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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 12.6.2009
COM(2009) 267 final

2009/0076 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

concerning the placing on the market and use of biocidal products

(Text with EEA relevance)

{SEC(2009) 773}
{SEC(2009) 774}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Grounds for and objectives of the proposal

Directive 98/8/EC of the European Parliament and the Council of 16 February 1998 concerning the placing of biocidal products on the market (hereinafter 'the Directive') establishes a harmonised regulatory framework for the authorisation and the placing on the market of biocidal products, the mutual recognition of these authorisations within the Community and the establishment at Community level of a positive list of active substances that may be used in biocidal products. In its Article 18(5), the Directive requires the Commission to draw up a report seven years after its entry into force and to submit the report to the Council. The report shall address the implementation of the Directive and the functioning up to that date of the simplified procedures (frame formulations, low-risk biocidal products and commodity substances). In accordance with the same provision, the Commission may accompany its report, if necessary, by proposals for amendment of the Directive.

The Commission submitted the report on 8 October 2008 (COM(2008)620) and proposed at this occasion to extend the review programme, the transitional period, and certain provisions on data protection that accompany this period for an additional three years.

Further to the proposal already presented, and based on the conclusions of the 'seven years' report, the present proposal for revision of Directive 98/8/EC aims to tackle the identified weaknesses of the regulatory framework during the first eight years of its implementation, to improve and update certain elements of the system and to avoid problems anticipated in the future.

1.2. General context

The review of the implementation of the Directive has indicated that for the evaluation of active substances, the simplified procedures provided for in the Directive, notably for low-risk products (Annex IA to the Directive), have no real effect, and that in addition the data requirements and data waiving provisions may be unclear or inconsistently applied or lead to a disproportionate burden in some circumstances.

In addition, although product authorisation has not yet started, simplification of the procedures concerning the authorisation of biocidal products in the Member States may be beneficial in reducing costs and administrative burden for companies and public authorities alike. The proposal is seeking to improve the existing regulatory framework, without reducing the high level of protection for the environment and human and animal health.

The proposal also intends to simplify the data protection rules, to avoid duplicating vertebrate animal studies through mandatory data-sharing, increase harmonisation of fees systems in the Member States, establish rules for parallel trade of biocidal products, and cover articles or materials treated with biocidal products.

1.3. Existing provisions in the area of the proposal

The current regulatory framework for biocidal products is established by Directive 98/8/EC of the European Parliament and the Council of 16 February 1998 concerning the placing of biocidal products on the market and a number of implementing Commission Regulations, in particular Commission Regulation (EC) No 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. .

1.4. Consistency with the other policies and objectives of the Union

The proposal to revise the Directive takes into consideration the recent revision of EU legislation on Chemicals with the adoption of Regulation (EC) No 1907/2006 (REACH) as well as Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Due note is also taken of changes in horizontal legislation that affect the biocides regulatory framework, such as those related to the procedures for the exercise of implementing powers conferred on the Commission (recent amendment of Decision 1999/468/EC). Furthermore, it also takes into consideration the general rules and the obligations for Member States under Regulation (EC) No 765/2008 organising the market surveillance relating to the marketing of products.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

2.1. Consultation of interested parties

2.1.1. Consultation methods, main sectors targeted and general profile of respondents

1. A first consultation workshop was held on 21-22 January 2008 in Ljubljana under the auspices of the Slovenian Presidency of the EU. The objective of this workshop was to allow a first informal exchange of views between Member States and Commission representatives on issues to be addressed in the revision of the Directive. An outline of these issues is available at: <http://ec.europa.eu/environment/biocides/workshop.htm>
2. An additional discussion was organised in Bonn on 7-8 April 2008 gathering more than 140 representatives of industry, NGOs and competent authorities. Participants debated about the need to streamline the scope of the Directive, among others by clarifying border cases and product-types definition, about the product authorisation (e.g. frame formulation, central versus mutual recognition), about data protection rules, as well as simplified or more flexible data requirements approach.
3. A wider consultation of stakeholders was organised through a conference hosted by the Commission in Brussels on 23 May 2008 with the participation of representatives from different sectors of the biocides industry, individual companies, consultants and national governments. After the participants were informed about the key issues for the revision (presentations given by Commission officers) they had the opportunity to comment and debate specific issues of interest.

4. A targeted stakeholder consultation was also carried out in the framework of a study in preparation of the impact assessment for the revision of the Directive. The consultation involved interviews with representatives of the industry (including small and medium-sized enterprises), national administrations/controlling bodies, environmental protection and consumers' associations and others, based on questionnaires that were previously sent to these stakeholders to prepare the discussions.

2.1.2. *Summary of responses and how they have been taken into account*

1. The consultation conference in Ljubljana (Commission & Member States) and the succeeding conference in Bonn (Member States & Industry) focused on numerous topics of interest for the revision, the most prominent of those being:
 - the revision of the data protection provisions and (mandatory) data-sharing;
 - the scope of the regulatory framework (to include or not the use phase; to add provisions about *in-situ* generated substances and active substance precursors; the relationship with other pieces of Community legislation; reduction or not of the number of product-types; definition of a biocidal product and definition of placing on the market; how to regulate articles/materials containing biocides);
 - the lack of harmonised provisions in the current Directive regarding product authorisation or the procedure to follow after the inclusion of an active substance in the Community positive list;
 - the possibility to have a single Community authorisation for biocidal products; the role of a centralised Agency for biocides; effectiveness of implementation and enforcement at Member State level;
 - how to facilitate the (future) mutual recognition procedure;
 - the harmonisation and proportionality of fees charged by Member States, and ways to alleviate the financial burden of compliance for SMEs;
 - the performance so far of the Directive's simplified procedures (Annex IA; Annex IB; prospects for frame formulation concept);
 - the need to clarify the possibility for waiving data requirements; the use in the new instrument of data-waiving provisions from the REACH Regulation; the establishment of a tiered system of data requirements (as was the original idea when the Directive was adopted);
 - specific rules for low-volume or 'niche' market biocides;
 - the need to develop harmonised efficacy requirements.

Finally, the appropriateness of adopting specific provisions on parallel trade; and the pros and cons of turning the Directive into a Regulation were also discussed. The Commission has taken into consideration all the - sometimes conflicting - opinions expressed by the Member States in the development of its proposal, while trying to

identify the best elements amongst them that would contribute to a coherent and workable regulatory framework.

2. During the consultation event in May 2008 in Brussels (participation of various stakeholders, mostly industry and enterprises' representatives), the participants had a chance to express their opinions on simplified procedures; data requirements; data protection and data-sharing; the procedure for biocidal product authorisation; the fees applied by Member States and articles or materials containing biocides.

In general (although many varying opinions were voiced), the simplified procedures of Annex IA and Annex IB were considered a failure; the frame formulation procedure has not been tried yet but there seems to be some confusion as to how it would work and different expectations as to what it would offer; the data requirements are seen as particularly strict and in some cases as non-proportionate or inflexible; the data protection system could be further clarified and simplified, and certain elements of it should be amended; the industry seems to have come to terms with introducing mandatory sharing of vertebrate animal studies; providing for harmonised authorisation procedures is seen as a plus by the industry, and even better if a centralised procedure were adopted; the fees or at least the fee systems will need to be harmonised; and a solution should be found for articles or materials that are containing biocidal products, in particular those articles or materials imported from third countries. All these concerns were taken into consideration and are reflected in the proposal.

3. The targeted consultation served mostly the purpose of obtaining the necessary quantitative/qualitative information for preparing the impact assessment report presented in support to this proposal. It covered all the issues discussed with the Member States in Ljubljana, in Bonn and with the stakeholders in Brussels and the responses were mostly the same with those expressed in the three consultation events.

An open consultation was conducted over the internet from 15/11/2006 to 15/01/2007. The Commission received 250 response(s). The results of the open internet consultation were incorporated in the Commission report on the impacts of the implementation of Directive 98/8/EC available at: <http://ec.europa.eu/environment/biocides/study.htm> .

2.2. Collection and use of expertise

To support this proposal, several studies were carried out by external contractors:

- a study to assess the impact of the revision of Directive 98/8/EC concerning the placing of biocidal products on the market;
- a study on impacts of possible measures to manage articles or materials treated with biocides, in particular when imported;
- a study on the impacts of the implementation of Directive 98/8/EC on biocidal products; and

- a study on the assessment of different options to address risks from the use phase of biocides.

These studies were evaluated by the Commission and taken into consideration while preparing the current proposal. In particular, the study to assess the impact of the revision of Directive 98/8/EC concerning the placing of biocidal products on the market evaluated the economic, social and environmental impacts of the different policy options. The conclusions of this study are directly reflected in the impact assessment described in the following section.

More information on the studies is available at:
<http://ec.europa.eu/environment/biocides/study.htm> and
<http://ec.europa.eu/environment/biocides/revision.htm>.

2.3. Impact assessment

The Impact Assessment addresses five policy issues that require action:

POLICY ISSUE 1: SCOPE

- Unchanged policy;
- Extend scope to cover processing aids and food contact materials;
- Extend scope to cover treated materials containing biocides.

The assessment concluded that including materials containing biocides in the scope of the Directive would significantly increase the costs to industry. However, although the equal treatment of industry, and environmental and human health benefits are difficult to quantify, they are likely to be significant. Including, in particular food processing aids in the scope of the Directive is likely to result in a complicated process of authorisation under two legal frameworks which may lead to some duplication of efforts. The related costs are likely to outweigh the limited benefits resulting from better control of environmental impacts and greater regulatory certainty.

POLICY ISSUE 2: PRODUCT AUTHORISATION

- Unchanged policy;
- Strengthening of mutual recognition;
- Single Member State authorisation;
- Community authorisation.

The assessment concluded that a Community authorisation or a single Member State authorisation would be the most efficient systems and would provide incentives for innovation of products based on new active substances/low-risk products. However, as the Member States have expressed significant concerns about a full centralisation of the product authorisation or a single Member State authorisation due to reduced role for the other Member States, a combination of the Community authorisation for certain products with the strengthening of the mutual recognition process for other products appears to be the most acceptable solution.

POLICY ISSUE 3: DATA-SHARING

- Unchanged policy;
- Mandatory sharing of vertebrate animal test data for product authorisation;
- Mandatory sharing of vertebrate animal test data for active substance approval and for product authorisation.

The assessment concluded that mandatory data-sharing for active substance approval and for product authorisation implies the highest total cost savings to applicants, possibly the highest number of safer products remaining on the market and the highest number of animals saved.

POLICY ISSUE 4: DATA REQUIREMENTS

- Unchanged policy;
- Rewording provisions concerning data waiving and the use of existing information;
- Reformulating the system for low-risk substances/products.

The policy options address two types of problems: high data requirements and low attractiveness of the simplified procedures, in particular for low-risk and basic substances. The assessment concluded that all the options have significant potential to reduce costs for industry and that the last two options would also significantly reduce the numbers of vertebrate animal tests. In order to meet the objectives of the revision, the best option seems to be a combination of data waiving with the use of existing information and a new approach to low-risk biocidal products.

POLICY ISSUE 5: FEES CHARGED BY MEMBER STATES FOR CARRYING OUT THE PROCEDURES OF THE DIRECTIVE

- Unchanged policy;
- Partially harmonised fee structure;
- Centralised fee system;
- Specific provisions for SMEs.

The assessment concluded that a partially harmonised fee structure may encourage the development of more new active substances and the retention of more existing active substances. It should also reduce the costs for the approval of active substances for several product types. The last option will make the procedure less costly for SMEs, which should help them to stay on the market. A fully centralised fee system would raise questions concerning the subsidiarity principle as it would transfer the competences over setting the levels of fees from the Member States to the Community.

The Commission carried out an impact assessment which is attached to this proposal.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Summary of the proposed action

The revision of the Biocides Directive intends to remedy a number of weaknesses that were identified during the first eight years of its implementation, to anticipate problems with the upcoming authorisation and mutual recognition procedure, and to update and adapt the instrument to recent policy developments.

First, the Directive is turned into a Regulation. As a result, there will be no need for a transposition period or for national transposition measures, which is also expected to ensure more harmonised implementation of the regulatory framework in the Member States.

Among the proposed amendments of the scope, particularly relevant are the extension of the scope to biocides in materials that might come into contact with food and the new provisions on articles or materials containing biocidal products.

In particular with regard to the latter, under the current situation, if an article is treated in the EU then only a biocidal product that is authorised for that purpose may be used. However, if the article is treated with a biocidal product outside the EU and then imported, there is no control over the substance it may incorporate. This could represent risks for human health or for the environment if active substances that are not assessed or even banned in the EU are incorporated in such goods which are then imported into the EU. In addition, this situation is discriminatory to the EU industry, and could lead to the production of treated articles or materials being moved out of the EU in order to circumvent restrictions on certain substances. As part of the revision of the Biocides Directive, it is proposed that all articles or materials must be treated only with biocidal products authorised for that purpose in at least one Member State.

Labelling requirements are accompanying the provision on articles or materials treated with biocides. These have two objectives: to inform consumers that the article was treated with a biocidal product; and to alert competent and/or customs authorities in the Member States and trigger any existing inspection provisions aimed at ensuring compliance. The labelling provisions apply equally to EU and non EU manufacturers.

The proposed Regulation provides also for harmonised procedures for the authorisation of biocidal products, an element that is significantly underdeveloped in the current Directive. The provisions regarding mutual recognition of authorisations are reworked and clarified, in particular the resolution of disputes between Member States, or between Member States and applicants. This is expected to contribute to a smooth functioning of the upcoming authorisations of biocidal products.

Apart from the case of authorisations granted by the Member States, a centralised authorisation system is proposed. This will be available for products identified as low-risk - without having to go through a separate evaluation of the active substance first- and for products containing new active substances. The latter is expected to promote research and innovation in the biocides field.

The technical and scientific tasks relevant to this centralised system will be carried out by the European Chemicals Agency (ECHA). To this end, the proposal incorporates the necessary provisions governing the procedural and organisational details. In addition, ECHA will

undertake the coordination of organisational and technical tasks for the evaluation of all applications for inclusion of active substances in Annex I (the Community positive list for active substances) which were until now attributed to the Commission Joint Research Centre.

The simplified procedures involving the current Annex IA and IB are repealed, as very little or no use of them has been made so far. The simplified procedure involving frame formulations - which has not yet been put into practice - is modified so as to allow, within a group of products belonging to the same frame formulation, the replacement of any non-active ingredient by other non-active ingredients. Currently, this is restricted to pigments, dyes, and perfumes. The Regulation will also incorporate rules governing the modalities and conditions to apply for modifications to authorisations that are already granted.

The rules on comparative assessment are also modified, as the current system does not seem sufficiently clear - for instance, it is rather problematic to apply comparative assessment during the review programme, where all existing substances are being evaluated. The proposed system comprises a first stage where active substances that even though overall acceptable still give rise to concern are listed in Annex I, but are also flagged for substitution. Biocidal products containing these active substances may be compared with others that are available on the market for the same or similar use pattern, and if they present significantly higher risk than those, their authorisations are refused or cancelled at Member State level.

In line with recent policy developments in REACH and the draft Regulation on the placing of plant protection products on the market, sharing of vertebrate animal studies in exchange for equitable compensation becomes mandatory. This is expected to save costs and animal lives by prohibiting the duplication of these studies.

The data protection system is significantly simplified, without cutting back on any acquired rights under the current system. It also grants protection to data submitted after the inclusion of the active substance in Annex I (mainly during product authorisation): these studies are not protected by the current legislation. The proposed data protection system also covers the case of newly generated studies that, contrary to the legislator's intention, do not benefit from data protection because certain Member States required their submission for the purposes of national authorisation during the transitional period (only data submitted for the first time in support of the first inclusion of the active substance are protected by the current system).

The data requirements of the Directive are modified. First, the principle of proposing and accepting adaptations to the data requirements is formalised and Member States have to inform and if possible assist the applicants with their adaptation requests. Second, the grounds for data waiving provided for in REACH will apply also for the proposed Regulation. Third, the core data requirements are modified and certain long-term animal studies are only required when necessary - these happen to be the most costly data requirements, in terms of lives of test animals and in terms of money.

The confidentiality provisions are slightly modified and aligned with those of REACH. This is to facilitate their application by ECHA, which would otherwise have to apply two different sets of confidentiality rules in its everyday operations.

For the purpose of facilitating the movement of biocidal products in the EU territory, the proposal provides for specific parallel trade rules: authorised biocidal products that have the same use, contain the same active substance and have essentially identical composition to

products authorised in another Member State may be placed on the market of that other Member State via a simplified administrative procedure.

Finally, the proposal provides for a number of transitional measures to facilitate the transition from the system of the Directive to that of the draft Regulation, to introduce ECHA into the biocides regulatory framework, and to safeguard any acquired rights under the current system.

3.2. Legal basis

Article 95 of TEC.

3.3. Subsidiarity principle

The purpose of this Regulation is to facilitate the free movement of biocidal products within the Community. In order to ensure the functioning of the internal market with biocidal products, it is necessary to harmonise the conditions of their placing on the market at the level of the Community.

Individual measures of Member States stemming from the different levels of protection could result in obstacles to trade in biocidal products. This could compromise the achievement of objectives related to the internal market. The Community is, therefore, better placed to take action with regards to the conditions of placing on the market and use of biocidal products.

The subsidiarity principle was also closely considered when deciding on the distribution of tasks between the competent authorities of Member States, the Agency and the Commission, in particular with respect to the authorisation of biocidal products.

3.4. Proportionality principle

The proposal complies with the proportionality principle for the following reason(s).

The proposed Regulation aims to harmonise the conditions for placing biocidal products on the market but with respect to the majority of biocidal products it leaves it to the Member States to authorise these products in accordance with these conditions. The centralised procedure in which the Commission grants a Community authorisation will be restricted to two categories of biocidal products: products based on new active substances and low-risk biocidal products. For these categories of biocidal products centralisation is justified because of its positive impact on innovation and instant access to the entire Community market.

The proportionality principle was also respected with respect to the fees. The Commission will adopt another Regulation setting out a harmonised structure for fees but the decision on the amount of the fees will remain within the competence of the Member States.

Furthermore, the proposed Regulation does not go further than what is necessary with respect to its scope and the administrative burden on the industry as well as the competent authorities. In fact, the administrative and financial burden on the industry and the competent authorities will be reduced compared to Directive 98/8/EC because of the following reasons:

- the provision of strict deadlines for each procedural step will increase the predictability and facilitate the access of biocidal products to the market;

- the centralised authorisation will save time and costs for both the industry and competent authorities;
- the possibility of a mutual recognition in parallel will provide for a closer cooperation among the Member States concerning the evaluation of a biocidal product while saving financial and human resources;
- the mandatory data sharing with respect to vertebrate animal data will save the costs for the industry and avoid repeated evaluating of the same data by the competent authorities.

3.5. Choice of instruments

Proposed instruments: Regulation.

Other means would not be adequate for the following reason(s).

