogenicity and infectiveness to humans and other mammals under conditions of immunosuppression		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
7.2. Basic studies		
7.2.1. Sensitisation		
7.2.2. Acute toxicity, pathogenicity, and infectiveness		
7.2.2.1. Acute oral toxicity, pathogenicity and infectiveness		
7.2.2.2. Acute inhalatory toxicity, pathogenicity and infectiveness		
7.2.2.3. Intraperitoneal/subcutaneous single dose		
7.2.3. *In vitro* genotoxicity testing		
7.2.4. Cell culture study		
7.2.5. Information on short-term toxicity and pathogenicity	ADS	
7.2.5.1. Health effects after repeated inhalatory exposure	ADS	
7.2.6. Proposed treatment: first aid measures, medical treatment		
7.3. Specific toxicity, pathogenicity and infectiveness studies	ADS	
7.4. Genotoxicity — *in vivo* studies in somatic cells	ADS	
7.5. Genotoxicity — *in vivo* studies in germ cells	ADS	
7.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation		
7.7. Residues in or on treated articles, food and feedingstuffs	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
7.7.1. Persistence and likelihood of multiplication in or on treated articles, feedingstuffs or foodstuffs	ADS	
7.7.2. Further information required	ADS	
7.7.2.1. Non-viable residues	ADS	
7.7.2.2. Viable residues	ADS	
7.8. Summary and evaluation of residues in or on treated articles, food and feedingstuffs	ADS	
8. EFFECTS ON NON-TARGET ORGANISMS		
8.1. Effects on aquatic organisms		
8.1.1. Effects on fish		
8.1.2. Effects on freshwater invertebrates		
8.1.3. Effects on algae growth		
8.1.4. Effects on plants other than algae	ADS	
8.2. Effects on earthworms		
8.3. Effects on soil micro-organisms		
8.4. Effects on birds		
8.5. Effects on bees		
8.6. Effects on arthropods other than bees		
8.7. Further studies	ADS	
8.7.1. Terrestrial plants	ADS	
8.7.2. Mammals	ADS	
8.7.3. Other relevant species and processes	ADS	
8.8. Summary and evaluation of effects on non-target organisms		
9. ENVIRONMENTAL FATE AND BEHAVIOUR		
9.1. Persistence and multiplication		
9.1.1. Soil		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
9.1.2. Water		
9.1.3. Air		
9.1.4. Mobility		
9.1.5. Summary and evaluation of fate and behaviour in the environment		
10. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT		
10.1. Recommended methods and precautions concerning handling, storage, transport or fire		
10.2. Emergency measures in case of an accident		
10.3. Procedures for destruction or decontamination		
10.4. Procedures for waste management		
10.5. Monitoring plan to be used for the active micro-organism including handling, storage, transport and use		
11. CLASSIFICATION, LABELLING AND PACKAGING OF THE MICRO-ORGANISM		
11.1. Relevant risk group specified in Article 2 of Directive 2000/54/EC		
12. SUMMARY AND EVALUATION The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed.		

ANNEX III

INFORMATION REQUIREMENTS FOR BIOCIDAL PRODUCTS

1. This Annex sets out the information requirements that shall be included in the dossier for the biocidal product accompanying an application for the approval of an active substance in accordance with point (b) of Article 6 (1) and the dossier accompanying an application for the authorisation of a biocidal product in accordance with point (a) of Article 19(1).

2. The data elements set down in this Annex comprise a Core Data Set (CDS) and an Additional Data Set (ADS). The data elements belonging to the CDS are considered as the basic data which should, in principle, be provided for all biocidal products.

   With regard to the ADS, the data elements to be provided for a specific biocidal product shall be determined by considering each of the ADS data elements indicated in this Annex taking into account, inter alia, the physical and chemical properties of the product, existing data, information which is part of the CDS and the types of products and the exposure patterns related to these uses.

Specific indications for the inclusion of some data elements are provided in column 1 of the Annex III table. The general considerations regarding adaptation of information requirements as set out in Annex IV to this Regulation shall also apply. In light of the importance of reducing testing on vertebrate animals, column 3 of the table gives specific indications for the adaptation of some of the data elements which might require the use of such tests on vertebrate animals.

For some of the information requirements set out in this Annex it may be possible to satisfy these requirements based on available information of the properties of the active substance(s) contained in the product and the properties of non-active substance(s) included in the product. For non-active substances, applicants shall use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006, where relevant, and the information made available by ECHA in accordance with point (e) of Article 77(2) of that Regulation.

The relevant calculation methods used for the classification of mixtures as laid down in Regulation (EC) No 1272/2008 shall, where appropriate, be applied in the hazard assessment of the biocidal product. Such calculation methods shall not be used if, in relation to a particular hazard, synergistic and antagonistic effects between the different substances contained in the product are considered likely.

Detailed technical guidance regarding the application of this Annex and the preparation of the dossier is available on the web-site of the Agency.

The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set out in Article 61(2), applicants may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrate animals that the applicant proposes to carry out.

Additional information may need to be submitted if necessary to carry out the evaluation as indicated in Article 28(3) or 43(2).

The information submitted shall, in any case, be sufficient to support a risk assessment demonstrating that the criteria in Article 18(1)(b) are met.

3. A detailed and full description of studies conducted and of the methods used shall be included. It is important to ensure that the data available is relevant and is of sufficient quality to fulfil the requirements.

4. The formats made available by the Agency shall be used for submission of the dossiers. In addition, IUCLID shall 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.

5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. However, if a method is inappropriate or not described, other methods shall be used which are, whenever possible, internationally recognised and scientifically appropriate and must be justified in the application.

6. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Directive 2010/63/EC 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. Tests on physico-chemical properties and safety-relevant substance data should be performed at least according to international standards.

7. Where testing is done, a detailed quantitative and qualitative description (specification) of the product used for each test and its impurities must be provided.

8. 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, on a case-by-case basis, taking into account, among other factors, the need to avoid unnecessary testing.