The current regulatory framework for the placing on the market of biocidal products is Directive 98/8/EC. The Commission - in line with recent proposals concerning the plant protection products legislation and general chemicals legislation (the REACH Regulation and the Regulation on classification, labelling and packaging of substances and mixtures) - is proposing to replace that Directive with a Regulation. This will eliminate the need for a transitional period and will advance the implementation of urgently needed provisions by approximately two years. A Regulation will also ensure the uniform application of the new instrument throughout the EU, in particular the procedures and deadlines for authorisation of biocidal products and mutual recognition of those authorisations. Differences in the transposition of measures and/or the implementation would have very serious consequences for the functioning of the internal market in biocidal products.

The choice of the legal instrument will also reduce the administrative burden and ensure the clarity for the industry.

4. BUDGETARY IMPLICATION

The proposal will have budgetary implications as there is a need to support the European Chemicals Agency (the Agency) in taking up the additional tasks related to the assessment and inclusion of active substances used in biocidal products in Annex I of the Regulation and the centralised authorisation of certain biocidal products. The Agency will receive specific fees from applicants for certain of these activities as well as an annual fee on products centrally authorised by the Community. The revenue from the fees will have to be supplemented by a subsidy from the Community. It is, however, expected that this support from the Community will be limited in time as the activities of the Agency should be self-funding through fee revenues after a number of years. Detailed rules on the budget of the Agency and its implementation are already laid down in REACH Regulation (EC) No. 1907/2006. These rules shall apply accordingly in the context of this Regulation.

5. ADDITIONAL INFORMATION

5.1. Simplification

The proposal provides for simplification of legislation, simplification of administrative procedures for public authorities (EU or national), and for private parties.

Apart from the obvious economy of dispensing with transposition measures, transposition periods and transposition conformity controls that is achieved by replacing the current Directive with a Regulation, the proposal clarifies in much greater detail than in the present text the procedures to be followed for granting authorisations by the Member States and the procedures for mutual recognition of those authorisations.

In particular, the acceptable grounds for opposing mutual recognition are made clear and procedural steps are provided for the resolution of disputes.

In addition, the grounds for waiving data requirements are set out in more detail, enhancing legal certainty for the applicants. In the current system, while the principle of waiving data requirements is recognised, little is provided as conditions for implementing the principle. As a result, Member States are sometimes reluctant to allow that certain studies listed in the core data set need not be submitted by the applicant as the safety of a substance is sufficiently established by other available information.

The data protection provisions are simplified and better aligned with the objectives of the Community policy (recovery of costs - protection for newly generated data).

Lastly, the establishment of a centralised system for the authorisation of certain products is an obvious simplification as the products concerned will not need individual authorisation in all or some of the 27 Member States.

The Member States competent authorities will have a more harmonised framework for granting authorisations (e.g. harmonised content of an authorisation document). They will also have specific deadlines and procedures for all the tasks related to authorisation and mutual recognition.

With the handling of the procedure for the evaluation of active substances by ECHA there will be greater transparency, co-ordination and efficiency of the process compared to the current system. This will among others avoid the same active substance being evaluated in parallel by two different Member States.

The proposal foresees that Member States will have a common structure on the basis of which they can rationally develop their fees' systems.

Enterprises supporting the placing on the market of a low-risk product or a product containing a new active substance will be able to obtain only one (Community) authorisation valid for the whole EU territory. Consequently, the Member States will not need to carry out an evaluation as those products will be approved via centralised authorisations. There will also be no need for mutual recognition or multiple provisional authorisation procedures for these products, as those will be handled at Community level by ECHA.

Enterprises will now have to consult only one legal text that applies in the EU instead of 27 national transposition instruments.

Authorisation and mutual recognition procedures are better defined and predictable and specific deadlines are added.

The legal certainty is increased with regard to the protection afforded to studies submitted in support of an application.

The proposal is included in the Commission's rolling programme for up-date and simplification of the *acquis communautaire* and its Work and Legislative Programme under the reference COM(2007) 640.

5.2. Repeal of existing legislation

The adoption of the proposal will lead to the repeal of existing legislation, in particular Directive 98/8/EC.

5.3. Review/revision/sunset clause

The proposal includes a review clause.

5.4. Recasting

The proposal does not involve recasting.

5.5. European Economic Area

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

concerning the placing 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 establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Having regard to the opinion of the Committee of the Regions³,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁴,

Whereas:

- (1) Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured products. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patterns.
- (2) Biocidal products should not be placed on the market or used unless they comply with the authorisation granted in accordance with this Regulation.
- (3) The purpose of this Regulation is to increase the free movement of biocidal products within the Community. In order to remove as far as possible obstacles to trade in biocidal products stemming from the different levels of protection in the Member States, harmonised rules should be laid down for the approval of active substances and the placing on the market and use of biocidal products, including the rules on the mutual recognition of authorisations and on parallel trade.
- (4) Rules concerning the placing on the market of biocidal products in the Community were initially adopted in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the

¹ OJ C , , p. .

² OJ C , , p. .

³ OJ C , , p. .

⁴ OJ C , , p. .

market⁵. It is necessary to adapt that system on the basis of a report on the first seven years of its implementation submitted by the Commission to the European Parliament and the Council⁶, which analyses problems and weaknesses of that Directive.

- (5) Taking into account the main adaptations which are introduced in the existing regulatory system, a Regulation is the appropriate legal instrument to replace Directive 98/8/EC as it imposes clear and detailed rules which do not give room for diverging transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Community.
- (6) A difference should be made between existing active substances which were on the market in biocidal products on 14 May 2000 and new active substances which were not yet on the market in biocidal products by this date. That date was initially set in Directive 98/8/EC as the date by which that Directive had to be transposed into national legislation. That date made a difference between substances which were on the market on that date and those which were not. A work programme is carried out for the review of all existing substances with view to their inclusion in Annex I to Directive 98/8/EC. During that review, biocidal products containing existing substances can continue being placed on the market in order to prevent a situation where no biocidal products would be available on the market. New active substances should be reviewed before biocidal products containing them could be placed on the market so as to ensure that only safe new products could be placed on the market.
- (7) During the work programme, and at most up until the decision on inclusion of the active substance in Annex I to Directive 98/8/EC, Member States may temporarily authorise biocidal products not complying with the provisions of this Regulation under certain conditions. Following the decision on inclusion, Member States should grant, cancel or modify authorisations in accordance with this Regulation.
- (8) In order to ensure legal certainty, it is necessary to establish a Community list of active substances permitted for use in biocidal products. A procedure should be laid down for assessing whether or not an active substance can be entered in the Community list. The information that interested parties should submit in support of an inclusion of an active substance in the Community list should be specified.
- (9) The risks associated with the production, use and disposal of a chemically active substance and materials and articles treated with it are to be assessed and managed in a similar way as they are in Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC⁷.
- (10) With view to achieving a high level of environmental and human health protection, active substances with the worst hazard profiles should not be approved for use in

⁵ OJ L 123, 24. 04. 1998, p.1.

⁶ COM(2008)620

⁷ OJ L 396, 30.12.2006, p. 1

biocidal products except in specific situations. These should include situations when the approval is justified because of a negligible exposure of humans to the substance, public health reasons or disproportionate negative impacts of a possible non-inclusion provided no alternatives exist.

- (11) In order to prevent the use of active substances with the worst hazard profiles, in particular when their use is not authorised under Regulation (EC) No XXX/2009 of the European Parliament and of the Council of 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC⁸, it is appropriate to restrict their approval to situations when the exposure of humans to the substance is negligible or the substance is necessary for public health reasons.
- (12) The active substances in the Community list should be regularly examined to take account of developments in science and technology. Where there are serious indications that an active substance used in biocidal products may pose higher risk than previously thought, the Commission should be able to review an inclusion of the active substance.
- (13) Active substances can, on basis of their intrinsic hazardous properties, be designated as candidates for substitution with other active substances, whenever such substances considered as efficient towards the targeted harmful organisms become available in sufficient variety to avoid the development of resistances amongst harmful organisms. In order to allow for a regular examination of substances identified as candidates for substitution, the inclusion period for these substances should not, even in the case of renewal, exceed ten years. Furthermore, the identification of substances which are considered as candidates for substitution should be considered as a first step of a comparative assessment.
- (14) In course of the authorisation or renewal of biocidal product authorisations, it should be possible to compare two or more biocidal products with regard to risks posed by them and benefits accrued through their use. As a result of such a comparative assessment, authorised biocidal products containing active substances indicated as candidates for substitution could be replaced with others that present significantly less risk to health or to the environment and where there are no significant adverse economic or practical impacts. Appropriate phase-out periods should be foreseen in such cases.
- (15) In order to avoid unnecessary administrative and financial burden for the industry as well as competent authorities, a full in-depth evaluation of an application to renew the inclusion of an active substance in the Community list or the authorisation should only be carried out if the competent authority that was responsible for the initial evaluation decides so on basis of the available information.
- (16) There is a need to ensure effective coordination and management of the technical, scientific and administrative aspects of this Regulation at Community level. The European Chemicals Agency set up under Regulation (EC) No 1907/2006 should carry out specified tasks with regard to the evaluation of active substances as well as

⁸ OJ L , , p. .

the authorisation of certain categories of biocidal products and related tasks in the Community territory. Consequently, a Biocidal Products Committee should be established within the Agency to carry out the tasks attributed to the European Chemicals Agency by this Regulation.

- (17) It is recognised that biocidal products intended to be used not only for purposes of this Regulation but also in connection with medical devices, such as disinfectants used for the disinfection of surfaces in hospitals as well as medical devices, may pose risks different from those covered by this Regulation. Therefore, it should be required that such biocidal products comply, in addition to the requirements laid down in this Regulation, with the relevant essential requirements of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices⁹, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices¹⁰ or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices¹¹.
- (18) As the costs of the application of this Regulation to food or feedingstuffs used for biocidal purposes would be disproportionate to the benefits thereof, food and feedingstuffs used for biocidal purposes should not be covered by this Regulation. Furthermore, the safety of food and feedingstuffs is subject to Community 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 safety¹².
- (19) Processing aids are covered by existing Community legislation in particular, Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption¹³ and Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹⁴. Therefore, it is appropriate to exclude them from the scope of this Regulation.
- (20) As products used for the preservation of food or feedstocks by the control of harmful organisms, previously covered by product type 20, are covered by Council Directive 89/107/EEC and Regulation (EC) No 1831/2003 of the European Parliament and of the Council, it is not appropriate to maintain this product type.
- (21) As the International Convention for the Control and Management of Ships' Ballast Water and Sediments provides for an effective assessment of the risks posed by ballast water management systems, the final approval and subsequent type approval of such systems should be considered equivalent to the product authorisation required under this Regulation.

⁹ OJ L 189, 20.7.1990, p. 17.

¹⁰ OJ L 169, 12.7.1993, p. 1.

¹¹ OJ L 331, 7.12.1998, p. 1.

¹² OJ L 31, 1.2.2002, p. 1

¹³ OJ L 40, 11.2.1989, p. 27

¹⁴ OJ L 268, 18.10.2003, p. 29

- (22) To take account of the specific nature of some biocidal products and the low level of risk associated with their proposed use, and to encourage the development of biocidal products containing new active substances, it is appropriate to provide for a Community authorisation of those products.
- (23) In order to ensure that only biocidal products that comply with the relevant provisions of this Regulation are placed on the market, biocidal products should be subject to authorisation either by competent authorities for placing on the market or use in a territory of a Member State, or a part of it, or by the Commission for placing on the market or use in the Community.
- (24) In order to facilitate access to the internal market and to avoid the additional costs and time involved in obtaining separate national authorisations in separate Member States, the Commission, taking into account the experience with the provisions on Community authorisations, may decide to extend the scope of the Community authorisation procedure to other biocidal products.
- (25) To ensure a harmonised application of the low-risk criteria by competent authorities, it is necessary to specify those criteria in the Regulation as far as possible. The criteria should be based on the hazard characteristics of the biocidal products and the exposure to the product associated with its use. The use of low-risk biocidal products should not lead to a high risk of developing resistance in target organisms.
- (26) In order to encourage the use of low-risk biocidal products with more favourable environmental or human health profile compared to other biocidal products, it should be allowed to authorise low-risk biocidal products without prior approval of the active substances contained therein.
- (27) In view of the provisions on low-risk biocidal products in this Regulation, it seems appropriate to exempt active substances contained in those products from the registration obligations under Regulation (EC) 1907/2006. This is, in particular, necessary because these substances do not fulfil the conditions in Article 15(2) of that Regulation.
- (28) It is necessary to provide common principles for the evaluation and authorisation of biocidal products to ensure a harmonised approach by competent authorities.
- (29) In order to evaluate the risks that would arise from the proposed uses of biocidal products, it is appropriate that the applicants submit dossiers which contain the necessary information. Defining a data set for active substances and for biocidal products in which they are contained is necessary so as to assist both the applicants seeking authorisation and competent authorities carrying out the evaluation to decide on the authorisation.
- (30) In the light of the diversity of both the active substances and the biocidal products, the data and test requirements should suit the individual circumstances and allow an overall risk assessment. Therefore, an applicant should be able to request adaptations of the data requirements, as appropriate, including the waiving of data requirements which are not necessary or impossible to submit in view of the nature or the proposed uses of the product. Applicants should provide the appropriate technical and scientific justification to support their requests.

- (31) In order to ensure that the applicant can effectively exercise his right to request an adaptation of the data requirements, the competent authorities should inform the applicant about this possibility and the grounds on which such request could be made. Furthermore, in order to facilitate the preparation of the request, in particular by small- and medium-sized enterprises (SMEs), the competent authority should assist the applicant, where possible, in preparing such a request.
- (32) In order to facilitate access to the market of biocidal products belonging to one group of products, it should be possible to authorise such groups of biocidal products with similar uses and allow for limited variations with regard to the reference biocidal product provided that those changes do not affect the level of the risk and the efficacy of the products.
- (33) When biocidal products are being authorised, it is necessary to ensure that, when properly used for the purpose intended, they are sufficiently effective and have no unacceptable effect on the target organisms such as resistance, and, in the case of vertebrate animals, unnecessary suffering and pain, and have, in the light of current scientific and technical knowledge, no unacceptable effect on the environment and on human or animal health. When deciding whether a biocidal product should be authorised, due consideration should be given to the benefits from its use.
- (34) In order to avoid duplication of the evaluation procedures and to ensure free movement of biocidal products, as well as of materials and articles treated with them, within the Community, procedures should be established to ensure that authorisations of products granted in one Member States are recognised in all other Member States.
- (35) Specific provisions should lay down procedures to ensure the smooth operation of mutual recognition of authorisations granted by Member States, and in particular the resolution of any disagreements without undue delay.
- (36) In order to enable Member States to co-operate in the evaluation of biocidal products and to facilitate the access of biocidal products to the market, it should be possible to launch the process of the mutual recognition together with the application for the first authorisation.
- (37) There is a need to provide for a dispute settlement mechanism at Community level to ensure an effective functioning of mutual recognition. If a competent authority refuses to mutually recognise an authorisation or proposes to restrict it, the Commission should be empowered to take a decision. In case of technical or scientific questions, the Commission may consult the Agency before preparing the decision.
- (38) While envisaging harmonised provisions for all biocidal product types, including those intended to control vertebrates, the actual use of such product types might give rise to concern. Therefore, Member States should be allowed to derogate from the principle of mutual recognition for biocidal products falling under certain particular types of biocides when intended to control particular kinds of vertebrates, in so far as such derogations are justified and do not jeopardise the purpose of this Regulation regarding an appropriate level of protection of the internal market.
- (39) In order to facilitate the functioning of the authorisation and mutual recognition procedures, it is appropriate to establish a system for the mutual exchange of

information and Member States, the Commission and the Agency should make available to each other on request the particulars and scientific documentation submitted in connection with applications for authorisation of biocidal products.

- (40) If the use of a biocidal product is in the interest of a Member State, but there is no applicant interested in the placing of the market of such product in the Member State, pest control bodies and other professional organisations should be allowed to apply for an authorisation. In the case they are granted an authorisation, they should possess the same rights and obligations as any other authorisation holder.
- (41) In order to take account of the scientific and technical developments as well as the needs of the authorisation holders, it should be specified under which conditions authorisations can be cancelled, reviewed or amended. Provisions on the notification and exchange of information which may affect the authorisations should be set out so as to enable the competent authorities and the Commission to take appropriate action.
- (42) In the event of an unforeseen danger threatening public health or the environment which cannot be contained by other means, it should be possible for Member States to authorise, for a limited period of time, biocidal products which do not comply with the requirements laid down in this Regulation.
- (43) In order to encourage the development of new active substances, the procedure for the evaluation of a newly developed active substance should not prevent Member States or the Community from authorising, for a limited period of time, biocidal products containing that active substance before the latter is entered in Annex I, provided that a dossier meeting all requirements has been submitted and it is believed that the active substance and the biocidal product satisfy the conditions set for them.
- (44) In order to encourage the research and development in active substances and biocidal products, it is necessary to establish rules under which unauthorised biocidal products or active substances may be placed on the market for the purposes of research and development.
- (45) In view of the benefits for the internal market and for the consumer, it is desirable to establish harmonised rules for parallel trade of substantially identical biocidal products that are authorised in different Member States.
- (46) For purposes of the protection of human and animal health and of the environment, as well as for the non-discrimination between articles or materials originating in the Community and articles or materials imported from third countries, all treated articles or materials placed on the internal market should contain only authorised biocidal products.
- (47) For the purpose of enabling consumers to make informed choices and facilitating the enforcement of this Regulation by competent authorities, articles or materials treated with biocidal products should be appropriately labelled.
- (48) Applicants that have invested in supporting the inclusion of an active substance in Annex I or in the authorisation of a biocidal product in accordance with the provisions of this Regulation 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 inclusions or authorisations is made for the benefit of subsequent applicants.

- (49) In view of ensuring that all proprietary information submitted in support of an inclusion of an active substance or an authorisation of a biocidal product is protected from the moment of its submission and to prevent situations where some information is without protection, the provision on information protection periods should also apply to information submitted for the purposes of Directive 98/8/EC.
- (50) In order to encourage the development of new active substances and biocidal products containing them, it is necessary to provide for a period of protection with respect to the proprietary information submitted in support of the inclusion of active substances or authorisations of products which is longer than the period of protection for information concerning existing active substances and products containing them.
- (51) It is essential to minimise the number of tests on animals and to ensure that testing should be made dependent on the purpose and use of a product. Applicants should share, and not duplicate, vertebrate animal studies in exchange for equitable compensation. In 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 the decision on the compensation made by national courts. A Community register listing the contact details of the owners of such studies should be established and put at the disposal of all authorities to inform prospective applicants.
- (52) 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.
- (53) In order to ensure that the requirements laid down in respect of authorised biocidal products are satisfied when they are placed on the market, the Member States should take measures for appropriate control and inspection arrangements.
- (54) It is necessary to provide for the effective communication of information on risks resulting from biocidal products and risk management measures as it forms an essential part of the system established by this Regulation. While facilitating access to information, competent authorities, the Agency and the Commission should respect the principle of confidentiality and avoid any disclosure of information which could be harmful for the commercial interests of the person concerned.
- (55) In order to increase the efficiency of monitoring and control, and to provide information relevant for addressing the risks of biocidal products, producers, importers and professional users should be required to keep records of the products they produce, place on the market or use. The Commission should adopt implementing rules on data collection, transmission and processing.
- (56) In order to facilitate the exchange of information between competent authorities, the Agency and the Commission, the Community Register for Biocidal Products should be established.