9. New tests involving vertebrate animals shall be conducted as the last available option to comply with the data requirements set out in this Annex when all the other data sources have been exhausted. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall also be avoided.

* OJ: insert the date of the entry into force of this Regulation.

TITLE 1

CHEMICAL PRODUCTS

CORE DATA SET AND ADDITIONAL DATA SET FOR CHEMICAL PRODUCTS

Information required to support the authorisation of a biocidal product is listed in the table below.

For each information requirement set down in this Annex the indications given in columns 1 and 3 of Annex II for the same information requirement shall also apply.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
1. APPLICANT		
1.1. Name and address, etc		
1.2. Contact person		
1.3. Manufacturer and formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))		
2. IDENTITY OF THE BIOCIDAL PRODUCT		
2.1. Trade name or proposed trade name		
2.2. Manufacturer's development code and number of the product, if appropriate		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
2.3. Complete quantitative (g/kg, g/l or % w/w (v/v)) composition of the biocidal product, i.e. declaration of all active substances and co-formulants (substance or mixture according to Article 3 of Regulation (EC) No 1907/2006), which are intentionally added to the biocidal product (formulation) as well as detailed quantitative and qualitative information on the composition of the active substance(s) contained. For co-formulants, a safety data sheet in compliance with Article 31 of Regulation (EC) No 1907/2006 has to be provided. In addition, all relevant information on individual ingredients, their function and, in case of a reaction mixture, the final composition of the biocidal product shall be given.		
2.4. Formulation type and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution		
3. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES		
3.1. Appearance (at 20°C and 101.3 kPa)		
3.1.1. Physical state (at 20°C and 101.3 kPa)		
3.1.2. Colour (at 20°C and 101.3 kPa)		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
3.1.3. Odour (at 20°C and 101.3 kPa)		
3.2. Acidity/alkalinity The test is applicable when the pH of the biocidal product or its dispersion in water (1%) is outside the pH range 4-10		
3.3. Relative density (liquids) and bulk, tap density (solids)		
3.4. Storage stability, stability and shelf-life		
3.4.1. Storage stability tests		
3.4.1.1. Accelerated storage test		
3.4.1.2. Long term storage test at ambient temperature		
3.4.1.3. Low temperature stability test (liquids)		
3.4.2. Effects on content of the active substance and technical characteristics of the biocidal product		
3.4.2.1 Light		
3.4.2.2 Temperature and humidity		
3.4.2.3 Reactivity towards container material		
3.5. Technical characteristics of the biocidal product		
3.5.1. Wettability		
3.5.2. Suspensibility, spontaneity and dispersion stability		
3.5.3. Wet sieve analysis and dry sieve test		
3.5.4. Emulsifiability, re-emulsifiability and emulsion stability		
3.5.5. Disintegration time		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
3.5.6. Particle size distribution, content of dust/fines, attrition, friability		
3.5.7. Persistent foaming		
3.5.8. Flowability / Pourability / Dustability		
3.5.9. Burning rate- smoke generators		
3.5.10. Burning completeness- smoke generators		
3.5.11. Composition of smoke -smoke generators		
3.5.12. Spraying pattern -aerosols		
3.5.13. Other technical characteristics		
3.6. Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised		
3.6.1. Physical compatibility		
3.6.2. Chemical compatibility		
3.7. Degree of dissolution and dilution stability		
3.8. Surface tension		
3.9. Viscosity		
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERIESTICS		
4.1. Explosives		
4.2. Flammable gases		
4.3. Flammable aerosols		
4.4. Oxidising gases		
4.5. Gases under pressure		
4.6. Flammable liquids		
4.7. Flammable solids		
4.8. Self-reactive substances and mixtures		
4.9. Pyrophoric liquids		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
4.10. Pyrophoric solids		
4.11. Self heating substances and mixtures		
4.12. Substances and mixtures which in contact with water emit flammable gases		
4.13. Oxidising liquids		
4.14. Oxidising solids		
4.15. Organic peroxides		
4.16. Corrosive to metals		
4.17. Additional physical indications of hazard		
4.17.1. Auto-ignition temperatures of products (liquids and gases)		
4.17.2. Relative self ignition temperature for solids		
4.17.3. Dust explosion hazard		
5. METHODS OF DETECTION AND IDENTIFICATION		
5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product		
5.2. In so far as not covered by Annex II 5.2 and 5.3, analytical methods for monitoring purposes including recovery rates and the limits of determination of relevant components of the biocidal product and/or residues thereof, where relevant in or on the following:	ADS	

Column 1 Information required:		Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
5.2.1.	Soil	ADS	
5.2.2.	Air	ADS	
5.2.3.	Water (including drinking water) and sediment	ADS	
5.2.4.	Animal and human body fluids and tissues	ADS	
5.3.	Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (not necessary if neither the active substance or the material treated with it does not come into contact with food producing animals, food of plant and animal origin or feeding stuffs)	ADS	
6.	EFFECTIVENESS AGAINST TARGET ORGANISMS		
6.1.	Function, e.g. fungicide, rodenticide, insecticide, bactericide Mode of control e.g. attracting, killing, inhibiting		
6.2.	Representative organism(s) to be controlled and products, organisms or objects to be protected		
6.3.	Effects on representative target organisms		
6.4.	Likely concentration at which the active substance will be used		
6.5.	Mode of action (including time delay)		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
6.6. The proposed label claims for the product and, where label claims are made, for treated articles		
6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		
6.8. Any known limitations on efficacy 6.8.1. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies 6.8.2. Observations on undesirable or unintended side effects e.g. on beneficial and other non-target organisms		
6.9. Summary and evaluation		
7. INTENDED USES AND EXPOSURE		
7.1. Field(s) of use envisaged for biocidal products and, where appropriate, treated articles		
7.2. Product type		
7.3. Detailed description of intended use pattern(s) for biocidal products and, where appropriate, treated articles		
7.4. User e.g. industrial, trained professional, professional or general public (non-professional)		