- (57) It is necessary to specify that provisions concerning the Agency laid down in Regulation (EC) No 1907/2006 should apply accordingly in the context of biocidal active substances and products. Where separate provisions need to be made with respect to the tasks and functioning of the Agency under this Regulation, it should be specified in the provisions of this Regulation.
- (58) The costs of the procedures associated with the operation of this Regulation need to be recovered from those seeking to place or placing biocidal products on the market and from those supporting the entries of active substances in Annex I. In order to promote the smooth operation of the internal market, the Commission should adopt measures to harmonise the structure of fee systems established by the Member States and the Agency taking into account the special needs of SMEs.
- (59) It is necessary to provide for the possibility of an appeal against certain decisions of the Agency. The Board of Appeal set up within the Agency by Regulation (EC) No 1907/2006 should also guarantee processing of appeals against decisions adopted by the Agency under this Regulation.
- (60) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission¹⁵.
- (61) In particular, the Commission should be empowered to adopt measures to decide on the application to include the active substance in Annex I or to renew or review the inclusion, to specify the procedures related to the renewal and review of an inclusion of an active substance in Annex I, to extend the provisions on Community authorisations to other categories of biocidal products, to specify the criteria and procedures related to a cancellation of an authorisation or amendments of the terms and conditions of an authorisation, including a dispute settlement mechanism, to specify the overall applicable maximum quantities of active substances or biocidal products that may be released during experiments and the minimum data to be submitted, to establish a harmonised structure of fees and other rules concerning the payment of fees and charges to the competent authorities and the Agency, to adapt the Annexes to scientific and technical progress, to carry out the work programme and to specify the related rights and obligations of the competent authorities and the participants in the programme and to extend the duration of the work programme for a determined period. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, inter alia, by supplementing this Regulation with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (62) When, on imperative grounds of urgency, the normal time limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of decisions to amend the inclusion of an active substance in Annex I or to remove it from that Annex on basis of Article 13.

¹⁵ OJ L 184, 17.7.1999, p. 23.

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

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Subject matter

This Regulation lays down rules for:

- (1) the placing on the market and use of biocidal products within the Member States or the Community;
- (2) the mutual recognition of authorisations within the Community;

- (3) the establishment at Community level of a list of active substances which may be used in biocidal products.

Article 2

Scope

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

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

2. This Regulation shall not apply to biocidal products that are within the scope of the following instruments:

- (a) Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products¹⁶;
- (b) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition¹⁷;
- (c) Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production¹⁸;
- (d) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives¹⁹;
- (e) Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community²⁰;
- (f) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices²¹;
- (g) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market²²;
- (h) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices²³;
- (i) European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners²⁴;

¹⁶ OJ L 262, 27.9.1976, p. 169.

¹⁷ OJ L 213, 21.7.1982, p. 8.

¹⁸ OJ L 184, 15.7.1988, p. 61.

¹⁹ OJ L 354, 31.12.2008, p. 16.

²⁰ OJ L 92, 7.4.1990, p. 42.

²¹ OJ L 7, 11.1.1994, p. 20.

²² OJ L 230, 19.8.1991, p. 1.

²³ OJ L 169, 12.7.1993, p. 1.

²⁴ OJ L 61, 18.3.1995, p. 1.

- (j) Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC²⁵;
- (k) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices²⁶;
- (l) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products²⁷;
- (m) 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 use²⁸;
- (n) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition²⁹;
- (o) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs³⁰;
- (p) 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 origin³¹.

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

- (a) Council Directive 67/548/EEC 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances³²;
- (b) Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances³³;
- (c) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work³⁴;

²⁵ OJ L 125, 23.5.1996, p. 35.

²⁶ OJ L 331, 7.12.1998, p. 1

²⁷ OJ L 311 , 28.11.2001, p. 1.

²⁸ OJ L 311 , 28.11.2001, p. 67.

²⁹ OJ L 268, 18.10.2003, p. 29.

³⁰ OJ L 139, 30.4.2004, p. 1.

³¹ OJ L 139, 30.4.2004, p. 55.

³² OJ 196, 16.8.1967, p. 1.

³³ OJ L 33, 8.2.1979, p. 36.

³⁴ OJ L 183, 29.6.1989, p. 1.

- (d) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)³⁵;
 - (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 preparations³⁶;
 - (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 work³⁷;
 - (g) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC³⁸;
 - (h) Directive 2006/114/EC of 12 December 2006 of the European Parliament and of the Council concerning misleading and comparative advertising³⁹;
 - (i) Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals⁴⁰;
 - (j) [proposal for a Directive of the European Parliament and of the Council establishing a framework for Community action to achieve the sustainable use of pesticides];
 - (k) 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006⁴¹.
4. Article 58 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.
 5. This Regulation shall not apply to food or feedingstuffs that are used for biocidal purposes.
 6. This Regulation shall not apply to processing aids that are used for biocidal purposes.

³⁵ OJ L 131, 5.5.1998, p. 11.

³⁶ OJ L 200, 30.7.1999, p. 1.

³⁷ OJ L 262, 17.10.2000, p. 21.

³⁸ OJ L 396, 30.12.2006, p. 1.

³⁹ OJ L 376, 27.12.2006, p. 21.

⁴⁰ OJ L 204, 31.7.2008, p. 1.

⁴¹ OJ L 353, 31.12.2008, p. 1.

7. Where a biocidal product is intended by its manufacturer to be used for the purpose of exerting a controlling effect on any harmful organism present on medical devices and for other purposes covered by this Regulation, the relevant essential requirements of Directives 90/385/EEC, 93/42/EEC or 98/79/EC shall also be fulfilled.
8. Biocidal products which obtained the final approval under the International Convention for the Control and Management of Ships' Ballast Water and Sediments shall be considered as authorised under Chapter VII of this Regulation. Articles 38 and 57 shall apply accordingly.

Article 3
Definitions

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

- (a) 'biocidal products' means

active substances or mixtures containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

All substances, mixtures and devices placed on the market with the intention to generate active substances shall also be considered biocidal products;

- (b) 'micro-organism' means

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

- (c) 'active substance' means

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

- (d) 'existing active substance' means

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

- (e) 'new active substance' means

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

- (f) 'substance of concern' means

any substance, other than the active substance, which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is

produced in a biocidal product in sufficient concentration to present risks of such an effect;

(g) 'harmful organism' means

organisms, including pathogenic agents, which have an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, or on animals or the environment;

(h) 'residues' means

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

(i) 'placing on the market' means

the first supply of a biocidal product for distribution or for use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;

(j) 'use' means

all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with view to export of the biocidal product outside the Community;

(k) 'treated material or article' means

any substance, mixture, material or article which was treated with or incorporates one or more biocidal products with the intention to protect the substance, mixture, material or article from deterioration caused by harmful organisms;

(l) 'national authorisation' means

an administrative act by which the competent authority of a Member State authorises the placing on the market and the use of a biocidal product in its territory or in a part thereof;

(m) 'Community authorisation' means

an administrative act by which the Commission authorises the placing on the market and the use of a biocidal product in the territory of the Community or in a part thereof;

(n) 'authorisation' means

national authorisation or Community authorisation;

(o) 'unique product formulation' means

a biocidal product with no variations as to the percentage of the active substance, the percentage composition of the non-active substances, or the perfumes, dyes or pigments it contains;

(p) 'frame formulation' means

a group of biocidal products having similar uses and presenting limited variations in their composition with regard to a reference biocidal product belonging to that group which contains the same active substances of the same specifications where such permitted variations do not adversely affect the level of risk or the efficacy of these products;

(q) 'letter of access' means

an original document, signed by the owner or owners of information, which states that the information may be used by the competent authorities, the European Chemicals Agency, or the Commission for the purpose of evaluating an active substance or granting an authorisation;

(r) 'food and feedingstuff' means

food as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁴² and feedingstuff as defined in Article 3(4) of that Regulation.

(s) 'food contact materials' means

any material and article intended to come into contact with food which are covered by Regulation (EC) No 1935/2004⁴³;

(t) 'processing aid' means

any substance which:

(i) is not consumed as a food or feedingstuff by itself;

(ii) is intentionally used in the processing of raw materials, foods or feedingstuff or their ingredients, to fulfil a certain technological purpose during treatment or processing; and

(iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product;.

(u) 'technical equivalence' means

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

⁴² OJ L 31, 1.2.2002, p. 1

⁴³ OJ L 338, 13.11.2004, p. 4

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

CHAPTER II

INCLUSION OF AN ACTIVE SUBSTANCE IN ANNEX I

Article 4

Conditions for inclusion

1. An active substance shall be included in Annex I for an initial period not exceeding 10 years if the biocidal products containing that active substance fulfil the conditions laid down in point (b) of Article 16(1).
2. The inclusion in Annex I of an active substance shall be restricted to those product types in Annex V for which relevant data have been submitted in accordance with Article 6.
3. An active substance shall, where appropriate, be included in Annex I together with any of the following conditions:
 - (a) the minimum degree of purity of the active substance;
 - (b) the nature and maximum content of certain impurities;
 - (c) the product type as outlined in Annex V;
 - (d) manner and area of use;
 - (e) designation of categories of users;
 - (f) other particular conditions based on the evaluation of the information related to that active substance.
4. Where appropriate, maximum residue limits shall be established with respect to active substances included in Annex I in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council⁴⁴ [and Council Regulation (EEC) No 2377/90].

⁴⁴ OJ L 70, 16.3.2005, p. 1

Article 5
Exclusion criteria

1. Notwithstanding Article 4(1), active substances referred to in paragraph 2 shall be included in Annex I only if at least one of the following conditions is met:
 - (a) the exposure of humans to that active substance in a biocidal product, under normal conditions of use, is negligible, in particular where the product is used in closed systems or strictly controlled conditions;
 - (b) it is shown that the active substance is necessary to control a serious danger to public health;
 - (c) it is shown that not including the active substance in Annex I would cause disproportionate negative impacts when compared with the risk to human health or the environment arising from the use of the substance and that there are no suitable alternative substances or technologies.

Point (c) shall not apply to active substances for product types 4 and 14 to 19.

2. The following active substances shall be included in Annex I where at least one of the conditions set out in paragraph 1 is met:
 - (a) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meets 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 under Article 57(f) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties.

Article 6
Data requirements for an application

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

The application shall be accompanied by the fees payable under Article 70.

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

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

4. The Commission shall adopt the measures designed to set the criteria defining what constitutes adequate justification to adapt the data required under paragraph 1 on the ground referred to in paragraph 2(a).

Those measures designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).

Article 7

Submission and validation of applications

1. The applicant shall submit an application to include an active substance in Annex I, or to make subsequent amendments to the conditions of inclusion of an active substance, to the European Chemicals Agency (hereinafter referred to as 'the Agency') and inform it of the name of the competent authority of the Member State that he chooses to evaluate his application. That competent authority (hereinafter referred to as 'the evaluating competent authority') shall be responsible for the evaluation of the application.
2. The Agency shall, within one month from the receipt of the application, notify the evaluating competent authority that the application is available in the Agency database.
3. Within two months after the receipt of an application, the Agency shall validate the application if it complies with the following requirements:
 - (a) dossiers referred to in points (a) and (b) of Article 6(1) have been submitted;
 - (b) it is accompanied by the fees payable under Article 70.

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

4. If the Agency considers that the application is incomplete, it shall inform the applicant 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.

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

The Agency shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant thereof. In such cases a part of the fee paid to the Agency in accordance with Article 70 shall be reimbursed.

5. An appeal may be brought, in accordance with Article 67, against Agency decisions under the third subparagraph of paragraph 4.
6. If the Agency, on the basis of the validation made pursuant to paragraph 3, considers that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

Article 8

Evaluation of applications

1. The evaluating competent authority shall, within 12 months after the validation, evaluate the dossiers in accordance with Article 4 including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3).

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

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

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

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

3. If the evaluating competent authority considers that there are concerns with regard to the cumulative effects from the use of biocidal products containing the same active substance, it shall document its concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 and include this as part of its conclusions.

4. Within nine months after the receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the inclusion of the active substance in Annex I.
5. On receipt of the opinion of the Agency, the Commission shall adopt a decision on the application to include the active substance in Annex I. That decision, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).
6. Notwithstanding Article 7(1), the evaluation of the application may be carried out by the competent authority other than the one which has received the copy of the application.

The competent authority that has been notified of the application for the evaluation may submit a duly substantiated request to appoint another evaluating competent authority to the Commission within one month after the receipt of the notification referred to in Article 7(2). The Commission shall take the decision in accordance with the procedure referred to in Article 72(2). The 12-month period referred to in paragraph 1 shall commence on the date when this decision is taken.

Article 9

Active substances which are candidates for substitution

1. An active substance fulfilling at least one of the following criteria shall be considered a candidate for substitution in accordance with the procedure referred to in paragraph 2:
 - (a) its acceptable daily intake, acute reference dose or acceptable operator exposure level is significantly lower than those of the majority of the active substances included in Annex I for the same product type;
 - (b) it meets two of the criteria to be considered as a persistent, bio-accumulative and toxic substance as set out in Annex XIII of Regulation (EC) No 1907/2006;
 - (c) there are reasons for concern linked to the nature of the critical effects, in particular developmental neurotoxic or immunotoxic effects, which, in combination with the use patterns, amount to use that could still cause concern, even with very restrictive risk management measures;
 - (d) it contains a significant proportion of non-active isomers;
 - (e) it is classified or meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, mutagen category 1A or 1B or toxic for reproduction category 1A or 1B;
 - (f) it is considered to have endocrine disrupting properties that may cause adverse effect on humans on the basis of the assessment of Community or internationally agreed test guidelines or other available data.

2. When preparing an opinion on the inclusion or renewal of the inclusion of an active substance in Annex I, the Agency shall examine whether the active substance fulfils any of the criteria listed in paragraph 1 and address the matter in its opinion.
3. Prior to submitting the opinion on the inclusion or renewal of the inclusion of an active substance in Annex I to the Commission, the Agency shall make publicly available information on potential candidates for substitution with a reasonable period during which relevant information, including information on available substitutes, may be submitted by interested third parties. The Agency shall take due account of the information received when finalising its opinion.
4. By way of derogation from Article 10(3), the inclusion of an active substance in Annex I that is considered as a candidate for substitution shall be renewed for a period not exceeding ten years.
5. Active substances that are considered as candidates for substitution in accordance with paragraph 1 shall be identified as such in Annex I.

CHAPTER III

RENEWAL AND REVIEW OF AN ACTIVE SUBSTANCE INCLUSION

Article 10

Conditions for renewal

1. The Commission shall renew the inclusion of an active substance in Annex I if the active substance still complies with the requirements referred to in Article 4.
2. Based on new elements examined or adaptations to technical progress, the renewal of the inclusion may be accompanied, as appropriate, by conditions and restrictions.
3. Unless otherwise specified in the decision to renew the inclusion of an active substance in Annex I, the renewal shall be for an unlimited period of time.

Article 11

Submission and validation of applications

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

The application shall be accompanied by the fees payable under Article 70.

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

2. The Agency shall, within one month after the receipt of the application, notify the evaluating competent authority that carried out the initial evaluation of the

application for inclusion in Annex I that the application is available in the Agency database.

3. Within two months after the receipt of an application, the Agency shall validate the application if it complies with the following requirements:
 - (a) information referred to paragraph 1 has been submitted;
 - (b) it is accompanied by the fees payable under Article 70.

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

4. If the Agency considers that the application is incomplete, it shall inform the applicant 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.

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

The Agency shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant thereof. In such cases a part of the fee paid to the Agency in accordance with Article 70 shall be reimbursed.

5. An appeal may be brought, in accordance with Article 67, against Agency decisions under the third subparagraph of paragraph 4.
6. If the Agency, on basis of the validation made pursuant to paragraph 3, considers that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

Article 12

Evaluation of applications for renewal

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

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

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

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

3. On the receipt of the recommendation from the evaluating competent authority, the Agency shall make it available to the Commission, the competent authorities of other Member States and the applicant and allow a period of three months during which they may submit written comments to it.
4. The Commission may ask the Agency for an opinion on scientific or technical matters raised by a competent authority objecting to the recommendation referred to in paragraph 2. The Agency shall issue an opinion within six months from the date on which the matter was referred to it.
5. At the end of the period referred to in paragraph 3 or on receipt of the opinion of the Agency, the Commission shall adopt a decision concerning a renewal of the inclusion of the active substance in Annex I. That decision, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).
6. Where, for reasons beyond the control of the applicant, the inclusion of the active substance in Annex I is likely to expire before a decision has been taken on its renewal, the Commission shall, in accordance with the procedure referred to in Article 72(2), adopt a decision postponing the expiry date of inclusion for a period sufficient to enable it to examine the application.
7. Where the Commission decides not to renew the inclusion of an active substance in Annex I, it may grant a period of grace for the disposal, storage, placing on the market and use of existing stocks of biocidal products containing that active substance.

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

Article 13

Review of inclusion of an active substance in Annex I

1. The Commission may review the inclusion of an active substance in Annex I at any time where there are serious indications that the requirements referred to in Article 4 are no longer complied with. Where those indications are confirmed, the Commission shall adopt a decision amending the inclusion of an active substance in Annex I or removing it from that Annex.

That decision, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 72(5).

2. The Commission may consult the Agency on any questions of a scientific or technical nature related to the review of inclusion of an active substance in Annex I. The Agency shall, within nine months from the request, prepare an opinion and submit it to the Commission.
3. Where the Commission removes the entry of an active substance from Annex I, it may grant a period of grace for the disposal, storage, placing on the market and use of existing stocks of biocidal products containing that active substance.

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

Article 14

Implementing measures

The Commission may adopt detailed measures for the implementation of Articles 10 to 13 of this Regulation specifying the procedures related to the renewal and review of an inclusion of an active substance in Annex I.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).

CHAPTER IV GENERAL PRINCIPLES OF AUTHORISATION OF BIOCIDAL PRODUCTS

Article 15

Placing on the market and use of biocidal products

1. No biocidal product may be placed on the market or used unless an authorisation has been issued for that biocidal product in accordance with this Regulation.
2. Application for authorisation shall be made by, or on behalf of, the person who shall be responsible for the placing on the market of a biocidal product in a particular Member State or in the Community.

Application for national authorisation in a Member State shall be submitted to the competent authority of that Member State (hereinafter referred to as 'the receiving competent authority').

Application for Community authorisation shall be submitted to the Agency.

A holder of an authorisation shall have a permanent office within the Community.

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

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

Proper use shall also involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary.

Article 16

Conditions for granting an authorisation

1. A biocidal product shall be authorised only if the following conditions are met:
- (a) the active substances included therein are listed in Annex I and any conditions included in that Annex together with those active substances are complied with;
 - (b) it is established according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI, that the biocidal product, when used as authorised and having regard to the factors referred to in paragraph 2, complies with the following criteria:
 - (i) it is sufficiently effective;
 - (ii) it has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
 - (iii) it has no unacceptable effects itself or as a result of its residues, directly or indirectly, on human or animal health;
 - (iv) it has no unacceptable effects itself, or as a result of its residues, on the environment having particular regard to the following considerations:
 - its fate and distribution in the environment;
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil;
 - its impact on non-target organisms;
 - its impact on biodiversity and the ecosystem;
 - (c) the nature, the quantity and the technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant impurities and non-active substances, and its 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) its physical and chemical properties have been determined and deemed acceptable for purposes of the appropriate use, storage and transport of the product.
2. The evaluation of the compliance of the biocidal product with the criteria set out in point (b) of paragraph 1 shall take into account the following factors:
 - (a) all normal conditions under which the biocidal product may be used;
 - (b) how any material or article treated with it or containing it may be used;
 - (c) the consequences of its use and disposal.
 3. An authorisation to place a low-risk biocidal product on the market shall be subject to compliance with the requirements of points (b), (c) and (d) of paragraph 1.
 4. A biocidal product shall only be authorised for uses for which relevant information has been submitted in accordance with Article 18.
 5. A biocidal product shall not be authorised for placing on the market to, or use by, the general public if it fulfils any of the following criteria for classification:
 - (a) toxic, very toxic or a category 1 or 2 carcinogen, or a category 1 or 2 mutagen or toxic for reproduction category 1 or 2 according to Directive 1999/45/EC;
 - (b) toxic, very toxic or a category 1A or 1B carcinogen, or a category 1A or 1B mutagen or toxic for reproduction category 1A or 1B according to Regulation (EC) No 1272/2008.
 6. In the case of a frame formulation, a reduction in the percentage of the active substance in the reference biocidal product may be allowed, and/or an alteration in percentage composition of one or more non-active substances, and/or the replacement of one or more non-active substances by others presenting the same or lower risk.

Article 17

Criteria for low-risk biocidal products

1. A biocidal product shall be considered a low-risk biocidal product if both the following conditions are fulfilled:
 - (a) for any given environmental compartment, the ratio of the predicted environmental concentration (PEC) to predicted no-effect concentration (PNEC) may be derived and does not exceed 0.1;
 - (b) for any effect to human health, the margin of exposure (the ratio of no observed adverse effect level (NOAEL) and exposure concentration) is higher than 1,000.

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

- (a) it contains one or more active substances which fulfil the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII of Regulation (EC) No 1907/2006;
 - (b) it contains one or more active substances qualified as endocrine disrupters;
 - (c) it contains one or more active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as or which meets the criteria to be classified as one of the following:
 - (i) carcinogenic;
 - (ii) mutagenic;
 - (iii) neurotoxic;
 - (iv) immunotoxic;
 - (v) toxic to reproduction;
 - (vi) sensitising.
2. Notwithstanding paragraph 1, a biocidal product shall be considered a low-risk biocidal product if the active substances in the biocidal product are contained in such way that only a negligible exposure can take place under normal conditions of use and the product is handled under strictly controlled conditions during all other stages of its lifecycle.
3. For a low-risk biocidal product it shall be demonstrated that the potential for the development of resistance in target organisms due to the use of the biocidal product is low.
4. In addition to the active substances referred to in Article 15(2) of Regulation (EC) No 1907/2006, active substances manufactured or imported for use in low-risk biocidal products that are authorised for placing on the market in accordance with Article 15 shall be regarded as being registered and the registration as completed for manufacture or import for use in a low-risk biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of Title II of that Regulation.

Article 18

Data requirements for an application for authorisation

1. The applicant for an authorisation shall submit the following documents together with the application:
- (a) a dossier or letter of access for the biocidal product satisfying the requirements set out in Annex III;
 - (b) a proposal for a summary of the biocidal product characteristics that includes the information referred to in points (a), (b) and (e) to (m) of Article 20(2);

- (c) for other than low-risk biocidal products, a dossier or a letter of access to a dossier satisfying the requirements set out in Annex II for each active substance in the biocidal product;
 - (d) for low-risk biocidal products, any relevant information in support of the conclusion that the biocidal product is to be considered a low-risk biocidal product.
2. The application for authorisation shall be accompanied by the fees payable under Article 70.
 3. The receiving competent authority may require that applications for a national authorisation be submitted in one or more of the official languages of the Member State where that competent authority is situated.
 4. 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(7), it shall be accompanied by a declaration of conformity regarding the compliance with the relevant essential requirements of Directives 90/385/EEC, 93/42/EEC or 98/79/EC.
 5. The Commission, in accordance with the procedure referred to in Article 72(2), shall draw up technical notes for guidance to facilitate the implementation of point (d) of paragraph 1.

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

Article 19

Waiving of data requirements

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

The competent authority shall inform the applicant about the possibility of proposing the adaptation of data requirements, the grounds on which such an adaptation can be requested and, where possible, shall provide assistance in preparing such a proposal.
3. The Commission shall adopt the measures designed to set the criteria defining what constitutes adequate justification to adapt the data required under Article 18 on the ground referred to in paragraph 1(a).

Those measures designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).

Article 20

Content of authorisation

1. An authorisation shall stipulate the terms and the conditions relating to the placing on the market and use of the biocidal product.
2. An authorisation shall include the summary of the biocidal product characteristics listing the following information:
 - (a) trade name of the biocidal product;
 - (b) name and address of the authorisation holder;
 - (c) date of the authorisation and its date of expiry;
 - (d) authorisation number;
 - (e) qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge of which is essential for proper use of the biocidal product;
 - (f) manufacturers of the biocidal product (names and addresses including location of manufacturing sites);
 - (g) manufacturers of the active substances (names and addresses including location of manufacturing sites);
 - (h) physical state and nature of the biocidal product;
 - (i) hazard and precautionary statements;
 - (j) the product-type in accordance with Annex V and the target harmful organisms;
 - (k) application doses and instructions for use;
 - (l) categories of users;
 - (m) particulars of likely direct or indirect adverse effects and first aid instructions;
 - (n) instructions for safe disposal of the product and its packaging;
 - (o) in the case of a biocidal product that is intended by its manufacturer to be used also for the purposes referred to in Article 2(7), 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.
3. In addition to paragraph 2, in the case of a frame formulation, the authorisation shall indicate, as appropriate, the following information:

- (a) the reference biocidal product within the group of products comprising the frame formulation that has the highest allowed concentration of the active substances;
- (b) the permitted alteration of the composition of this reference biocidal product expressed in percentage of the non-active substances contained in the biocidal products which are considered to belong to that frame formulation;
- (c) the non-active substances that may be substituted in the authorised biocidal products belonging to that frame formulation.

Article 21

Comparative assessment of biocidal products

1. The receiving competent authority or, in the case of evaluation of an application for a Community authorisation, the evaluating competent authority shall perform a comparative assessment as part of the evaluation of an application for an authorisation or a renewal of an authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 9(1).
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 Community authorisation, also to the Commission.
3. The receiving competent authority or, in the case of a decision on an application for a Community authorisation, the Commission shall prohibit or restrict the placing on the market or use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment weighing up the risks and benefits in accordance with Annex VI demonstrates that all the following criteria are met:
 - (a) for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents significantly lower risk for human or animal health or the environment;
 - (b) the biocidal product or non-chemical control or prevention method referred to in point (a) does not present significant economic or practical disadvantages;
 - (c) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.
4. By way of derogation from paragraph 1, a biocidal product containing an active substance that is a candidate for substitution shall be authorised without comparative assessment in 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 the Community 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 the decision in accordance with Article 72(3).

The Commission shall adopt implementing rules specifying the procedures related to comparative assessments involving questions of Community interest. Those rules, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).

6. Notwithstanding Article 15(4), an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted for 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 the decision or at the end of the inclusion period of the candidate for substitution, whichever is the earlier.

CHAPTER V

NATIONAL AUTHORISATIONS OF BIOCIDAL PRODUCTS

Article 22

Submission and validation of application

1. Within one month after the receipt of an application for a national authorisation referred to in Article 15, the receiving competent authority shall validate the application if it complies with the following requirements:
 - (a) the information referred to in Article 18 has been submitted;
 - (b) it is accompanied by the fees payable under Article 70.

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

2. If 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.

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

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

3. If the receiving competent authority, on basis of the validation made pursuant to paragraph 1, considers that the application is complete, it shall without delay inform the applicant thereof.

Article 23
Evaluation of application

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

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

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

The receiving competent authority shall approve the summary of the biocidal product characteristics referred to in Article 20(2). It shall forward the applicant a copy of the final assessment report.

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

Article 24
Renewal of a national authorisation

1. The authorisation holder or his representative shall submit an application for renewal of a national authorisation to the receiving competent authority at least 18 months before the expiry date of the authorisation.

The application shall be accompanied by the fees payable under Article 70.

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

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

4. Within one month after the receipt of an application for a renewal of a national authorisation, the receiving competent authority shall validate the application if it complies with the following requirements:
 - (a) the information referred to in paragraph 3 has been submitted;
 - (b) it is accompanied by the fees payable under Article 70.

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

5. If the receiving competent authority considers that the application is incomplete, it shall inform the applicant 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.

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

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

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

6. The decision on the application for renewal of the national authorisation shall be taken within six months after the validation.
7. If, when the application for renewal is evaluated, it appears that additional information is necessary in order to carry out a full evaluation of the application, the receiving competent authority shall ask that the applicant submits such information. The six-month period referred to in paragraph 6 shall be suspended from the date of the request until the date the information is received.
8. Where, for reasons beyond the control of the holder of the national authorisation, no decision is taken on the renewal of the national authorisation before its expiry, the

receiving competent authority shall grant the renewal of the national authorisation for the period necessary to complete the evaluation.

9. As soon as the competent authority has taken a decision concerning the renewal of a national authorisation, it shall enter the information referred to in Article 23(5) in the *Community Register of Biocidal Products*.

CHAPTER VI MUTUAL RECOGNITION PROCEDURES

Article 25

Mutual recognition of national authorisations in sequence

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

The application shall be accompanied by the fees payable under Article 70.

3. The receiving competent authority may require a translation of the national authorisation and application into one or several of the official languages of the Member State where that competent authority is situated.
4. The receiving competent authority shall decide on the application within four months of the receipt of the application.
5. The receiving competent authority shall authorise the biocidal product concerned under the same conditions as the reference competent authority.
6. As soon as the competent authorities have taken a decision on an application for mutual recognition of a national authorisation under this Article, they shall enter the information referred to in points (a) and (c) of Article 23(5) in the *Community Register of Biocidal Products*.

Article 26

Application for mutual recognition by pest control bodies

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

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

The application shall be accompanied by the fees payable under Article 70.

2. By way of derogation from paragraph 1, where the authorisation holder does not give his consent, the applicant may indicate that in the application and the competent authority of the Member State concerned may accept the application on grounds of public interest.
3. If the competent authority of the concerned Member State considers that the biocidal product fulfils the conditions referred to in Article 16 and the conditions under this Article are complied with, the competent authority shall authorise the placing of the biocidal product on the market.
4. The official or scientific bodies involved in pest control activities or professional organisations shall have the rights and obligations of the authorisation holder.

Article 27

Objections regarding the conditions for a national authorisation

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

The Commission shall adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

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

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

Article 28

Mutual recognition of national authorisations in parallel

1. If the applicant seeks to receive national authorisations for a biocidal product in more than one Member State in parallel, he shall submit to a reference competent authority of his choice an application containing:
 - (a) information referred to in Article 18;
 - (b) a list of all other Member States where a national authorisation is sought (hereinafter referred to as the 'other concerned Member States').

The application shall be accompanied by the fees payable under Article 70.

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

2. The applicant shall submit to the competent authorities of the other concerned Member States an application for mutual recognition of the authorisation for which it has applied to the reference competent authority. This application shall contain:
 - (a) an electronic summary of the dossier as required in Annex III;
 - (b) the names of the reference competent authority and of the other concerned Member States.
3. The reference competent authority shall, within one month after the receipt of an application referred to in paragraph 1, validate the application if it complies with the following requirements:
 - (a) the information referred to in paragraph 1 has been submitted;
 - (b) it is accompanied by the fees payable under Article 70.

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

4. If the reference competent authority considers that the application is incomplete, it shall inform the applicant 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. The reference competent authority shall also inform the other concerned Member States.

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

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

5. If the reference competent authority, on the basis of the validation made pursuant to paragraph 3, considers that the application is complete, it shall without delay inform the applicant and the other concerned Member States.
6. The reference competent authority shall evaluate the information referred to in paragraph 1 and prepare a report summarising the conclusions of its assessment and a draft of the summary of the biocidal product characteristics within 12 months from the receipt of a valid application and shall communicate the report and the draft summary to the competent authorities of other concerned Member States and the applicant. The reference competent authority shall send the draft assessment report to the applicant who shall be provided with the opportunity to submit oral or written comments within one month. The reference competent authority shall take due account of these comments when finalising its assessment.
7. Within four months after receipt of the documents referred to in paragraph 6, the competent authorities of other concerned Member States shall approve the assessment report and the summary of the product characteristics, and shall inform the reference competent authority accordingly.
8. The reference competent authority and the competent authorities of the other concerned Member States shall authorise the biocidal product on the basis of the approved assessment report and the summary of the biocidal product characteristics within one month after the end of the period referred to in paragraph 7.
9. If one or more competent authorities of other concerned Member States have not approved the assessment report and the summary of the biocidal product characteristics within four months after receipt of the documents referred to in paragraph 6, they shall notify the Commission, the applicant, the reference competent authority and the competent authorities of other concerned Member States and shall provide them with an explanatory document identifying the biocidal product and its specifications and setting out the grounds on which they propose to refuse to recognise, or to restrict, the national authorisation.

The Commission shall adopt a decision on whether the grounds set out by the competent authority justify refusal to recognise, or restriction of, the national authorisation in accordance with the procedure referred to in Article 72(3).

If the Commission decision dismisses the grounds presented for refusing or restricting the national authorisation the competent authority that proposed to refuse to recognise the authorisation, or to restrict the authorisation, shall without delay authorise the biocidal product concerned in accordance with the national authorisation issued by the reference competent authority.

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

Article 29
Adjustment to local circumstances

1. The competent authority that has received an application for mutual recognition in accordance with Articles 25 or 28 may, within two months from the receipt of the application, propose to the applicant that certain conditions referred to in points (e), (f), (h), (j) and (l) of Article 58(2) in the authorisation be adjusted to local circumstances, so that conditions for issue of an authorisation laid down in Article 16 are satisfied, and shall inform the Commission thereof, if it establishes that, in its territory, one of the following conditions is met:
 - (a) the target species is not present in harmful quantities;
 - (b) unacceptable tolerance or resistance of the target organism to the biocidal product is demonstrated;
 - (c) the relevant circumstances of use, in particular the climate or the breeding period of the target species, differ significantly from those in the Member State where the initial evaluation was carried out or the Member State where the initial national authorisation was issued, and an unchanged national authorisation may therefore present unacceptable risks to humans or to the environment.

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

2. If, within 2 months, an agreement on the proposed adjustments is not reached between the applicant and the competent authority that has received an application for mutual recognition, that competent authority shall without delay inform the Commission thereof and provide an explanatory document on the proposed adjustments identifying the biocidal product and its specifications and setting out the grounds on which it proposes to adjust the conditions of the national authorisation.

The Commission shall adopt a decision on the proposed adjustment of the conditions of the national authorisation to local circumstances in accordance with the procedure referred to in Article 72(3). The competent authority of the concerned Member State shall without delay adopt all appropriate measures to comply with that decision.

Article 30
Opinion of the Agency

1. The Commission may ask the Agency for an opinion on scientific or technical matters raised by a Member State objecting to the mutual recognition of a national authorisation or seeking to adjust the authorisation to local circumstances. The Agency shall issue an opinion within 6 months from the date on which the matter was referred to it.
2. Before issuing its opinion, the Agency shall provide the applicant or the authorisation holder with an opportunity to present written or oral explanations within a specified time limit not exceeding one month.

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

Article 31

Derogation regarding certain product-types

By way of derogation from Articles 25 and 28, competent authorities of Member States may refuse mutual recognition of national authorisations granted for product types 15, 17 and 23 of Annex V provided that such a refusal can be justified on grounds of the protection of health of humans, animals or plants, the protection of national treasures possessing artistic, historic or archaeological value, or the protection of industrial and commercial property. Competent authorities of Member States shall without delay inform each other and the Commission of any decision taken in this respect and shall indicate the reasons thereof.

**CHAPTER VII
COMMUNITY AUTHORISATIONS OF BIOCIDAL
PRODUCTS**

Section 1

Granting of Community authorisations

Article 32

Community authorisation

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

Article 33

Biocidal products for which Community authorisation may be granted

1. The Community authorisation may be granted to the following categories of biocidal products:
 - (a) biocidal products containing one or more new active substances;
 - (b) low-risk biocidal products.
2. Following the report of the Commission on the implementation of this Regulation referred to in Article 54(4) and in light of the experience gained with the Community authorisations, the Commission may add other categories of biocidal products in paragraph 1 of this Article.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).

Article 34

Submission and validation of application

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

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

2. Within two months after the receipt of an application, the Agency shall validate the application if it complies with the following requirements:
 - (a) the information referred to in Article 18 has been submitted;

(b) it is accompanied by the fees payable under Article 70.

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

3. If the Agency considers that the application is incomplete, it shall inform the applicant 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.

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

The Agency shall reject the application if the applicant fails to complete his application within the deadline and inform the applicant and the evaluating competent authority thereof. In such cases a part of the fee paid to the Agency in accordance with Article 70 shall be reimbursed.

4. An appeal may be brought, in accordance with Article 67, against Agency decisions under the third subparagraph of paragraph 3.
5. If the Agency, on the basis of the validation made pursuant to paragraph 2, considers that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

Article 35

Evaluation of applications

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

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

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

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

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

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

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

- (a) a statement on whether the conditions of points (b), (c) and (d) of Article 16(1) are fulfilled, and a draft summary of the biocidal product characteristics, as referred to in Article 20(2);
 - (b) where relevant, details of any terms or conditions which should be imposed on the placing on the market or use of the biocidal product;
 - (c) the final assessment report on the biocidal product.
4. On receipt of the opinion of the Agency, the Commission shall adopt a decision on the Community authorisation of the biocidal product in accordance with the procedure referred to in Article 72(3). As soon as the Commission has taken a decision to grant a Community authorisation, it shall enter the information referred to in Article 23(5) in the *Community Register of Biocidal Products*.