Column 1 Information required:		Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
7.5.	Likely tonnage to be placed on the market per year		
7.6.	Method of application and a description of this method		
7.7.	Application rate and if appropriate, the final concentration of the biocidal product and active substance in a treated article or in the system in which the product is to be used, e.g. cooling water, surface water, water used for heating purposes.		
7.8.	Number and timing of applications, and where relevant, any particular information relating to geographical location or climatic variations including necessary waiting periods, clearance times, withdrawal periods or other precautions to protect human and animal health and the environment		
7.9.	Proposed instructions for use		
7.10.	Exposure data in conformity with Annex VI to Regulation XXXX/20YY		
7.10.1.	Information on human exposure associated with production and formulation, proposed/expected uses and disposal		
7.10.2.	Information on environmental exposure associated with production and formulation, proposed/expected uses and disposal		
7.10.3.	Information on exposure from treated articles including leaching data (either laboratory studies or model data)		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
7.10.4. Information regarding other products that the product is likely to be used together with, in particular the identity of the active substances in these products, if relevant, and the likelihood of any interactions		
8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS		
8.1. Skin corrosion or skin irritation The assessment of this endpoint shall be carried out according to the sequential testing strategy for dermal irritation and corrosion set out in the Appendix to Test Guideline B.4. Acute Toxicity-Dermal Irritation/Corrosion (Annex B.4. to Regulation (EC) No 440/2008)		Testing on the product/mixture does not need to be conducted if: - there is valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.2. Eye irritation[1] The assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5.Acute Toxicity: Eye Irritation/Corrosion (Annex B.5. to Regulation (EC) No 440/2008)		Testing on the product/mixture does not need to be conducted if: - there is valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/ECand Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected.
8.3. Skin 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 Murine Local Lymph Node Assay (LLNA) including, where appropriate, the reduced variant of the assay, is the first-choice method for *in vivo* testing. If another skin sensitisation test is used justification shall be provided.		Testing on the product/mixture does not need to be conducted if: - there is valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected.

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

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
		- the available information indicates that the product should be classified for skin sensitisation or corrosivity; or - the substance is a strong acid (pH < 2.0) or base (Ph > 11.5)
8.4. Respiratory sensitisation	ADS	Testing on the product/mixture does not need to be conducted if: - there is valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected.

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.5. Acute toxicity - Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach		Testing on the product/mixture does not need to be conducted if: - there is valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected.
8.5.1. By oral route		
8.5.2. By inhalation		
8.5.3. By dermal route		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.5.4. For biocidal products that are intended to be authorised for use with other biocidal products consideration should be given to testing combinations of the products for acute dermal toxicity and skin and eye irritation.		Testing on the mixture of products does not need to be conducted if: - there is valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected.
8.6. Information on dermal absorption Information on dermal absorption when exposure occurs to the biocidal product. The assessment of this endpoint shall proceed using a tiered approach		

Column 1 Information required:		Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.7.	Available toxicological data relating to: - co-formulants (i.e. substance(s) of concern), or - a mixture that a substance(s) of concern is a component of If no data is available, then the appropriate test(s) described in Annex II, shall be carried out for the co-formulants (i.e. substance(s) of concern) or a mixture that a substance(s) of concern is a component of		Testing on the product/mixture does not need to be conducted if: - there is valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP).
8.8.	Food and feedingstuffs studies	ADS	
8.8.1.	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	ADS	
8.9.	Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product	ADS	
8.10.	Other test(s) related to the exposure to humans Suitable test(s) and a reasoned case will be required for the biocidal product In addition, for certain biocides which are applied directly or around livestock (including horses) residue studies might be needed.	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
9. ECOTOXICOLOGICAL STUDIES		
9.1. Sufficient information relating to the ecotoxicity of the biocidal product such as to enable a decision to be made concerning the classification of the product is required. - Where there is valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP) - Where valid data on the components is not available or where synergistic effects may be expected then testing of components and/or the biocidal product itself may be necessary.		
9.2. Further Ecotoxicological studies Further studies chosen from among the endpoints referred to in section 9 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product		
9.3. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk	ADS	

Column 1 Information required:		Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
9.4.	If the biocidal product is in the form of bait or granules the following studies may be required:		
9.4.1.	Supervised trials to assess risks to non-target organisms under field conditions		
9.4.2.	Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk		
9.5.	Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated.	ADS	
10.	ENVIRONMENTAL FATE AND BEHAVIOUR The test requirements below are applicable only to the relevant components of the biocidal product		
10.1.	Foreseeable routes of entry into the environment on the basis of the use envisaged		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
10.2. Further studies on fate and behaviour in the environment Further studies chosen from among the endpoints referred to in section 10 of Annex II for relevant components of the biocidal product or the biocidal product itself may be required. For products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance. Data are required unless it is scientifically justified that the fate of the components in the product is covered by the data provided for the active substance and other identified substances of concern	ADS	
10.3. Leaching behaviour	ADS	
10.4. Testing for distribution and dissipation in the following:	ADS	
10.4.1. Soil	ADS	
10.4.2. Water and sediment	ADS	
10.4.3. Air	ADS	
10.5. 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 or plants under field conditions	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
10.6. If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions	ADS	
11. MEASURES TO BE ADOPTED TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT		
11.1. Recommended methods and precautions concerning handling, use, storage, disposal, transport or fire		
11.2. Identity of relevant combustion products in cases of fire		
11.3. Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment		
11.4. Possibility of destruction or decontamination following release in or on the following:		
11.4.1. Air		
11.4.2. Water, including drinking water		
11.4.3. Soil		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
11.5. Procedures for waste management of the biocidal product and its packaging for industrial use, use by trained professionals, professional users and non-professional users (e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration		
11.6. Procedures for cleaning application equipment where relevant		
11.7. Specify any repellents or poison control measures included in the product that are present to prevent action against non-target organisms		
12. CLASSIFICATION, LABELLING, AND PACKAGING As established in point (b) of Article 19(1), proposals including justification for the hazard and precautionary statements in accordance with the provisions set in Directive 1999/45/EC and Regulation (EC) No 1272/2008 must be submitted. Example labels, instructions for use and safety data sheets shall be provided		
12.1. Hazard Classification		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
12.2. Hazard pictogram		
12.3. Signal word		
12.4. Hazard statements		
12.5. Precautionary statements including prevention, response, storage and disposal		
12.6. Proposals for safety-data sheets should be provided, where appropriate		
12.7. Packaging (type, materials, size, etc.), compatibility of the product with proposed packaging materials to be included		
13. EVALUATION AND SUMMARY The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed.		

TITLE 2

MICRO-ORGANISMS

CORE DATA SET AND ADDITIONAL DATA SET

Information required to support the authorisation of a biocidal product is listed in the table below.

For each information requirement set down in this Annex the indications given in columns 1 and 3 of Annex II for the same information requirement shall also apply.

Column 1 Information required:		Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
1.	APPLICANT		
1.1.	Name and address		
1.2.	Contact person		
1.3.	Manufacturer and 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		
2.2.	Manufacturer's development code and number of the biocidal product, if appropriate		
2.3.	Detailed quantitative (g/kg, g/l or % w/w (v/v)) and qualitative information on the constitution, composition and function of the biocidal product, e.g. micro-organism, active substance(s) and product co-formulants and any other relevant components. All relevant information on individual ingredients and the final composition of the biocidal product shall be given.		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
2.4. Formulation type and nature of the biocidal product		
3. BIOLOGICAL, PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT		
3.1. Biological properties of the micro-organism in the biocidal product		
3.2. Appearance (at 20°C and 101.3 kPa)		
3.2.1. Colour (at 20°C and 101.3 kPa)		
3.2.2. Odour (at 20°C and 101.3 kPa)		
3.3. Acidity, alkalinity and pH value		
3.4. Relative density		
3.5. Storage stability, stability and shelf-life		
3.5.1. Effects of light		
3.5.2. Effects of temperature and humidity		
3.5.3. Reactivity towards the container		
3.5.4. Other factors affecting stability		
3.6. Technical characteristics of the biocidal product		
3.6.1. Wettability		
3.6.2. Suspensibility and suspension stability		
3.6.3. Wet sieve analysis and dry sieve test		
3.6.4. Emulsifiability, re-emulsifiability, emulsion stability		
3.6.5. Particle size distribution content of dust/ fines, attrition and friability		
3.6.6. Persistent foaming		
3.6.7. Flowability / Pourability / Dustability		
3.6.8. Burning rate - smoke generators		
3.6.9. Burning completeness - smoke generators		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
3.6.10. Composition of smoke - smoke generators		
3.6.11. Spraying patterns - aerosols		
3.6.12. Other technical characteristics		
3.7. Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered		
3.7.1. Physical compatibility		
3.7.2. Chemical compatibility		
3.7.3. Biological compatibility		
3.8. Surface tension		
3.9. Viscosity		
4. PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISITICS		
4.1. Explosives		
4.2. Flammable gases		
4.3. Flammable aerosols		
4.4. Oxidising gases		
4.5. Gases under pressure		
4.6. Flammable liquids		
4.7 Flammable solids		
4.8. Oxidising liquids		
4.9. Oxidising solids		
4.10. Organic peroxides		
4.11. Corrosive to metals		
4.12. Other physical indications of hazard		
4.12.1. Auto-ignition temperatures of products (liquids and gases)		
4.12.2. Relative self-ignition temperature for solids		
4.12.3. Dust explosion hazard		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
5. METHODS OF DETECTION AND IDENTIFICATION		
5.1. Analytical method for determining the concentration of the micro-organism(s) and substances of concern in the biocidal product		
5.2. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant (not necessary if neither the active substance nor the article treated with it does not come into contact with food producing animals, food of plant and animal origin or feeding stuffs)	ADS	
6. EFFECTIVENESS AGAINST TARGET ORGANISM		
6.1. Function and mode of control		
6.2. Representative pest organism(s) to be controlled and products, organisms or objects to be protected		
6.3. Effects on representative target organisms		
6.4. Likely concentration at which micro-organism will be used		
6.5. Mode of action		
6.6. The proposed label claims for the product		

Column 1 Information required:		Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
6.7.	Efficacy data to support these claims, including any available standard protocols, laboratory tests, or field trials used including performance standards, where appropriate and relevant		
6.8.	Any other known limitations on efficacy including resistance		
6.8.1.	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
6.8.2.	Observations on undesirable or unintended side effects		
7.	INTENDED USES AND EXPOSURE		
7.1.	Field of use envisaged		
7.2.	Product type		
7.3.	Detailed description of intended use		
7.4.	User e.g. industrial, trained professional, professional or general public (non-professional)		
7.5.	Method of application and a description of this method		
7.6.	Application rate and if appropriate the final concentration of the biocidal product or the micro-organism active substance in a treated article or the system in which the product is to be used (e.g. in the application device or bait)		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
7.7. Number and timing of applications and duration of protection Any particular information relating to the geographical location or climatic variations including necessary waiting periods for re-entry or necessary withdrawal period or other precautions to protect human and animal health and the environment		
7.8. Proposed instructions for use		
7.9. Exposure data		
7.9.1. Information on human exposure associated with the proposed/expected uses and disposal		
7.9.2. Information on environmental exposure associated with the proposed/expected uses and disposal		
8. TOXICOLOGICAL PROFILE FOR HUMANS AND ANIMALS		Testing on the product/mixture does not need to be conducted if: - there is valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.1. Skin corrosion or irritation		
8.2. Eye irritation		
8.3. Skin sensitisation		
8.4. Respiratory sensitisation	ADS	
8.5. Acute toxicity - Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach		
8.5.1. Oral		
8.5.2. Inhalation		
8.5.3. Dermal		
8.5.4. Additional acute toxicity studies		
8.6. Information on dermal absorption if required		
8.7. Available toxicological data relating to: - co-formulants (i.e. substance(s) of concern), or - a mixture that a substance(s) of concern is a component of If no data is available, then the appropriate test(s) described in Annex II, shall be carried out for the co-formulants (i.e. substance(s) of concern) or a mixture that a substance(s) of concern is a component of		Testing on the product/mixture does not need to be conducted if: - there is valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
8.8. Supplementary studies for combinations of biocidal products For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate		Testing on the mixture of products does not need to be conducted if: - there is valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP) and synergistic effects between any of the components are not expected
8.9. Residues in or on treated articles, food and feedingstuffs	ADS	
9. ECOTOXICOLOGICAL STUDIES		
9.1. Sufficient information relating to the ecotoxicity of the biocidal product such as to enable a decision to be made concerning the classification of the product is required. - Where there is valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture can be made according to the rules laid down in Directive 1999/45/EC, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP)		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
- Where valid data on the components is not available or where synergistic effects may be expected then testing of components and/or the biocidal product itself may be necessary.		
9.2. Further ecotoxicological studies Further studies chosen from among the endpoints referred to in section 8 of Annex II Micro-organisms for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product		
9.3. Effects on any other specific non-target organisms (flora and fauna) believed to be at risk	ADS	
9.4. If the biocidal product is in the form of bait or granules 9.4.1. Supervised trials to assess risks to non-target organisms under field conditions 9.4.2. Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk	ADS	
9.5. Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated.	ADS	