The Commission may, on the request of a Member State, decide that the Community authorisation shall not apply in the territory of that Member State for a biocidal product of the product-types 15, 17 or 23 of Annex V provided that such a request can be justified on grounds of the protection of health of humans, animals or plants, the protection of national treasures possessing artistic, historic or archaeological value, or the protection of industrial and commercial property.

The Commission may, on the request of a Member State, decide that certain conditions of the Community authorisation should be adjusted to the different local circumstances in that Member State in accordance with Article 29.

5. If the decision referred to in paragraph 4 refuses to grant a Community authorisation to a biocidal product because it does not fulfil the criteria for a low-risk biocidal product in accordance with Article 17, the applicant may apply, if relevant, for a Community authorisation in accordance with point (a) of Article 33(1) or a national authorisation in accordance with Chapter V.
6. The competent authority that has been notified of the application for the evaluation as referred to in Article 34(1) may, within one month after the receipt of the notification, submit a duly substantiated request to the Commission to appoint another evaluating competent authority. The Commission shall take a decision in accordance with the procedure referred to in Article 72(2).

Section 2

Renewal of Community authorisations

Article 36

Submission and validation of applications

1. The authorisation holder or his representative shall submit an application for renewal of a Community authorisation to the Agency at least 18 months before the expiry date of the authorisation.

The application shall be accompanied by the fees payable under Article 70.

2. The Agency shall, within one month after the receipt of the application, notify the evaluating competent authority that carried out the initial evaluation of the application for Community authorisation that the application is available in the Agency database.
3. The Commission shall renew a Community authorisation, provided that the conditions set out in Article 16 are still satisfied.
4. When applying for renewal, the applicant shall submit a list of all data relating to the biocidal product that have been generated since the previous authorisation and a justification as to whether the conclusions of the initial assessment of the biocidal product are still valid.

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

5. Within two months after the receipt of an application, the Agency shall validate the application if it complies with the following requirements:
 - (a) information referred to paragraph 4 has been submitted;
 - (b) it is accompanied by the fees payable under Article 70.

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

6. If the Agency considers that the application is incomplete, it shall inform the applicant 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.

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

The Agency shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant thereof. In such cases

a part of the fee paid to the Agency in accordance with Article 70 shall be reimbursed.

7. An appeal may be brought, in accordance with Article 67, against Agency decisions under the third subparagraph of paragraph 6.
8. If the Agency, on basis of the validation made pursuant to paragraph 5, considers that the application is complete, it shall without delay inform the applicant and the evaluating competent authority thereof.

Article 37

Evaluation of applications for renewal

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

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

2. If the evaluating competent authority that carried out the initial evaluation of the application for Community authorisation decides that a full evaluation of the application is not necessary, it shall, within twelve months after the validation, prepare and submit to the Agency a recommendation on the renewal of the authorisation.

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

3. On the receipt of the recommendation from the evaluating competent authority, the Agency shall make it available to the competent authorities of other Member States and the applicant and allow a period of three months during which they may submit written comments to it.
4. The Commission may ask the Agency for an opinion on scientific or technical matters raised by a competent authority objecting to the recommendation referred to in paragraph 2. The Agency shall issue an opinion within six months from the date on which the matter was referred to it.
5. At the end of the period referred to in paragraph 3 or on receipt of the opinion of the Agency, the Commission shall adopt a decision to renew, or to refuse to renew, the Community authorisation in accordance with the procedure referred to in Article 72(3). As soon as the Commission has taken a decision, it shall update the

information referred to in Article 23(5) in the *Community Register of Biocidal Products*.

6. Where, for reasons beyond the control of the holder of the Community authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Commission shall grant the renewal of the Community authorisation for the period necessary to complete the evaluation in accordance with the procedure referred to in Article 72(2).

CHAPTER VIII CANCELLATION, REVIEW AND AMENDMENTS OF AUTHORISATIONS

Article 38

Obligation for notification of new information

1. If the holder of an authorisation becomes aware of information concerning the authorised biocidal product or the active substance(s) it contains, which may affect the authorisation he shall without delay notify the competent authority that granted the national authorisation and the Agency or, in the case of a Community authorisation, the Commission and the Agency. In particular, the following shall be notified:
 - (a) new knowledge or information on the effects of the active substance or biocidal product for humans or the environment;
 - (b) data indicating the potential of the active substance for the development of resistance;
 - (c) new knowledge or information indicating that the biocidal product is not sufficiently effective.
2. The competent authority that granted the national authorisation or in the case of a Community authorisation, the Agency, shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 39.
3. The competent authority that granted the national authorisation or in the case of a Community authorisation, the Agency, shall without delay notify competent authorities of other Member States and, where appropriate, the Commission of any such information it received.

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

Article 39

Cancellation or amendment of an authorisation

1. The competent authority of a Member State or, in the case of a Community authorisation, the Commission, may at any time cancel or amend an authorisation it has granted in the following cases:
 - (a) the requirements referred to in Article 16 are not satisfied;
 - (b) false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted;
 - (c) a condition included in the authorisation has not been complied with;
 - (d) the authorisation holder fails to comply with his obligations resulting from this Regulation.
2. Where the competent authority or, in the case of a Community authorisation, the Commission, intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give him the opportunity to submit written or oral comments or additional information within a specified time limit. The evaluating competent authority shall take due account of these comments when finalising its decision.
3. Where the competent authority or, in the case of a Community authorisation, the Commission, cancels or amends an authorisation in accordance with paragraph 1, it shall without delay notify the authorisation holder, the competent authorities of other Member States and, where relevant, the Commission.

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

In the case of disagreement between competent authorities of certain Member States, the points of disagreement shall be referred without delay to the Commission and the procedure laid down in Articles 27 and 30 shall apply *mutatis mutandis*.
4. As soon as the competent authority or the Commission in the case of a Community authorisation, has taken a decision to cancel or amend an authorisation, it shall update the information referred to in Article 23(5) relating to the biocidal product concerned in the *Community Register of Biocidal Products*.

Article 40

Cancellation of an authorisation at the request of the authorisation holder

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

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

Article 41

Amendment of an authorisation at the request of the authorisation holder

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

The application shall be accompanied by the fees payable under Article 70.

Article 42

Implementing measures

The Commission shall adopt implementing measures specifying the criteria and procedures related to a cancellation of an authorisation or amendments of the terms and conditions of an authorisation under Articles 39 to 41, including a dispute settlement mechanism.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).

Article 43

Period of grace

Notwithstanding Article 77, where the competent authority or in the case of a biocidal product authorised at Community level, the Commission, cancels or amends an authorisation or decides not to renew it, it shall grant a period of grace for the disposal, storage, placing on the market and use of existing stocks except in cases where continued placing on the market or use of the product would constitute an unacceptable risk to human health or the environment.

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

Article 44
Parallel trade

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

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

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

2. A parallel trade permit shall be granted within two months from submission of an application. The competent authority of the Member State of introduction may request from the competent authority of the Member State of origin additional information necessary to determine whether the product is substantially identical to the reference product. The competent authority of the Member State of origin shall provide the requested information within one month of receiving the request.
3. A biocidal product shall be considered as substantially identical to the reference product if one of the following conditions is met:
 - (a) the source of the active substances it contains is the same in terms of manufacturer and location of the production plant;
 - (b) it is either the same or similar with regard to the non-active substances present and the type of formulation;
 - (c) it is either the same or equivalent in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.
4. An application for a parallel trade permit shall include the following information and items:
 - (a) name and authorisation number of the biocidal product in the Member State of origin;
 - (b) the competent authority of the Member State of origin that authorised the reference product;
 - (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 product intended to be placed on the market in the Member State of introduction;
- (h) a sample of the product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;
- (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 placing on the market and use as the authorisation of the reference product.
- 6. The parallel trade permit shall be valid for the duration of authorisation of the reference product in the Member State of introduction.

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

- 7. Without prejudice to specific provisions in this Article, Articles 38 to 41 and Chapter XIII shall apply *mutatis mutandis* to biocidal products placed on the market under a parallel trade permit.
- 8. The competent authority of the Member State of introduction may withdraw a parallel trade permit if the authorisation of the introduced biocidal product is withdrawn in the Member State of origin because of safety or efficacy reasons.
- 9. Where a decision concerning the application for a parallel trade permit is taken in accordance with the provisions of this Article, the competent authorities of Member States which have taken such a decision shall enter the information referred to in Article 23(5) in the *Community Register of Biocidal Products*.

CHAPTER IX DEROGATIONS

Article 45

Derogation from the requirements

1. By way of derogation from Articles 15 and 16, a competent authority may authorise for a period not exceeding nine months, the placing on the market of a biocidal product not complying with the provisions of this Regulation for a limited and controlled use if 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 a revocation of such action.

The Commission shall without delay decide whether, and under what conditions, the action taken by the competent authority may be extended for a period not exceeding 18 months in accordance with the procedure referred to in Article 72(3).

2. By way of derogation from point (a) Article 16(1) and until an active substance is listed in Annex I, competent authorities and the Commission may authorise, for a period not exceeding three years, the placing on the market of a biocidal product containing a new active substance not listed in Annex I.

Such an 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 inclusion of the new active substance in Annex I and the competent authority which received the application for the provisional authorisation or in case of Community authorisation, the Agency, considers that the biocidal product may be expected to comply with points (c) and (d) of Articles 16(1).

The competent authorities or the Commission shall enter the information on the authorisation referred to in Article 23(5) in the *Community Register of Biocidal Products*.

If the Commission decides not to include an active substance in Annex I, the competent authority which granted an authorisation referred to in the first subparagraph or the Commission shall cancel that authorisation.

Where a decision on the inclusion of an active substance in Annex I has not yet been adopted by the Commission when the period of three years expires, the competent authority which granted a provisional authorisation, or the Commission, may extend the provisional authorisation for a period not exceeding one year, provided there are good reasons to believe that the active substance will satisfy the requirements of Article 4. Competent authorities which extended the provisional authorisation shall inform the other competent authorities and, where appropriate, the Commission of such action.

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

Article 46

Research and development

1. By way of derogation from Article 15, an experiment or a test for the purposes of research or development involving the placing on the market of an unauthorised biocidal product or an active substance intended exclusively for use in a biocidal product may only take place in the case of scientific research and development or in the case of product and process-oriented research and development, and under the conditions laid down in the second and third subparagraphs.

In the case of scientific research and development, the person who intends to carry out the experiment or the test shall notify the competent authority prior to the start. The person shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The persons concerned shall, if requested, make this information available to the competent authority.

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

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

If the proposed experiments or tests referred to in paragraphs 1 and 2 may have harmful effects on human or animal health or any unacceptable adverse effect on the

environment, the competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The competent authority shall without delay inform the Commission and other competent authorities about such measures.

4. The Commission shall adopt measures to specify the overall applicable maximum quantities of active substances or biocidal products that may be released during experiments and the minimum data to be submitted in accordance with paragraph 2.

Those measures designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).

CHAPTER X TREATED ARTICLES OR MATERIALS

Article 47

Placing on the market of treated articles or materials

1. Treated materials or articles that incorporate one or more biocidal products shall not be placed on the market unless the biocidal product(s) used for treating the materials or articles are authorised for this use in the Community or in at least one Member State.
2. Treated articles or materials shall be labelled with the following information:
 - (a) the name of all active substances that were used to treat the article or materials or that were incorporated in the articles or materials;
 - (b) where relevant, the biocidal property attributed to treated articles or materials;
 - (c) the authorisation number of all biocidal products that were used for the treatment or were incorporated in the articles or materials;
 - (d) any hazard statement or precautionary statement set out in the authorisation for the biocidal product.

The labelling shall be clearly visible, easily legible and appropriately durable.

Where this is necessary because of the size or the function of the treated article or material, the labelling shall be printed on the packaging, on the instructions for use or on the warranty of the treated article or material.

CHAPTER XI

DATA PROTECTION AND DATA-SHARING

Article 48

Protection of information held by competent authorities or the Agency

1. Information submitted for the purposes of this Regulation shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except in one of the following cases:
 - (a) the subsequent applicant has written agreement in the form of a letter of access from the first applicant that he can use that information,
 - (b) the relevant time limit for data protection has expired.
2. When an applicant submits any information to a competent authority or to the Agency, he shall also provide a list of all the information submitted. In the list he shall specify whether he is the owner of the information or whether he only holds a letter of access to that information. In the latter case, the list shall contain the name and contact details of the owner. The applicant shall inform the competent authority or the Agency about any changes to the ownership of the information.
3. On receipt of the list referred to in paragraph 2, the competent authorities shall send it to the Agency.
4. The list referred to in paragraph 2 shall be entered by the Agency in the Biocides Data Sharing Register.
5. The Commission, the Agency, the advisory scientific committees set up under Commission Decision 2004/210/EC setting up Scientific Committees in the field of consumer safety, public health and the environment⁴⁵ and the competent authorities shall have access to the information referred to in paragraph 1.

Article 49

Information protection periods

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

Information protected under Directive 98/8/EC 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.

⁴⁵ OJ L 66, 4.3.2004, p. 45

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

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

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

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

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

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

4. By way of derogation from the first subparagraph of paragraph 2, the protection period for information submitted to a Member State under national systems or practices for the approval of biocidal products, before it was submitted for the purposes of Directive 98/8/EC or of this Regulation, shall end at the expiry of any remaining period provided for under national rules or on 14 May 2014, whichever is the earlier, unless this information has been generated after 14 May 2000.

Article 50 **Letter of access**

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

Article 51
Mandatory information sharing

1. 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, hereinafter "the prospective applicant", shall ask the competent authority or the Agency whether such tests or studies have already been submitted in connection with a previous application. The competent authority or the Agency shall verify if there is any data on such tests or studies in the Biocides Data Sharing Register.

Where those tests or studies have already been submitted in connection with a previous application, the competent authority or the Agency shall without delay communicate the name and contact details of the owner of the information to the prospective applicant.

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

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

Article 52
Compensation for mandatory information sharing

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

5. An appeal may be brought, in accordance with Article 67, against Agency decisions under paragraph 3 of this Article.

Article 53

Use of data for subsequent applications for authorisations

1. In the case of a biocidal product which has already been authorised in accordance with Articles 15, 25 or 28, and where all periods of protection of information according to Article 49 have expired, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the biocidal product is similar to and its active substances are technically equivalent to the one formerly authorised, including degree of purity and nature of impurities.

An appeal may be brought, in accordance with Article 67, against Agency decisions under the first subparagraph of this paragraph.

2. Notwithstanding paragraph 1, subsequent applicants shall provide the following information accordingly to the receiving competent authority or the Agency:
 - (a) all necessary data for the identification of the biocidal product, including its composition;
 - (b) the information needed to identify the active substance and to establish technical equivalence of the active substance;
 - (c) all necessary data for the evaluation of substances of concern contained in the biocidal product;
 - (d) the data needed to demonstrate that the biocidal product has comparable efficacy to the biocidal product formerly authorised in accordance with Articles 15, 25 or 28.

CHAPTER XII INFORMATION AND COMMUNICATION

Section 1

Monitoring and reporting

Article 54

Compliance with requirements

1. Competent authorities shall take the necessary arrangements for biocidal products which have been placed on the market on their own or incorporated in treated materials to be monitored to establish whether they comply with the requirements of this Regulation. Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93⁴⁶ shall apply accordingly.
2. Competent authorities shall carry out official controls in order to enforce compliance with this Regulation.
3. Every three years, starting in 2013, competent authorities 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 involving biocidal products.
4. The Commission shall draw up a report on the implementation of this Regulation and, in particular, on the functioning of the Community authorisation procedure and mutual recognition, by 1 January 2023. The Commission shall submit the report to the European Parliament and the Council.

Article 55

Confidentiality

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents⁴⁷ and the rules of the Management Board of the Agency, adopted in accordance with Article 118(3) Regulation (EC) No 1907/2006, shall apply to documents held by the Agency for the purposes of this Regulation.
2. Disclosure of the following information shall be deemed to undermine the protection of the commercial interests of the concerned person:
 - (a) details of the full composition of a biocidal product;

⁴⁶ OJ L 218, 13.8.2008, p. 30

⁴⁷ OJ L 145, 31.5.2001, p. 43.

- (b) the precise use, function or application of a substance or mixture;
- (c) the precise tonnage of the substance or mixture manufactured or placed on the market;
- (d) links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product.

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

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

Article 56

Electronic public access

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

- (d) physicochemical data concerning the active substance and data on pathways and environmental fate;
- (e) the result of each toxicological and ecotoxicological study;
- (f) acceptable exposure level or predicted no-effect concentration established in accordance with Annex VI to this Regulation;
- (g) the guidance on safe use provided in accordance with Annex II and Annex III to this Regulation;
- (h) analytical methods if requested in accordance with Annex II or III to this Regulation which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

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

2. The following information on active substances whether on their own, in mixtures or in materials or articles, or information on biocidal products shall be made publicly available, free of charge, except where a party submitting the information submits a justification in accordance with Article 55(3), accepted as valid by the competent authority, the Agency or, as appropriate, the Commission, as to why such publication is potentially harmful for the commercial interests of the applicant or any other party concerned:

- (a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;
- (b) the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e) 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.

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

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

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

Article 57

Record-keeping and reporting

1. Producers, importers and professional users of biocidal products shall keep records of the biocidal products they produce, place on the market or use for at least three years. They shall make available the relevant information contained in these records to the competent authority on request.
2. The Commission shall adopt implementing measures to specify the form and content of the information in the records, and to ensure the uniform application of paragraph 1 in accordance with the procedure referred to in Article 72(3).

Section 2

Information about biocidal products

Article 58

Classification, packaging and labelling of biocidal products

1. Biocidal products shall be classified, packaged and labelled in accordance with Directive 1999/45/EC and, where applicable, Regulation (EC) 1272/2008 and the approved summary of the biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 20(2) of this Regulation.

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

2. Labels shall not be misleading and, in any case, shall not mention the indications ‘low-risk biocidal product’, ‘non-toxic’, ‘harmless’ 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;
 - (c) the type of mixture;
 - (d) the uses for which the biocidal product is authorised;
 - (e) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorisation;
 - (f) particulars of likely direct or indirect adverse side effects and any directions for first aid;
 - (g) if accompanied by a leaflet, the sentence ‘Read attached instructions before use’;
 - (h) directions for safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on reuse of packaging;
 - (i) the formulation batch number or designation and the expiry date relevant to normal conditions of storage;
 - (j) the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by man or animals to the area where the biocidal product has been used, including particulars concerning

decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use, storage and transport;

- (k) where applicable, the categories of users to which the biocidal product is restricted;
- (l) where applicable, information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water;
- (m) 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 (c), (e), (f), (h), (i), (j) and (l) may be indicated on the packaging or on an accompanying leaflet integral to the packaging.

3. Member States may require that biocidal products placed on the market of their territories are labelled in their national language or languages.

Article 59

Safety Data Sheets

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

Article 60

Community Register of Biocidal Products

1. A *Community Register for Biocidal Products* shall be established and maintained by the Commission.
2. The Community Register for Biocidal Products shall be used for the exchange of information between competent authorities, the Agency and the Commission.
3. Applicants shall use the Community Register for Biocidal Products to generate the application form for all procedures relating to the authorisation of biocidal products, the mutual recognition and the parallel trade permit.
4. Competent authorities shall update in the Community Register for Biocidal Products the information relating to biocidal products which have been authorised within their territory or for which a national authorisation has been refused, amended, renewed or cancelled. The Commission shall update the information relating to biocidal products which have been authorised in the Community or for which a Community authorisation has been refused, amended, renewed or cancelled.

5. The Commission may adopt detailed rules on the types of information to be entered in the Community Register for Biocidal Products and the procedures related to it, in accordance with the procedure referred to in Article 72(2).

Article 61

Biocides Data Sharing Register

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

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

Article 62

Advertising

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

Article 63

Poison control

1. Member States shall appoint a body or bodies responsible for receiving information on biocidal products which have been placed on the market, including information on the chemical composition of such products, and for making such information available in cases where suspected poisoning arises from biocidal products.

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

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

CHAPTER XIII THE AGENCY

Article 64

Role of the Agency

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

Article 65

Biocidal Products Committee

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

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

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

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

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

Article 66

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

1. Articles 78 to 84, 89 and 90 of Regulation (EC) No 1907/2006 shall apply *mutatis mutandis* taking into account the role of the Agency with respect to this Regulation.
2. The Secretariat of the Agency referred to in point (g) of Article 76(1) of Regulation (EC) No 1907/2006 shall undertake the following tasks:
 - (a) establishing and maintaining the Biocides Data Sharing Register;
 - (b) performing the tasks relating to the validation of the applications referred to in Articles 7(3), 11(3) and 34(2) of this Regulation;
 - (c) providing technical and scientific guidance and tools for the application of this Regulation by the Commission and the competent authorities of Member States;
 - (d) providing advice and assistance to applicants for the inclusion of an active substance in Annex I or for a Community authorisation;
 - (e) preparing explanatory information on this Regulation;
 - (f) establishing and maintaining database(s) with information on active substances and biocidal products;
 - (g) at the request of the Commission, providing technical and scientific support to improve cooperation between the Community, the competent authorities, international organisations and third countries on scientific and technical issues relating to biocidal products;
 - (h) notification of decisions taken by the Agency;
 - (i) provision of formats for submission of information to the Agency.
3. The Secretariat shall make the information identified in Article 56(1) and (2) in the database(s) publicly available, free of charge, over the Internet, except where a request made under Article 55(3) is considered justified. The Agency shall make other information in the databases available on request in accordance with Article 55.

Article 67

Appeal

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

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

A fee may be payable by a person bringing an appeal in accordance with Article 70(2) of this Regulation.

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

Article 68

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

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

Article 69

Formats and software for submission of information to the Agency

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

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

CHAPTER XIV

FINAL PROVISIONS

Article 70

Fees and charges

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

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted according to the regulatory procedure with scrutiny referred to in Article 72(4).

2. The harmonised structure of fees and conditions of payment shall be based on the following principles:
 - (a) a reduced fee shall be set for small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises⁴⁸;
 - (b) the fee structure shall take into account whether information has been submitted jointly or separately;
 - (c) in duly justified circumstances and where it is accepted by the competent authority or the Agency, it shall be possible to waive the fee;
 - (d) an annual fee shall be paid by persons placing biocidal products on the market; and
 - (e) the structure and amount of the fees shall take account of the work required by this Regulation to be carried out by the Agency and the competent authorities and shall be fixed at such level as to ensure that the revenue derived from the fees when combined with other sources of the Agency's revenue pursuant to this Regulation is sufficient to cover the cost of the services delivered.
3. Member States shall oblige those who have placed or are seeking to place biocidal products on the market and those supporting inclusion of active substances in Annex

⁴⁸ OJ L 124 of 20.5.2003, p. 36

I to pay fees in accordance with the harmonised structure of fees and conditions of payment to be adopted in accordance with paragraph 1.

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

The Agency may collect charges for other services it provides.

Article 71

Competent authorities

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

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

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

Article 72

Standing Committee

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

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

4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
5. Where reference is made to this paragraph, Article 5a (1), (2), (4) and (6), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 73

Adaptation to scientific and technical progress

The Commission may adapt the Annexes to scientific and technical progress.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).

Article 74

Updating of Annex I

By 1 January 2013, the Commission shall, in accordance with the procedure referred to in Article 72(3), amend Annex I with effect from the date of applicability of this Regulation in order to take into account any amendment to Annex I adopted under Directive 98/8/EC since the entry into force of this Regulation.

Article 75

Penalties

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

Article 76

Safeguard clause

Where, based on new evidence, a Member State has justifiable grounds to consider that a biocidal product, although satisfying the requirements of this Regulation, constitutes a serious risk to human or animal health or to the environment, it may take appropriate provisional measures. The Member State shall without delay inform the Commission and the other Member States thereof and give reasons for its decision based on the new evidence.

The Commission shall, in accordance with the procedure referred to in Article 72(3), either authorise the provisional measure for a time period defined in the decision or require the Member State to revoke the provisional measure.

Article 77

Transitional measures

1. The Commission shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC and achieve it by 14 May 2014. The Commission may adopt implementing rules to carry out the work programme and to specify the related rights and obligations of the competent authorities and the participants in the programme. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).

Depending upon the progress of the work programme, the Commission may extend the duration of the work programme for a determined period. That measure, designed

to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 72(4).

During the work programme, the Commission shall decide pursuant to the procedure laid down in Article 72(4) that an active substance shall be included in Annex I of this Regulation and under which conditions, or, in cases where the requirements of Article 4 are not satisfied or where the requisite information and data have not been submitted within the prescribed period, that such active substance shall not be included in Annex I of this Regulation. The decision shall specify the date on which the inclusion in Annex I becomes effective.

2. By way of derogation from Articles 15(1), 16(1) and 18(1) 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 placing biocidal products on the market until two years after the date on which the inclusion in Annex I becomes effective. It may, in particular, according to its national rules, authorise the placing on the market in its territory of a biocidal product containing existing active substances which are evaluated under Regulation (EC) No. 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market⁴⁹ but which are not yet listed in Annex I to this Regulation for that product type.

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

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

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

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

⁴⁹ OJ L 325, 11.12.2007, p. 3

an application for authorisation has not been submitted in accordance with the second subparagraph are allowed until eighteen months after the date on which the inclusion becomes effective.

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

Article 78

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

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

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

Article 79

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

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

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

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

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

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

Article 80

Transitional measures concerning in situ generated active substances

1. Applications for the authorisation of substances, mixtures and devices considered as biocidal products in accordance with the second sentence of point (a) of Article 3(1) which were available on the market on ... [OJ: insert the date referred to in the first subparagraph of Article 85] shall be submitted at the latest by 1 January 2017.
2. Substances, mixtures and devices considered as biocidal products in accordance with the second sentence of point (a) of Article 3(1) which were available on the market on ... [OJ: insert the date referred to in the first subparagraph of Article 85] and for which an application was submitted in accordance with paragraph 1 may continue to be placed on the market until the date of the decision granting the authorisation or refusing to grant the authorisation. In the case of a refusal to grant an authorisation to place such biocidal product on the market, such biocidal product shall no longer be placed on the market within six months after such decision.

Substances, mixtures and devices considered as biocidal products in accordance with the second sentence of point (a) of Article 3(1) which were available on the market on ... [OJ: insert the date referred to in the first subparagraph of Article 85] and for which an application was not submitted in accordance with paragraph 1 may continue to be placed on the market until six months after the date referred to in paragraph 1.

Disposal, storage and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission are allowed until twelve months 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.

Article 81

Transitional measures concerning treated articles and materials

By way of derogation from Article 47, treated articles and materials that incorporate biocidal products which are not authorised in the Community or in at least one Member State and

which were available on the market on ... [OJ: insert the date referred to in the first subparagraph of Article 85] may, until the date of a decision granting authorisation to these biocidal products, continue to be placed on the market if the application for authorisation is submitted at the latest by 1 January 2017. In the case of a refusal to grant an authorisation to place a biocidal product on the market, treated articles and materials that incorporate such biocidal product shall no longer be placed on the market within six months after such decision.

Article 82

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 [OJ: insert the date referred to in the first subparagraph of Article 85] shall be submitted at the latest 1 January 2017.

Food contact materials which were available on the market on [OJ: insert the date referred to in the first subparagraph of Article 85] for which an application was submitted in accordance with paragraph 1 may continue to be placed on the market until the date of the decision granting the authorisation or refusing to grant the authorisation. In case of a refusal to grant an authorisation to place such biocidal product on the market, such biocidal product shall no longer be placed on the market within six months after such decision.

Food contact materials which were available on the market on [OJ: insert the date referred to in the first subparagraph of Article 85] for which an application was not submitted in accordance with paragraph 1 may continue to be placed on the market until six months after the date referred to in paragraph 1.

2. Disposal, storage and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission is allowed until twelve months 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 83

Transitional measures concerning access to the active substance dossier

As of 1 January 2014, the person responsible for the placing on the market of a biocidal product containing one or more existing active substances shall own a dossier or have a letter of access to a dossier, or to each component of the dossier, satisfying the requirements set out in Annex II for each of these active substances unless all relevant protection periods referred to in Article 49 have expired.

Biocidal products for which the person responsible for the placing on the market does not fulfil the requirement of the first subparagraph shall no longer be placed on the market.

Disposal, storage and use of existing stocks of biocidal products which do not fulfil the requirement of the first subparagraph is allowed until 1 January 2015.

Article 84

Repeal

Without prejudice to Article 78 and 79, Directive 98/8/EC is hereby repealed.

References to the repealed Directive shall be construed as references to this Regulation.

Article 85

Entry into force

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

It shall apply from 1 January 2013.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS FOR INCLUSION IN BIOCIDAL PRODUCTS

Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 77(3) (except for products containing more than one active substance, for which the deadline to comply with Article 77(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
sulfuryl fluoride	sulfuryl difluoride EC No: 220-281-5 CAS No: 2699-79-8	994 g/kg	1 January 2009	31 December 2010	31 December 2018	8	Authorisations are subject to the following conditions: (1) the product may only be sold to and used by professionals trained to use it; (2) appropriate risk mitigation measures are included for operators and bystanders; (3) concentrations of sulfuryl fluoride in remote tropospheric air are monitored. Reports of the monitoring referred to in point (3)

							are to be transmitted by authorisation holders directly to the Commission every fifth year starting from 1 January 2009.
dichlofluanid	N-(Dichlorofluoromethylthio)-N',N'-dimethyl-N-phenylsulfamide EC No: 214-118-7 CAS No: 1085-98-9	960 g/kg	1 March 2009	28 February 2011	28 February 2019	8	Authorisations are subject to the following conditions: (1) Products authorised for industrial and/or professional use must be used with appropriate personal protective equipment. (2) In view of the risks identified for the soil compartment appropriate risk mitigation measures must be taken to protect that compartment. (3) Labels and/or safety-data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for re-use or disposal.
clothianidin	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine EC No: 433-460-1 CAS No: 210880-92-5	950 g/kg	1 February 2010	31 January 2012	31 January 2020	8	Authorisations are subject to the following conditions: In view of the risk identified for the soil, surface water and groundwater compartments, products shall not be authorised for the treatment of wood that will be used outdoors unless data is submitted to demonstrate that the product will meet the requirements of Article 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use indicate that freshly treated timber shall be stored after treatment on impermeable hard

							standing to prevent direct losses to soil and that any losses shall be collected for reuse or disposal.
Difethialone	3-[3-(4'-bromo[1,1'biphenyl]-4-yl)-1,2,3,4-tetrahydronaphth-1-yl]-4-hydroxy-2H-1-benzothiopyran-2-one EC No: n/a CAS No: 104653-34-1	976 g/kg	1 November 2009	31 October 2011	31 October 2014	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance shall be considered a candidate for substitution in accordance with Article 9. Authorisations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 0,0025 % w/w and only ready-for-use baits shall be authorised. (2) Products shall contain an aversive agent and, where appropriate, a dye. (3) Products shall not be used as tracking powder. (4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
etofenprox	3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-	970 g/kg	1 February 2010	31 January 2012	31 January 2020	8	Authorisations are subject to the following conditions:

	<p>methylpropylether</p> <p>EC No: 407-980-2</p> <p>CAS No: 80844-07-1</p>						<p>In view of the risk identified for workers, products cannot be used year round unless dermal absorption data is provided to demonstrate that there are no unacceptable risks from chronic exposure. In addition, products intended for industrial use shall be used with appropriate personal protective equipment.</p>
tebuconazole	<p>1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol</p> <p>EC No: 403-640-2</p> <p>CAS No: 107534-96-3</p>	950 g/kg	1 April 2010	31 March 2012	31 March 2020	8	<p>Authorisations are subject to the following conditions:</p> <p>In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal.</p> <p>In addition, products shall not be authorised for the <i>in situ</i> treatment of wood outdoors or for wood that will be in continuous contact with water unless data is submitted to demonstrate that the product will meet the requirements of Article 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures.</p>
carbon dioxide	<p>carbon dioxide</p> <p>EC No: 204-696-9</p> <p>CAS No: 124-38-9</p>	990 ml/l	1 November 2009	31 October 2011	31 October 2019	14	
→propiconazole	<p>1-[[2-(2,4-</p>	930 g/kg	1 April 2010	31 March 2012	31 March 2020	8	<p>Authorisations are subject to the following</p>

	<p>dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole</p> <p>EC No: 262-104-4</p> <p>CAS No: 60207-90-1</p>						<p>conditions:</p> <p>In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means.</p> <p>In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal.</p> <p>In addition, products shall not be authorised for the <i>in situ</i> treatment of wood outdoors or for wood that will be exposed to weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures.</p>
Difenacoum	<p>3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin</p> <p>EC No: 259-978-4</p>	960 g/kg	1 April 2010	31 March 2012	31 March 2015	14	<p>In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance shall be considered a candidate for substitution in accordance with Article 9.</p> <p>Authorisations are subject to the following</p>

	CAS No: 56073-07-5						<p>conditions:</p> <p>(1) The nominal concentration of the active substance in the products shall not exceed 75 mg/kg and only ready-for-use products shall be authorised.</p> <p>(2) Products shall contain an aversive agent and, where appropriate, a dye.</p> <p>(3) Products shall not be used as tracking powder.</p> <p>(4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.</p>
K-HDO	<p>Cyclohexylhydroxydi azene 1-oxide, potassium salt</p> <p>EC No: n/a</p> <p>CAS No: 66603-10-9</p> <p>(This entry also covers the hydrated forms of K-HDO)</p>	977 g/kg	1 July 2010	30 June 2012	30 June 2020	8	<p>Authorisations are subject to the following conditions:</p> <p>(1) in view of the possible risks for the environment and workers, products shall not be used in other systems than industrial, fully automated and closed ones unless the application for product authorisation demonstrates that risks can be reduced to acceptable levels in accordance with Article 16 and Annex VI;</p> <p>(2) in view of the assumptions made during the risk assessment, products shall be used</p>

							<p>with appropriate personal protective equipment, unless the application for product authorisation demonstrates that risks to users can be reduced to acceptable levels by other means;</p> <p>(3) in view of the risk identified for infants, products shall not be used for the treatment of wood that may enter in direct contact with infants.</p>
IPBC	<p>3-iodo-2-propynyl butylcarbamate</p> <p>EC No: 259-627-5</p> <p>CAS No: 55406-53-6</p>	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	<p>Authorisations are subject to the following conditions:</p> <p>In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means.</p> <p>In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal.</p>
Thiabendazole	2-thiazol-4-yl-1H-benzoimidazole	985 g/kg	1 July 2010	30 June 2012	30 June 2020	8	<p>Authorisations are subject to the following conditions:</p> <p>In view of the assumptions made during the risk</p>

	<p>EC No: 205-725-8</p> <p>CAS No: 148-79-8</p>						<p>assessment, products authorised for industrial and/or professional use, with respect to the double-vacuum and dipping application tasks, shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by others means.</p> <p>In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal.</p> <p>Products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures.</p>
thiamethoxam	<p>thiamethoxam</p> <p>EC No: 428-650-4</p> <p>CAS No: 153719-23-4</p>	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	<p>Authorisations are subject to the following conditions:</p> <p>In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable</p>

							<p>level by other means.</p> <p>In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures shall be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses shall be collected for reuse or disposal.</p> <p>Products shall not be authorised for the <i>in situ</i> treatment of wood outdoors or for wood that will be exposed to weathering, unless data have been submitted to demonstrate that the product will meet the requirements of Article 16 and Annex VI, if necessary by the application of appropriate risk mitigation measures.</p>
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(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website:
<http://ec.europa.eu/comm/environment/biocides/index.htm>

ANNEX II

Data requirements for active substances

1. Dossiers on active substances shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL), Predicted Environmental Concentration (PEC) and Predicted No-Effect Concentration (PNEC).
2. Information which is however not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied.
3. A detailed and full description of the studies conducted and of the methods used or a bibliographical reference to those methods shall be included.

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

4. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Council Regulation (EC) No 440/2008⁵⁰. 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.
5. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes⁵¹, 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 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 substances⁵² or other international standards recognised as being equivalent by the Commission or the Agency.
6. Where testing is done, a detailed description (specification) of the material used and its impurities must be provided.
7. Where test data exist that have been generated before ... [*OJ: insert the date referred to in the first subparagraph of Article 85*] 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.

⁵⁰ OJ L 142, 31.5.2008, p. 1.

⁵¹ OJ L 358, 18.12.1986, p. 1.

⁵² OJ L 50, 20.2.2004, p. 44.