Column 1 Information required:		Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
10.	ENVIRONMENTAL FATE AND BEHAVIOUR		
10.1	Foreseeable routes of entry into the environment on the basis of the use envisaged		
10.2.	Further studies on fate and behaviour in the environment Where relevant, all the information required in section 9 of Annex II "Micro-organisms" may be required for the product For products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance. Data are required unless it is scientifically justified that the fate of the components in the product is covered by the data provided for the active substance and other identified substances of concern	ADS	
10.3.	Leaching behaviour	ADS	
10.4.	If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees under field conditions	ADS	

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
11. MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMAL AND THE ENVIRONMENT		
11.1. Recommended methods and precautions concerning: handling, storage, transport or fire		
11.2. Measures in the case of an accident		
11.3. Procedures for destruction or decontamination of the biocidal product and its packaging		
11.3.1. Controlled incineration		
11.3.2. Others		
11.4. Packaging and compatibility of the biocidal product with proposed packaging materials		
11.5. Procedures for cleaning application equipment where relevant		
11.6. 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		

Column 1 Information required:	Column 2 All data is CDS unless indicated as ADS	Column 3 Specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing of vertebrate animals
12. CLASSIFICATION, LABELLING AND PACKAGING Example labels, instructions for use and safety data sheets shall be provided		
12.1. Indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC		
12.2. Precautionary statements including prevention, response, storage and disposal		
12.3. Proposals for safety-data sheets should be provided, where appropriate		
12.4. Packaging (type, materials, size, etc.), compatibility of the product with proposed packaging materials to be included		
13. SUMMARY AND EVALUATION The key information identified from the endpoints in each subsection (2-12) is summarised, evaluated and a draft risk assessment is performed.		

ANNEX IV

GENERAL RULES FOR THE ADAPTATION OF THE DATA REQUIREMENTS

This Annex sets out rules to be followed when the applicant proposes to adapt the data requirements set out in Annexes II and III in accordance with Article 6(2) and (3) or Article 20(1) and (2), without prejudice to the specific rules set out in Annex III on the use of the calculation methods for classification of mixtures to avoid testing on vertebrate animals.

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.

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 of the data for the purpose of classification and labelling and risk assessment;

(2) sufficient adequate and reliable documentation is provided to assess the equivalency 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 of the data for the purpose of classification and labelling and risk assessment;

(2) adequate and reliable coverage of the key parameters/end-points 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;

(4) adequate and reliable documentation of the study is provided; and

(5) the study is performed using a system of quality assurance.

1.1.3. Historical human data

As a general rule, in accordance with Article 7(3) of Regulation (EC) No 1272/2008, tests on humans shall not be performed for the purposes of this Regulation. However, existing 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.

Data collected on humans shall not be used to lower the safety margins resulting from tests or studies on animals.

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.

1.2. 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 does not have a particular dangerous property, while the information from each single source alone is considered insufficient to support this notion. There may be sufficient weight of evidence from the use of positive results 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 a particular dangerous property. However, if the newly developed test method has been approved by the Commission, but not yet been published, its results may be taken into account even where it leads to the conclusion that a substance does not have a particular dangerous property.

Where consideration of all the available data provides sufficient weight of evidence for the presence or absence of a particular dangerous property:

– further testing on vertebrate animals for that property shall not be undertaken,

– 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, but not the absence of a given dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:

– the 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,

– the results are adequate for the purpose of classification and labelling and risk assessment, and

– adequate and reliable documentation of the applied method is provided.

The Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide guidance on the use of (Q)SARs.

1.4. *In vitro* methods

Results obtained from suitable *in vitro* methods may indicate the presence of a given 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.

Where such *in vitro* tests are positive, it is necessary to confirm the dangerous property by adequate *in vivo* tests. However, 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 risk assessment; and

(3) adequate and reliable documentation of the applied method is provided.

In the case of negative results, these exemptions do not apply. A confirmation test may be requested on a case-by-case basis.

1.5. Grouping of substances and read-across approach

Substances whose physicochemical, toxicological and ecotoxicological properties are 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 indicating the presence of dangerous properties;

(2) common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals and indicates the presence of dangerous properties; 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 shall:

– 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; and

– cover an exposure duration comparable to or longer than the corresponding test method if exposure duration is a relevant parameter.

In all cases, adequate and reliable documentation of the applied method shall be provided.

The Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide guidance on technically and scientifically justified methodology for the grouping of substances.