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

TITLE 1 – CHEMICAL SUBSTANCES

TIER I

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

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

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

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

<i>Information required:</i>	<i>Unless otherwise indicated, all data shall be provided at Tier I.</i>	<i>Specific rules for adaptation from standard information required:</i>
1. Applicant		
1.1. Name and address		
1.2. Active substance manufacturer (name, address, location of plant)		
2. Identity of the active substance		
2.1. Common name proposed or accepted by ISO and synonyms		
2.2. Chemical name (IUPAC nomenclature)		
2.3. Manufacturer's development code number(s)		

2.4. CAS and EC numbers (if available)		
2.5. Molecular and structural formula (including full details of any isomeric composition), molecular mass		
2.6. Method of manufacture (syntheses pathway in brief terms) of active substance		
2.7. Specification of purity of the active substance in g/kg or g/l, as appropriate		
2.8. Identity of impurities and additives (e.g. stabilisers), together with the structural formula and the possible range expressed as g/kg or g/l, as appropriate		
2.9. The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower		
2.10. Exposure data in conformity with Annex VIIA to Directive 92/32/EEC		
3. Physical and chemical properties of the active substance		
3.1. State of the substance at 20°C and 101,3 kPa		
3.2. Melting/freezing point		3.2. The study does not need to be conducted below a lower limit of -20°C.
3.3. Boiling point		3.3. The study does not need to be conducted: <ul style="list-style-type: none"> – for gases; or – for solids which either melt above 300°C or decompose before boiling. In such cases the boiling point under reduced pressure may be estimated or measured; or – for substances which decompose before boiling (e.g. auto-oxidation, rearrangement, degradation, decomposition, etc.).
3.4. Relative density		3.4. The study does not need to be conducted if: <ul style="list-style-type: none"> – the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density is sufficient; or

		<p>– the substance is a gas. In this case, an estimation based on calculation shall be made from its molecular weight and the Ideal Gas Laws.</p>
3.5. Vapour pressure		<p>3.5. The study does not need to be conducted if the melting point is above 300°C.</p> <p>If the melting point is between 200°C and 300°C, a limit value based on measurement or a recognised calculation method is sufficient.</p>
3.6. Surface tension		<p>3.6. The study need only be conducted if:</p> <ul style="list-style-type: none"> – based on structure, surface activity is expected or can be predicted; or – surface activity is a desired property of the material. <p>If the water solubility is below 1 mg/l at 20°C the test does not need to be conducted.</p>
3.7. Water solubility		<p>3.7. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> – the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours); or – the substance is readily oxidisable in water. <p>If the substance appears "insoluble" in water, a limit test up to the detection limit of the analytical method shall be performed.</p>
3.8. Partition coefficient n-octanol/water		<p>3.8. The study does not need to be conducted if the substance is inorganic. If the test cannot be performed (e.g. the substance decomposes, has a high surface activity, reacts violently during the performance of the test or does not dissolve in water or in octanol, or it is not possible to obtain a sufficiently pure substance), a calculated value for log P as well as details of the calculation method shall be provided.</p>
3.9. Flash-point		<p>3.9. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> – the substance is inorganic; or – the substance only contains volatile organic components with flash-points above 100°C for aqueous solutions; or – the estimated flash-point is above 200°C; or

		<ul style="list-style-type: none"> – the flash-point can be accurately predicted by interpolation from existing characterised materials.
3.10. Flammability		<p>3.10. The study does not need to be conducted:</p> <ul style="list-style-type: none"> – if the substance is a solid which possesses explosive or pyrophoric properties. These properties should always be considered before considering flammability; or – for gases, if the concentration of the flammable gas in a mixture with inert gases is so low that, when mixed with air, the concentration is all time below the lower limit; or – for substances which spontaneously ignite when in contact with air.
3.11. Explosive properties		<p>3.11. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> – there are no chemical groups associated with explosive properties present in the molecule; or – the substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than –200; or – the organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties, but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500 °C; or - for mixtures of inorganic oxidising substances (UN Division 5.1) with organic materials, the concentration of the inorganic oxidising substance is: <ul style="list-style-type: none"> – less than 15 %, by mass, if assigned to UN Packaging Group I (high hazard) or II (medium hazard) – less than 30 %, by mass, if assigned to UN Packaging Group III (low hazard). <p>Note: Neither a test for propagation of detonation nor a test for sensitivity to detonative shock is required if the exothermic decomposition energy of organic materials is less than 800 J/g.</p>

3.12. Self-ignition temperature		<p>3.12. The study does not need to be conducted:</p> <ul style="list-style-type: none"> – if the substance is explosive or ignites spontaneously with air at room temperature; or – for liquids non flammable in air, e.g. no flash point up to 200°C; or – for gases having no flammable range; or – for solids, if the substance has a melting point < 160°C, or if preliminary results exclude self-heating of the substance up to 400°C.
3.13. Oxidising properties		<p>3.13. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> – the substance is explosive; or – the substance is highly flammable; or – the substance is an organic peroxide; or – the substance is incapable of reacting exothermically with combustible materials, for example on the basis of the chemical structure (e.g. organic substances not containing oxygen or halogen atoms and these elements are not chemically bonded to nitrogen or oxygen, or inorganic substances not containing oxygen or halogen atoms). <p>The full test does not need to be conducted for solids if the preliminary test clearly indicates that the test substance has oxidising properties.</p> <p>Note that as there is no test method to determine the oxidising properties of gaseous mixtures, the evaluation of these properties must be realised by an estimation method based on the comparison of the oxidising potential of gases in a mixture with that of the oxidising potential of oxygen in air.</p>
3.14. Granulometry		<p>3.14. The study does not need to be conducted if the substance is marketed or used in a non solid or granular form.</p>
3.15. Stability in organic solvents and identity of relevant degradation products	Tier II	<p>3.15. Stability in organic solvents and identity of relevant degradation products</p> <p>Only required if stability of the substance is considered to be critical.</p>

3.16. Dissociation constant	Tier II	3.16. Dissociation constant
3.17. Viscosity	Tier II	3.17. Viscosity
3.18. Solubility in organic solvents, including effect of temperature on solubility ⁵³	Tier II	
3.19. Stability in organic solvents used in biocidal products and identity of relevant breakdown products ⁵⁴	Tier II	
4. Methods of detection and identification		
4.1. Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of the active substance and additives (e.g. stabilisers)		
4.2. Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof		
4.3 Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, in/on food or feedingstuffs and other products where relevant	Tier II	
5. Effectiveness against target organisms and intended uses		
5.1. Function, e.g. fungicide, rodenticide, insecticide, bactericide		
5.2. Organism(s) to be controlled and products, organisms or objects to be protected		
5.3. Effects on target organisms, and likely concentration at which the active substance will be used		
5.4. Mode of action (including time delay)		
5.5. Field of use envisaged		
5.6. User: industrial, professional, general public (non-professional)		

⁵³ These data must be submitted for the purified active substance of stated specification.

⁵⁴ These data must be submitted for the active substance of stated specification.

5.7. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies		
5.8. Likely tonnage to be placed on the market per year		
6. Toxicological profile for man and animals including metabolism		
6.1. Skin irritation or skin corrosion		<p>6.1. The assessment of this endpoint shall comprise the following consecutive steps:</p> <ol style="list-style-type: none"> (1) an assessment of the available human and animal data, (2) an assessment of the acid or alkaline reserve, (3) in vitro study for skin corrosion, (4) in vitro study for skin irritation. <p>Steps 3 and 4 do not need to be conducted if:</p> <ul style="list-style-type: none"> – the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes; or – the substance is flammable in air at room temperature; or – the substance is classified as very toxic in contact with skin; or – an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight).
6.1.1. In vivo skin irritation		<p>6.1.1. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> – the substance is classified as corrosive to the skin or as a skin irritant; or – the substance is a strong acid (pH < 2,0) or base (pH > 11,5); or – the substance is flammable in air at room temperature; or – the substance is classified as very toxic in contact with skin; or – an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight).
6.2. Eye irritation		<p>6.2. The assessment of this endpoint shall comprise the following consecutive steps:</p>

		<p>(1) an assessment of the available human and animal data,</p> <p>(2) an assessment of the acid or alkaline reserve,</p> <p>(3) in vitro study for eye irritation.</p> <p>Step 3 does not need to be conducted if:</p> <ul style="list-style-type: none"> – the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes; or – the substance is flammable in air at room temperature.
6.2.1. In vivo eye irritation		<p>6.2.1. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> – the substance is classified as irritating to eyes with risk of serious damage to eyes; or – the substance is classified as corrosive to the skin and provided that the applicant classified the substance as eye irritant; or – the substance is a strong acid (pH < 2,0) or base (pH > 11,5); or – the substance is flammable in air at room temperature.
6.3. Skin sensitisation		<p>6.3. The assessment of this endpoint shall comprise the following consecutive steps:</p> <p>(1) an assessment of the available human, animal and alternative data,</p> <p>(2) In vivo testing.</p> <p>Step 2 does not need to be conducted if:</p> <ul style="list-style-type: none"> – the available information indicates that the substance should be classified for skin sensitisation or corrosivity; or – the substance is a strong acid (pH < 2,0) or base (pH > 11,5); or – the substance is flammable in air at room temperature. <p>The Murine Local Lymph Node Assay (LLNA) is the first-choice method for in vivo testing. Only in exceptional circumstances should another test be used. Justification for the use of another test shall be provided.</p>

6.4. Mutagenicity		6.4. Appropriate in vivo mutagenicity studies shall be considered in case of a positive result in any of the genotoxicity studies in Tier I.
6.4.1. In vitro gene mutation study in bacteria		6.4.1. Further mutagenicity studies shall be considered in case of a positive result.
6.4.2. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study		6.4.2. The study does not usually need to be conducted if: – adequate data from an in vivo cytogenicity test are available or – the substance is known to be carcinogenic category 1A or 1B or mutagenic category 1A, 1B or 2.
6.4.3. In vitro gene mutation study in mammalian cells, if a negative result in Tier I, sections 6.4.1. and section 6.4.2.		6.4.3. The study does not usually need to be conducted if adequate data from a reliable in vivo mammalian gene mutation test are available.
6.4.4. In vivo genotoxicity study	Tier II	6.4.4 If there is a positive result in any of the in vitro genotoxicity studies in Tier I and there are no results available from an in vivo study already, an appropriate in vivo somatic cell genotoxicity study shall be proposed by the applicant. If there is a positive result from an in vivo somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.
6.5. Acute toxicity		6.5. The study/ies do(es) not generally need to be conducted if: – the substance is classified as corrosive to the skin. In addition to the oral route (6.5.1), for substances other than gases, the information mentioned under 6.5.2 to 6.5.3 shall be provided for at least one other route. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route need be provided.
6.5.1. By oral route		6.5.1. The study need not be conducted if a study on acute toxicity by the inhalation route (6.5.2) is available.

6.5.2. By inhalation		6.5.2. Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.
6.5.3. By dermal route		6.5.3. Testing by the dermal route is appropriate if: (1) inhalation of the substance is unlikely; and (2) skin contact in production and/or use is likely; and (3) the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.
6.6. Repeated dose toxicity		
6.6.1. Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure.		6.6.1. The short-term toxicity study (28 days) does not need to be conducted if: – a reliable sub-chronic (90 days) or chronic toxicity study is available, provided that an appropriate species, dosage, solvent and route of administration were used; or – where a substance undergoes immediate disintegration and there are sufficient data on the cleavage products; or – relevant human exposure can be excluded in accordance with Annex IV section 3 The appropriate route shall be chosen on the following basis: Testing by the dermal route is appropriate if: (1) inhalation of the substance is unlikely; and (2) skin contact in production and/or use is likely; and (3) the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin. Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of

		<p>an inhalable size.</p> <p>The sub-chronic toxicity study (90 days) (Tier II, section 6.6.2) shall be proposed by the applicant if: the frequency and duration of human exposure indicates that a longer term study is appropriate;</p> <p>and one of the following conditions is met:</p> <ul style="list-style-type: none"> – other available data indicate that the substance may have a dangerous property that cannot be detected in a short-term toxicity study; or – 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. <p>Further studies shall be proposed by the applicant or may be required in case of:</p> <ul style="list-style-type: none"> – failure to identify a NOAEL in the 28 or the 90 days study, unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects; or – toxicity of particular concern (e.g. serious/severe effects); or – indications of an effect for which the available evidence 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); or – the route of exposure 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; or – particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected); or – 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.
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<p>6.6.2. Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure.</p>	<p>Tier II</p>	<p>6.6.2. The sub-chronic toxicity study (90 days) does not need to be conducted if:</p> <ul style="list-style-type: none"> – a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure; or – a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used; or – a substance undergoes immediate disintegration and there are sufficient data on the cleavage products (both for systemic effects and effects at the site of uptake); or – the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day "limit test", particularly if such a pattern is coupled with limited human exposure. <p>The appropriate route shall be chosen on the following basis:</p> <p>Testing by the dermal route is appropriate if:</p> <ol style="list-style-type: none"> (1) skin contact in production and/or use is likely; and (2) the physicochemical properties suggest a significant rate of absorption through the skin; and (3) one of the following conditions is met: <ul style="list-style-type: none"> – toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test; or – systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies; or – in vitro tests indicate significant dermal absorption; or – significant dermal toxicity or dermal penetration is recognised for structurally related substances.
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		<p>Testing by the inhalation route is appropriate if:</p> <ul style="list-style-type: none"> – exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size. <p>Further studies shall be proposed by the applicant or may be required in case of:</p> <ul style="list-style-type: none"> – failure to identify a NOAEL in the 90 days study unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects; or – toxicity of particular concern (e.g. serious/severe effects); or – indications of an effect for which the available evidence 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); or – particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected).
6.6.3. Long-term repeated toxicity study (≥ 12 months)	Tier II	<p>6.6.3. A long-term repeated toxicity study (≥ 12 months) may be proposed by the applicant or required if the frequency and duration of human exposure indicates that a longer term study is appropriate and one of the following conditions is met:</p> <ul style="list-style-type: none"> – serious or severe toxicity effects of particular concern were observed in the 28-day or 90-day study for which the available evidence is inadequate for toxicological evaluation or risk characterisation; or – effects shown in substances with a clear relationship in molecular structure with the substance being studied were not detected in the 28-day or 90-day study; or – the substance may have a dangerous property that cannot be detected in a 90-day study.
6.6.4. Further studies	Tier II	<p>6.6.4. Further studies shall be proposed by the applicant or may be required in case of:</p>

		<ul style="list-style-type: none"> – toxicity of particular concern (e.g. serious/severe effects); or – indications of an effect for which the available evidence is inadequate for toxicological evaluation and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity); or <p>– particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity is observed).</p> <p>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered.</p>
6.7. Reproductive toxicity	Tier II	<p>6.7. The studies need not be conducted if:</p> <ul style="list-style-type: none"> – the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or – the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or – the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure. <p>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered.</p> <p>If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a</p>

		robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.
6.7.1. Screening for reproductive/developmental toxicity, one species (OECD 421 or 422), if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from in vitro methods that the substance may be a developmental toxicant.		<p>6.7.1. This study does not need to be conducted if:</p> <ul style="list-style-type: none"> – the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or – the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or – relevant human exposure can be excluded in accordance with Annex IV section 3; or – a pre-natal developmental toxicity study (Tier II, 6.7.2) or a two-generation reproductive toxicity study (Tier II, section 6.7.3) is available. <p>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered.</p> <p>If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.</p> <p>In cases where there are serious concerns about the potential for adverse effects on fertility or development, either a pre-natal developmental toxicity study (Tier II, section 6.7.2) or a two generation reproductive toxicity study (Tier II, section 6.7.3) may be proposed by the applicant instead of the screening study.</p>
6.7.2. Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (B.31 of the Regulation (EC) No 440/2008 or OECD 414).	Tier II	6.7.2. The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data.

6.7.3. Two-generation reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided as part of Tier I requirements	Tier II	6.7.3. The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data.
6.8. Toxicokinetics		
6.8.1. Dermal absorption study		
6.9. Carcinogenicity study	Tier II	<p>6.9. A carcinogenicity study may be proposed by the applicant or may be required if:</p> <ul style="list-style-type: none"> – the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure; and – the substance is classified as mutagen category 2 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-neoplastic lesions. <p>If the substance is classified as mutagen category 1A or 1B, the default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required.</p>
6.9.1. Medical surveillance data on manufacturing plant personnel if available		
6.9.2. Direct observation, e.g. clinical cases, poisoning incidents if available		
6.9.3. Health records, both from industry and any other available sources		
6.9.4. Epidemiological studies on the general population, if available		
6.9.5. Diagnosis of poisoning including specific signs of poisoning and clinical tests, if available		
6.9.6. Sensitisation/allergenicity observations, if available		
6.9.7. Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known		
6.9.8. Prognosis following poisoning		

6.10. Summary of mammalian toxicology and conclusions, including no observed adverse effect level (NOAEL), no observed effect level (NOEL), overall evaluation with regard to all toxicological data and any other information concerning the active substances. Where possible any suggested worker protection measures should be included in summary form		
6.11 Additional studies	Tier II	Additional data which may be required depending on the characteristics and intended use of the active substance.
6.11.1 Neurotoxicity study	Tier II	If the active substance is an organophosphorus compound or if there are any other indications that the active substance may have neurotoxic properties then neurotoxicity studies will be required. The test species is the adult hen unless another test species is justified to be more appropriate. If appropriate, delayed neurotoxicity tests will be required. If anticholine esterase activity is detected a test for response to reactivating agents should be considered
6.11.2. Toxic effects on livestock and pets	Tier II	
6.11.3. Studies related to the exposure of the active substance to humans	Tier II	
6.11.4. Food and feedingstuffs	Tier II	If the active substance is to be used in mixtures for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored the tests referred to in Section 9.1 shall be required
6.11.5. If any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, are considered necessary, then the test(s) referred to in Section 9.1, Title I of Annex III shall be required	Tier II	
6.11.6. If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required	Tier II	
6.11.7. Mechanistic study - any studies necessary to clarify effects	Tier II	

reported in toxicity studies		
7. Ecotoxicological profile including environmental fate and behaviour		
7.1. Aquatic toxicity		7.1. Long-term toxicity testing shall be proposed by the applicant if the assessment performed under Tier I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the assessment performed under Tier I.
7.1.1. Short-term toxicity testing on invertebrates (preferred species Daphnia) The applicant may consider long-term toxicity testing instead of short-term.		7.1.1. The study does not need to be conducted if: – there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes; or – a long-term aquatic toxicity study on invertebrates is available; or – adequate information for environmental classification and labelling is available. The long-term aquatic toxicity study on Daphnia (Tier II, section 7.1.5) shall be considered if the substance is poorly water soluble.
7.1.2. Growth inhibition study aquatic plants (algae preferred)		7.1.2. The study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.
7.1.3. Short-term toxicity testing on fish: The applicant may consider long-term toxicity testing instead of short-term.		7.1.3. The study does not need to be conducted if: – there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes; or – a long-term aquatic toxicity study on fish is available.
7.1.4. Activated sludge respiration inhibition testing		7.1.4. The study does not need to be conducted if: – there is no emission to a sewage treatment plant; or – there are mitigating factors indicating that

		<p>microbial toxicity is unlikely to occur, for instance the substance is highly insoluble in water; or</p> <ul style="list-style-type: none"> – the substance is found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant. <p>The study may be replaced by a nitrification inhibition test if available data show that the substance is likely to be an inhibitor of microbial growth or function, in particular nitrifying bacteria.</p>
7.1.5. Long-term toxicity testing on invertebrates (preferred species Daphnia), (unless already provided as part of Tier I requirements)	Tier II	
7.1.6. Long-term toxicity testing on fish, (unless already provided as part of Tier I requirements)	Tier II	
The information shall be provided for one of the sections 7.1.6.1, 7.1.6.2 or 7.1.6.3.		
7.1.6.1. Fish early-life stage (FELS) toxicity test	Tier II	
7.1.6.2. Fish short-term toxicity test on embryo and sac-fry stages	Tier II	
7.1.6.3. Fish, juvenile growth test	Tier II	
7.2. Degradation		7.2. Further biotic degradation testing shall be considered if the assessment performed under Tier I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the assessment performed under Tier I and may include simulation testing in appropriate media (e.g. water, sediment or soil).
7.2.1. Biotic		
7.2.1.1. Ready biodegradability		7.2.1.1. The study does not need to be conducted if the substance is inorganic.
7.2.1.2. Simulation testing on ultimate degradation in surface water	Tier II	7.2.1.2. The study need not be conducted if: <ul style="list-style-type: none"> – the substances is highly insoluble in water; or – the substance is readily biodegradable.