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 some end-points in sections 8 and 9 of Annexes II and III, notwithstanding Article 6(2), may be omitted based on exposure considerations, where exposure data in accordance with Annex II or III are available.

In that case, the following conditions shall be met:

– An exposure assessment shall be performed, covering primary and secondary exposure under realistic worst case for all intended uses of the biocidal product that contains the active substance for which approval is applied, or of the biocidal product for which the authorisation is sought.

– If a new exposure scenario is introduced at a later stage, during the product authorisation process, additional data shall be submitted to assess whether the justification for data adaptation still applies.

– The reasons why the outcome of the exposure assessment justifies waiving of data requirements shall be clearly and transparently explained.

However, testing cannot be omitted for non-threshold effects. As a consequence, certain core data shall always be obligatory, e.g. genotoxicity testing.

If relevant, the Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide further guidance on the criteria established in accordance with Articles 6(4) and 20(4).

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 relevant Technical Notes for Guidance where available.

ANNEX V

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

MAIN GROUP 1: Disinfectants

Product-type 1: Human hygiene

Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.

Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.

Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.

Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.

Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.

Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.

Product-type 3: Veterinary hygiene

Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function.

Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

Product-type 4: Food and feed area

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.

Products used to impregnate materials which may enter into contact with food.

Product-type 5: Drinking water

Products used for the disinfection of drinking water for both humans and animals.

MAIN GROUP 2: Preservatives

Unless otherwise stated these product-types include only products to prevent microbial and algal development.

Product-type 6: Preservatives for products during storage

Products used for the preservation of manufactured products, other than foodstuffs, feedingstuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life.

Products used as preservatives for the storage or use of rodenticide or insecticide baits.

Product-type 7: Film preservatives

Products used for the preservation of films or coatings by the control of microbial deterioration or algal growth 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, including insects.

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 by the control of microbiological deterioration.

Product-type 10: Construction material preservatives

Products used for the preservation of masonry, composite materials, 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 disinfection of drinking water or of water for swimming pools 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: Working or cutting fluid preservatives

Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.

MAIN GROUP 3: Pest control

Product-type 14: Rodenticides

Products used for the control of mice, rats or other rodents, by means other than repulsion or attraction.

Product-type 15: Avicides

Products used for the control of birds,by means other than repulsion or attraction.

Product-type 16: Molluscicides, vermicides and products to control other invertebrates

Products used for the control of molluscs, worms and invertebrates not covered by other product types, by means other than repulsion or attraction.

Product-type 17: Piscicides

Products used for the control of fish,by means other than repulsion or attraction.

Product-type 18: Insecticides, acaricides and products to control other arthropods

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans**),** by means other than repulsion or attraction.

Product-type 19: Repellents and attractants

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of man or animals.

Product-type 20: Control of other vertebrates

Products used for the control of vertebrates other than those already covered by the other product-types of this main group, by means other than repulsion or attraction..

MAIN GROUP 4: Other biocidal products

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.

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS
FOR BIOCIDAL PRODUCTS

CONTENTS

Conclusions

– General Principles

– Effects on human and animal health

– Effects on the environment

– Effects on target organisms

– Efficacy

– Summary

Overall integration of conclusions

TERMS AND DEFINITIONS

Correspondence with the criteria set out in Article 18(1)(b)

The subheadings "Effects on human and animal health", "Effects on the Environment", "Effects on Target Organisms" and "Efficacy" used in the sections "Assessment" and "Conclusions" correspond to the four criteria set out in Article 18(1)(b) as follows:

"Efficacy" corresponds to criterion (i): "is sufficiently effective".

"Effects on Target Organisms" corresponds to criterion (ii): "has no unacceptable effects on target organisms, in particular unacceptable resistance or cross resistance or unnecessary suffering and pain for vertebrates".

"Effects on human and animal health" corresponds to criterion (iii): "has no immediate or delayed unacceptable effects itself or as a result of its residues on human and animal health, including that of vulnerable groups[1] either directly or through drinking water, food, feed, air or through other indirect effects".

"Effects on the environment" corresponds to criterion iv: "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".

[1] See definition of vulnerable groups in Article 3.

Technical 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, soil, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms.

INTRODUCTION

1. This Annex sets out the common principles for the evaluation of dossiers for biocidal products referred to in Article 18(1)(b). A decision by a Member State or the Commission to authorise a biocidal product shall be taken on the basis of the conditions set down in Article 18 taking account of the evaluation carried out according to this Annex. Detailed technical guidance regarding the application of this Annex is available on the web-site of the Agency.

2. The principles set out in this Annex can be applied in their entirety to the evaluation of biocidal products comprised of chemical substances. For biocidal products containing micro-organisms, these principles should be further developed in technical guidance taking into account practical experience gained, and be applied taking into account the nature of the product and the latest scientific information. In the case of biocidal products containing nanomaterials the principles set out in this Annex will also need to be adapted and elaborated in technical guidance to take account of the latest scientific information.

3. 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 that are identified. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product taking into account any cumulative and synergistic effects.

4. A risk assessment on the active substance(s) present in the biocidal product is always required. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.

5. Additional risk assessments shall be carried out, in the same manner as described above, on any substance of concern present in the biocidal product. Information submitted in the framework of Regulation (EC) No 1907/2006 shall be taken into account where appropriate.

6. In order to carry out a risk assessment data are required. These data are detailed in Annexes II and III and take account of the fact that there are a wide variety of applications as well as different product types and that this has an impact on the associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. The evaluating body shall take due consideration of the requirements of Article 6, Article 20 and Article 61 in order to avoid duplication of data submissions. Data may also be required on a substance of concern present in a biocidal product. In case of in-situ generated active substances the risk assessment includes also the possible risks from the precursor(s).

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

8. When making evaluations of a biocidal product the evaluating body 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.

9. The application of these common principles shall when taken together with the other conditions set out in Article 18 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. In the case of biocidal products containing active substances covered by the exclusion criteria in Article 5(1), the competent authorities or the Commission shall also evaluate whether the conditions of Article 5(2) can be satisfied.

11. During the process of evaluation, applicants and the evaluating bodies 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 18 and of this Annex. The administrative burden, especially for SMEs, shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.

12. The judgments made by the evaluating body during the evaluation must be based on scientific principles, preferably recognised at international level, and be made with the benefit of expert advice.

ASSESSMENT

General principles

13. The data submitted in support of an application for authorisation of a biocidal product shall be validated by the evaluating or receiving competent authority in accordance with the relevant Articles of the Regulation. After validation of these data the competent authorities shall utilise them by carrying out a risk assessment based on the proposed use. Information submitted in the framework of Regulation (EC) No 1907/2006 shall be taken into account where appropriate.

14. A risk assessment on the active substance present in the biocidal product shall always be carried out. If there are, in addition, any substances of concern present in the biocidal product then a risk assessment shall be carried out for each of these. The risk assessment shall cover the proposed normal use of the biocidal product together with a realistic worst-case scenario including any relevant production and disposal issue. The assessment shall also take account of how any "treated articles" treated with or containing the product may be used and disposed of. Active substances that are generated in-situ and the associated precursors shall also be considered.

15. In carrying out the assessment, the possibility of cumulative or synergistic effects shall also be taken into account.

16. For each active substance and each substance of concern present in the biocidal product, the risk assessment shall entail hazard identification and the establishment of appropriate reference values for dose or effect concentrations such as NOAEL or Predicted No Effect Concentrations (PNEC), where possible. It shall also include, as appropriate, a dose (concentration) - response (effect) assessment, together with an exposure assessment and a risk characterisation.

17. The results arrived at from a comparison of the exposure to the appropriate reference values for each of the active substances and any substances of concern shall be integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available the results of the qualitative assessments shall be integrated in a similar manner.

18. The risk assessment shall determine:

    (a) the hazards due to the physico-chemical properties,

    (b) the risk to humans and animals,

(c) the risk to the environment,

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

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

20. The information provided on the biocidal product family shall permit the evaluating body to reach a decision on whether all the products within the biocidal product family comply with the criteria under Article 18(1)(b).

21. The technical equivalence with reference to active substances already included in the list of approved substances, shall be established for every active substance contained in the product where relevant.

Effects on human and animal health

Effects on human health

22. 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.

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

– acute toxicity,

– irritation,

– corrosivity,

– sensitisation,

– repeated dose toxicity,

– mutagenicity,

– carcinogenicity,

– reproductive toxicity,

– neurotoxicity,

– immunotoxicity,

– disruption of the endocrine system,

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

– other effects due to physico-chemical properties.

24. The populations previously mentioned are:

– professional users,

– non-professional users,

– humans exposed directly or indirectly via the environment.

In considering these populations, particular attention should be given to the need to protect vulnerable groups within these populations.

25. 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.

26. The evaluating body shall apply points 27 to 30 when carrying out a dose (concentration) - response (effect) assessment on an active substance or a substance of concern present in a biocidal product.

27. 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, NOAEL identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified. Where appropriate, other dose-effect descriptors may be used as reference values.

28. 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 LD_{50} (median lethal dose) or LC_{50} (median lethal concentration) value or another appropriate dose-effect descriptor 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.

29. For mutagenicity and carcinogenicity, a non-threshold assessment should be carried out if the active substance or substance of concern is genotoxic and carcinogenic. If the active substance or a substance of concern is not genotoxic a threshold assessment shall be carried out.

30. 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, particularly 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 as a result of the use of the biocidal product.

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

32. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed directly or indirectly via the environment), for which exposure to a biocidal product occurs or can reasonably be foreseen with particular attention paid to the pathways of exposure relevant for vulnerable groups. 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, including relevant metabolites and degradation products to which a population is, or may be exposed during use of the biocidal product and articles treated with that product.

33. The exposure assessment shall be based on the information in the technical dossier provided in conformity with Article 6 and Article 20 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,

– Maximum Residue Levels,

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

34. When conducting the exposure assessment special consideration shall be given to adequately measured, representative exposure data if such data are available. 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.

35. Where, for any of the effects set out in point 23 a reference value has been identified, the risk characterisation shall entail comparison of the reference value with the evaluation of the dose/concentration to which the population will be exposed. Where a reference value cannot be established a qualitative approach shall be used.

Assessment factors account for the extrapolation from animal toxicity to the exposed human population. The setting of an overall assessment factor considers the degree of uncertainty in inter-species and intra-species extrapolation. In the absence of suitable chemical specific data, a default assessment factor of 100 is applied to the relevant reference value. Additional elements can also be considered for assessment factors, toxicokinetics and toxicodynamics, the nature and severity of the effect, human (sub-) populations, exposure deviations between study results and human exposure with regard to frequency and duration, study duration extrapolation (e.g. sub-chronic to chronic), dose-response relationship and the overall quality of the toxicity data package.

Effects on animal health

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

Effects on the Environment

37. 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.

38. 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.

39. A dose (concentration) - response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as PNEC. However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) - response (effect) then has to be made.

40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Article 6 and Article 19. It shall be calculated by applying an assessment factor to the reference values resulting from tests on organisms, e.g. LD_{50} (median lethal dose), LC_{50} (median lethal concentration), EC_{50} (median effective concentration), IC_{50} (concentration causing 50 % inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)). Where appropriate, other dose-effect descriptors may be used as reference values.

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

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

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

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

– adequately measured exposure data,

– the form in which the product is marketed,

– the type of biocidal product,

– the application method and application rate,

– the physico-chemical properties,

– breakdown/transformation products,

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

– the frequency and duration of exposure,

– long range environmental transportation.

45. When conducting the exposure assessment special consideration shall be given to adequately measured, representative exposure data if such data are available. 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 34. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.

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

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

Effects on Target Organisms

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

49. The evaluating body shall, where relevant, evaluate the possibility of the development of resistance or cross-resistance to an active substance in the biocidal product by the target organism.

Efficacy

50. Data submitted by the applicant shall be sufficient to substantiate the efficacy claims for the product. Data submitted by the applicant or held by the evaluating body 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 (if accepted by the evaluating body)

– individual producer standard method (if accepted by the evaluating body)

– data from the actual development of the biocidal product (if accepted by the evaluating body).

Summary

52. In each of the areas where risk assessments have been carried out, the evaluating body 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 shall also take account of any cumulative or synergistic effects.

53. For biocidal product containing more than one active substance any adverse effects shall also be considered together to produce an overall assessment for the biocidal product itself.

CONCLUSIONS

General principles

54. The purpose of the evaluation is to establish whether or not the product complies with the criteria set down in point (b) of Article 18(1). The evaluating body shall reach its conclusion 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 based on the assessment carried out in accordance with points 13 to 53 of this Annex.

55. In establishing compliance with the criteria set out in point (b) of Article 18(1) the evaluating body 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) that the biocidal product complies with the criteria;

(2) that subject to specific conditions/restrictions the biocidal product can comply with the criteria;

(3) that it is not possible, without additional data, to establish if the biocidal product complies with the criteria;

(4) that the biocidal product does not comply with the criteria.

56. The evaluating body shall, when seeking to establish whether a biocidal product complies with the criteria in point (b) of Article 18(1), take into account uncertainty arising from the variability in the data used in the evaluation process.

57. If the conclusion arrived at by the evaluating body is that additional information or data are required, then the evaluating body shall justify the need for any such information or data. This additional information or data shall be the minimum necessary to carry out a further appropriate risk assessment.

Effects on human and animal health

Effects on human health

58. The evaluating body shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environment. In reaching these conclusions particular attention shall be paid to vulnerable groups among the different populations.

59. The evaluating body shall examine the relationship between exposure and effect. 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 under consideration. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, immunotoxicity, reproductive toxicity, disruption of the endocrine system together with physico-chemical properties, and any other adverse properties of the active substance or substance of concern, or of their relevant metabolites or degradation products.

60. Typically the margin of exposure (MOE_{ref}) – the ratio between the dose descriptor and the exposure concentration - is in the region of 100 but a MOE_{ref} that is higher or lower than this may also be appropriate depending on, among other things, the nature of the critical effects and the sensitivity of the population.

61. The evaluating body shall, if appropriate, conclude that criterion (iii) under point (b) of Article 18(1) can only be complied with by application of prevention and protection measures including the design of work processes, engineering controls, use of adequate equipment and materials, application of collective protection measures and where exposure cannot be prevented by other means application of individual protection measures including the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles in order to reduce exposure for professional operators.

62. If for non-professional users the wearing of personal protective equipment would be the only possible method for reducing exposure to an acceptable level for this population the product shall not normally be considered as complying with criterion (iii) under point (b) of Article 18(1) for this population.

Effects on animal health

63. Using the same relevant criteria as described in the section dealing with effects on human health, the evaluating body shall consider whether criterion (iii) under point (b) of Article 18(1) is complied with for animal health.

Effects on the Environment

64. 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.

65. 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 evaluating body 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 appropriate risk reduction measures are necessary or if the biocidal product cannot comply with criterion (iv) under point (b) of Article 18(1).

Water

66. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) 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 organisms in the aquatic, marine or estuarine environment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

67. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) 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 Directive 98/83/EC; or

– the maximum concentration as laid down following the procedure for approving the active substance under 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.

68. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) if the foreseeable concentration of the active substance or a substance of concern or of relevant metabolites, breakdown or reaction products to be expected in surface water or its sediments after use of the biocidal product under the proposed conditions of use:

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

  – Directive 2000/60/EC,

  – Directive 98/83/EC, or

– has an impact deemed unacceptable on non-target organisms,

unless it is scientifically demonstrated that under relevant field conditions this concentration is not exceeded.

69. The proposed instructions for use of the biocidal product, including procedures for cleaning application equipment, must be such that, if followed, they minimise the likelihood of accidental contamination of water or its sediments.

Soil

70. Where contamination of soil is likely to occur, the evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) if the active substance or substance of concern contained in the product, after use of the biocidal product:

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

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

– 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

71. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) of point (b) of Article 18(1) where there is a reasonably foreseeable possibility of unacceptable effects on the air compartment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Non-target organisms

72. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) where there is a reasonably foreseeable possibility of non-target organisms being exposed to the biocidal product, and 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.

73. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) where there is a reasonably foreseeable possibility of aquatic organisms including marine and estuarine organisms being exposed to the biocidal product, and 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

– BCF is greater than 1000 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.

74. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) 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.

Effects on Target Organisms

75. If the development of resistance or cross resistance to the active substance in the biocidal product is likely, the evaluating body shall consider actions to minimise the consequences of this resistance. This may involve modification of the conditions under which an authorisation is given. However, if the development of resistance or cross-resistance cannot be reduced sufficiently, the evaluating authority shall conclude that the biocidal product does not satisfy criterion (ii) under point (b) of Article 18(1).

76. A biocidal product intended to control vertebrates shall not normally be regarded as satisfying criterion (ii) under point (b) of Article 18(1) 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

77. 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. The evaluating body shall evaluate dose-response data generated in appropriate 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

78. In relation to the criteria set out in points (iii) and (iv) of Article 18(1)(b), the evaluating body shall combine the conclusions arrived at for the active substance(s) and the substances of concern to produce overall summary conclusions for the biocidal product itself. A summary of the conclusions in relation to the criteria set out in points (i) and (ii) of Article 18(1)(b) shall also be made.

OVERALL INTEGRATION OF CONCLUSIONS

The evaluating body shall, on the basis of the evaluation carried out in accordance with the principles set down in this Annex, come to a conclusion as to whether or not it is established that the biocidal product complies with the criteria laid down under point (b) of Article 18(1).

ANNEX VII

CORRELATION TABLE*

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* The correlation table has not been updated to reflect the changes to the Commission's original proposal.

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