7.2.1.3. Soil simulation testing (for substances with a high potential for adsorption to soil)	Tier II	7.2.1.3. The study need not be conducted: – if the substance is readily biodegradable; or – if direct and indirect exposure of soil is unlikely.
7.2.1.4. Sediment simulation testing (for substances with a high potential for adsorption to sediment)	Tier II	7.2.1.4. The study need not be conducted: – if the substance is readily biodegradable; or – if direct and indirect exposure of sediment is unlikely.
7.2.2. Abiotic		
7.2.2.1. Hydrolysis as a function of pH.		7.2.2.1. The study does not need to be conducted if: – the substance is readily biodegradable; or – the substance is highly insoluble in water.
7.2.3. Identification of degradation products	Tier II	7.2.3. Unless the substance is readily biodegradable
7.3. Fate and behaviour in the environment		
7.3.1. Adsorption/desorption screening		7.3.1. The study does not need to be conducted if: – based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient); or – the substance and its relevant degradation products decompose rapidly.
7.3.2. Bioaccumulation in aquatic species, preferably fish	Tier II	7.3.2. The study need not be conducted if: – the substance has a low potential for bioaccumulation (for instance a log Kow < 3) and/or a low potential to cross biological membranes; or – direct and indirect exposure of the aquatic compartment is unlikely.
7.3.3. Additional information on adsorption/desorption depending on the results of the study required under Tier I	Tier II	7.3.3. The study need not be conducted if: – the substance has a low potential for bioaccumulation (for instance a log Kow < 3) and/or a low potential to cross biological membranes; or

		<p>– based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient); or</p> <p>– the substance and its degradation products decompose rapidly.</p>
7.4. Additional studies	Tier II	
7.4.1. Acute toxicity test on one other, non-aquatic, non-target organism	Tier II	
7.4.2. Any other biodegradability tests that are relevant from the results in section 7.2.1.1	Tier II	
7.4.3. Phototransformation in air (estimation method), including identification of breakdown products	Tier II	
7.4.4. If the results from section 7.4.2 indicate the need to do so, or the active substance has an overall low or absent abiotic degradation, then the tests described in sections 10.1.1 and 10.2.1 and, where appropriate, section 10.3 shall be required	Tier II	
8. Measures necessary to protect man, animals and the environment	Tier II	Additional data which may be required depending on the characteristics and intended use of the active substance.
<p>8.1. 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 substances⁵⁵.</p> <p>Notes:</p> <p>(1) These data must be submitted for the purified active substance of stated specification.</p> <p>(2) These data must be submitted for the active substance of stated specification.</p>	Tier II	
9. Additional human health-related studies	Tier II	Additional data which may be required depending on the characteristics and intended use of the active substance.
9.1. Food and feedingstuffs studies	Tier II	

⁵⁵ OJ L 20, 26.1.1980, p. 43.

9.1.1. Identification of degradation and reaction products and of metabolites of the active substance in treated or contaminated foods or feedingstuffs	Tier II	
9.1.2. Behaviour of the residue of the active substance, its degradation products and, where relevant, its metabolites on the treated or contaminated food or feedingstuffs including the kinetics of disappearance	Tier II	
9.1.3. Overall material balance for the active substance. Sufficient residue data from supervised trials to demonstrate that residues likely to arise from the proposed use would not be of concern for human or animal health	Tier II	
9.1.4. Estimation of potential or actual exposure of the active substance to humans through diet and other means	Tier II	
9.1.5. If residues of the active substance remain on feedingstuffs for a significant period of time then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin	Tier II	
9.1.6. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the active substance	Tier II	
9.1.7. Proposed acceptable residues and the justification of their acceptability	Tier II	
9.1.8. Any other available information that is relevant	Tier II	
9.1.9. Summary and evaluation of data submitted under 1.1 to 1.8	Tier II	
9.2. Other test(s) related to the exposure to humans Suitable test(s) and a reasoned case will be required	Tier II	
10. Additional studies on fate and behaviour in the environment	Tier II	10. If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in this Section shall be conducted.
10. Fate and behaviour in soil	Tier II	

10.1.1. Rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions	Tier II	
10.1.2. Absorption and desorption in at least three soil types and, where relevant, absorption and desorption of metabolites and degradation products	Tier II	
10.1.3. Mobility in at least three soil types and where relevant mobility of metabolites and degradation products	Tier II	
10.1.4. Extent and nature of bound residues	Tier II	
10.2. Fate and behaviour in water	Tier II	
10.2.1. Rate and route of degradation in aquatic systems (as far as is not covered by section 7.2) including identification of metabolites and degradation products	Tier II	
10.2.2. Absorption and desorption in water (soil sediment systems) and, where relevant, absorption and desorption of metabolites and degradation products	Tier II	
10.3. Fate and behaviour in air If the active substance is to be used in mixtures for fumigants, if it is to be applied by a spray method, if it is volatile, or if any other information indicates that this is relevant, then the rate and route of degradation in air shall be determined as far as is not covered by section 7.4.3	Tier II	
11. Additional ecotoxicological studies	Tier II	11. If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in this Section shall be conducted.
11.1. Effects on birds	Tier II	
11.1.1. Acute oral toxicity - this need not be done if an avian species was selected for study in section 7.4.1	Tier II	
11.1.2. Short-term toxicity - eight-day dietary study in at least one species (other than chickens)	Tier II	

11.1.3. Effects on reproduction	Tier II	
11.2. Effects on aquatic organisms	Tier II	
11.2.1. Prolonged toxicity to an appropriate species of fish	Tier II	
11.2.2. Effects on reproduction and growth rate on an appropriate species of fish	Tier II	
11.2.3. Bioaccumulation in an appropriate species of fish	Tier II	
11.2.4. Daphnia magna reproduction and growth rate	Tier II	
11.3. Effects on other non-target organisms	Tier II	
11.3.1. Acute toxicity to honeybees and other beneficial arthropods, e.g. predators. A different test organism shall be chosen from that used in section 7.4.1	Tier II	
11.3.2. Toxicity to earthworms and to other soil non-target macro-organisms	Tier II	
11.3.3. Effects on soil non-target micro-organisms	Tier II	
11.3.4. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk	Tier II	
12. Classification and labelling		
13. Summary and evaluation of Sections 1 to 12		

TITLE 2 - MICRO-ORGANISMS

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

Where the micro-organism has been genetically modified within the meaning of Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC⁵⁶, a copy of the evaluation of the data concerning the assessment of the risks to the environment as established in Article 4(2) of that Directive, shall also be submitted.

If the biocidal product action is known to be partly or entirely due to the effect of a toxin/metabolite, or if significant residues of toxins/metabolites are to be expected not related to the effect of the active micro-organism, a dossier for the toxin/metabolite shall be submitted in accordance with the requirements of Title 1.

The following data will be required to support submissions.

1. Identity of the micro-organism
 - 1.1. Applicant
 - 1.2. Manufacturer
 - 1.3. Name and species description, strain characterisation
 - 1.3.1. Common name of the micro-organism (including alternative and superseded names)
 - 1.3.2. Taxonomic name and strain indicating whether it is a stock variant, a mutant strain or a genetically modified organism (GMO); for viruses, taxonomic designation of the agent, serotype, strain or mutant
 - 1.3.3. Collection and culture reference number where the culture is deposited
 - 1.3.4. Methods, procedures and criteria used to establish the presence and identity of the micro-organism (e.g. morphology, biochemistry, serology, etc.)
 - 1.4. Specification of the material used for manufacturing of formulated products
 - 1.4.1. Content of the micro-organism
 - 1.4.2. Identity and content of impurities, additives, contaminating micro-organisms
 - 1.4.3. Analytical profile of batches
2. Biological properties of the micro-organism

⁵⁶ OJ L 106, 17.4.2001, p. 1

- 2.1. History of the micro-organism and its uses. Natural occurrence and geographical distribution
 - 2.1.1. Historical background
 - 2.1.2. Origin and natural occurrence
- 2.2. Information on target organism(s)
 - 2.2.1. Description of the target organism(s)
 - 2.2.2. Mode of action
- 2.3. Host specificity range and effects on species other than the target organism
- 2.4. Development stages/life cycle of the micro-organism
- 2.5. Infectiveness, dispersal and colonisation ability
- 2.6. Relationships to known plant or animal or human pathogens
- 2.7. Genetic stability and factors affecting it
- 2.8. Information on the production of metabolites (especially toxins)
- 2.9. Antibiotics and other anti-microbial agents
- 2.10. Robustness to environmental factors
- 2.11. Effects on materials, substances and products
3. Additional information on the micro-organism
 - 3.1. Function
 - 3.2. Field of use envisaged
 - 3.3. Product type(s) and category of users for which the micro-organism should be listed in Annex I
 - 3.4. Method of production and quality control
 - 3.5. Information on the occurrence or possible occurrence of the development of resistance of the target organism(s)
 - 3.6. Methods to prevent loss of virulence of seed stock of the micro-organism
 - 3.7. Recommended methods and precautions concerning handling, storage, transport or fire
 - 3.8. Procedures for destruction or decontamination
 - 3.9. Measures in case of an accident

- 3.10. Procedures for waste management
- 3.11. Monitoring plan to be used for the active micro-organism including handling, storage, transport and use
- 3.12. Classification of the micro-organism in the relevant risk group specified in Article 2 of Directive 2000/54/EC
- 4. Analytical methods
 - 4.1. Methods for the analysis of the micro-organism as manufactured
 - 4.2. Methods to determine and quantify residues (viable or non-viable)
- 5. Effects on human health

TIER I

- 5.1. Basic information
 - 5.1.1. Medical data
 - 5.1.2. Medical surveillance on manufacturing plant personnel
 - 5.1.3. Sensitisation/allergenicity observations
 - 5.1.4. Direct observation, e.g. clinical cases
- 5.2. Basic studies
 - 5.2.1. Sensitisation
 - 5.2.2. Acute toxicity, pathogenicity, and infectiveness
 - 5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness
 - 5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness
 - 5.2.2.3. Intraperitoneal/subcutaneous single dose
 - 5.2.3. In vitro genotoxicity testing
 - 5.2.4. Cell culture study
 - 5.2.5. Information on short-term toxicity and pathogenicity
 - 5.2.5.1. Health effects after repeated inhalatory exposure
 - 5.2.6. Proposed treatment: first aid measures, medical treatment
 - 5.2.7. Any pathogenicity and infectiveness to humans and other mammals under conditions of immunosuppression

END OF TIER I

TIER II

5.3. Specific toxicity, pathogenicity and infectiveness studies

5.4. Genotoxicity — In vivo studies in somatic cells

5.5. Genotoxicity — In vivo studies in germ cells

END OF TIER II

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

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

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

6.2. Further information required

6.2.1. Non-viable residues

6.2.2. Viable residues

6.3. Summary and evaluation of residues in or on treated materials, food and feedingstuffs

7. Fate and behaviour in the environment

7.1. Persistence and multiplication

7.1.1. Soil

7.1.2. Water

7.1.3. Air

7.2. Mobility

7.3. Summary and evaluation of fate and behaviour in the environment

8. Effects on non-target organisms

8.1. Effects on birds

8.2. Effects on aquatic organisms

8.2.1. Effects on fish

8.2.2. Effects on freshwater invertebrates

- 8.2.3. Effects on algae growth
- 8.2.4. Effects on plants other than algae
- 8.3. Effects on bees
- 8.4. Effects on arthropods other than bees
- 8.5. Effects on earthworms
- 8.6. Effects on soil micro-organisms
- 8.7. Further studies
 - 8.7.1. Terrestrial plants
 - 8.7.2. Mammals
 - 8.7.3. Other relevant species and processes
- 8.8. Summary and evaluation of effects on non-target organisms
- 9. Summary and evaluation of sections 1 to 8 including conclusions of the risk assessment and recommendations

ANNEX III

Data requirements for biocidal products

1. Dossiers on product shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL), Predicted Environmental Concentration (PEC) and Predicted No-Effect Concentration (PNEC).
2. Information which is however not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied.
3. A detailed and full description of the studies conducted and of the methods used or a bibliographical reference to those methods shall be included.
4. The formats made available by the Commission must be used for submission of the dossiers. In addition, the special software package (IUCLID) made available by the Commission must be used for those parts of the dossiers to which IUCLID applies. Formats and further guidance on data requirements and dossier preparation are available on the Agency homepage.
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 must be justified in the application.
6. Tests performed should comply with the relevant requirements of protection of laboratory animals, set out in Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes⁵⁷, 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 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 substances⁵⁸ or other international standards recognised as being equivalent by the Commission or the Agency.
7. Where testing is done, a detailed description (specification) of the material used and its impurities must be provided. Where necessary, data as established in Annex II shall be required for all the toxicologically/eco-toxicologically relevant chemical components of the biocidal product, in particular if the components are substances of concern as defined in Article 3.
8. Where test data exist that have been generated before ... [*OJ: insert the date referred to in the first subparagraph of Article 85*] 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

⁵⁷ OJ L 358, 18.12.1986, p. 1.

⁵⁸ OJ L 50, 20.2.2004, p. 44.

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 minimise testing on vertebrate animals.

9. All available relevant knowledge and information in literature should be provided.

TITLE 1 – Chemical products

Dossier requirements

The following data will be required to support submissions.

1. Applicant
 - 1.1. Name and address, etc.
 - 1.2. Formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))
2. Identity
 - 2.1. Trade name or proposed trade name, and manufacturer's development code number of the preparation, if appropriate
 - 2.2. Detailed quantitative and qualitative information on the composition of the biocidal product, e.g. active substance(s), impurities, adjuvants, inert components
 - 2.3. Physical state and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution
3. Physical, chemical and technical properties
 - 3.1. Appearance (physical state, colour)
 - 3.2. Explosive properties
 - 3.3. Oxidising properties
 - 3.4. Flash-point and other indications of flammability or spontaneous ignition
 - 3.5. Acidity/alkalinity and if necessary pH value (1 % in water)
 - 3.6. Relative density
 - 3.7. Storage stability - stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the biocidal product; reactivity towards container material
 - 3.8. Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability
 - 3.9. Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised
4. Methods of identification and analysis

- 4.1. Analytical method for determining the concentration of the active substance(s) in the biocidal product
- 4.2. In so far as not covered by Annex II, Section 4.2, analytical methods including recovery rates and the limits of determination for toxicologically and ecotoxicologically relevant components of the biocidal product and/or residues thereof, where relevant in or on the following:
 - 4.2.1. Soil
 - 4.2.2. Air
 - 4.2.3. Water (including drinking water)
 - 4.2.4. Animal and human body fluids and tissues
 - 4.2.5. Treated food or feedingstuffs
5. Intended uses and efficacy
 - 5.1. Product type and field of use envisaged
 - 5.2. Method of application including description of system used
 - 5.3. Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes
 - 5.4. Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals
 - 5.5. Function, e.g. fungicide, rodenticide, insecticide, bactericide
 - 5.6. Pest organism(s) to be controlled and products, organisms or objects to be protected
 - 5.7. Effects on target organisms
 - 5.8. Mode of action (including time delay) in so far as not covered by Annex II, Section 5.4
 - 5.9. User: industrial, professional, general public (non-professional)
 - 5.10. The proposed label claims for the product
 - 5.11. Efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate
 - 5.12. Any other known limitations on efficacy including resistance
6. Toxicological studies
 - 6.1. Acute toxicity

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

- 6.1.1. Oral
 - 6.1.2. Dermal
 - 6.1.3. Inhalation
 - 6.1.4. For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate
 - 6.2. Skin and eye irritation⁵⁹
 - 6.3. Skin sensitisation
 - 6.4. Information on dermal absorption
 - 6.5. Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)
 - 6.6. Information related to the exposure of the biocidal product to man and the operator
- Where necessary, the test(s) described in Annex II, shall be required for the toxicologically relevant non-active substances of the preparation
- 7. Ecotoxicological studies
 - 7.1. Foreseeable routes of entry into the environment on the basis of the use envisaged
 - 7.2. Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance itself
 - 7.3. Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern), such as information from safety data sheets
 - 8. Measures to be adopted to protect man, animals and the environment
 - 8.1. Recommended methods and precautions concerning handling, use, storage, transport or fire
 - 8.2. Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment; in so far as not covered by Annex II, Title1, point 8.3

⁵⁹ Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

- 8.3. Procedures, if any, for cleaning application equipment
- 8.4. Identity of relevant combustion products in cases of fire
- 8.5. Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public (non-professional users), e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration
- 8.6. Possibility of destruction or decontamination following release in or on the following:
 - 8.6.1. Air
 - 8.6.2. Water, including drinking water
 - 8.6.3. Soil
- 8.7. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms
- 8.8. Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms
9. Where relevant, the following additional data shall also be provided
 - 9.1. Further human health-related studies
 - 9.1.1. Food and feedingstuffs studies
 - 9.1.1.1. If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin
 - 9.1.1.2. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product
 - 9.1.2. Other test(s) related to the exposure to humans
Suitable test(s) and a reasoned case will be required for the biocidal product
 - 9.2. Further studies on fate and behaviour in the environment
 - 9.2.1. Where relevant all the information required in Annex II, Section 12
 - 9.2.2. Testing for distribution and dissipation in the following:
 - 9.2.2.1. Soil
 - 9.2.2.2. Water
 - 9.2.2.3. Air

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

9.3. Further Ecotoxicological studies

9.3.1. Effects on birds

9.3.1.1. Acute oral toxicity, if not already done in accordance with Annex II, Section 7

9.3.2. Effects on aquatic organisms

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

9.3.2.1.1. Particular studies with fish and other aquatic organisms

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

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

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

9.3.3. Effects on other non-target organisms

9.3.3.1. Toxicity to terrestrial vertebrates other than birds

9.3.3.2. Acute toxicity to honeybees

9.3.3.3. Effects on beneficial arthropods other than bees

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

9.3.3.5. Effects on soil non-target micro-organisms

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

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

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

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

10. Classification, packaging and labelling

- Proposals for safety-data sheets, where appropriate
- Hazard symbol(s)

- Indications of danger
- Hazard statements
- Precautionary statements
- Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials to be included

11. Summary and evaluation of Sections 2 to 10

TITLE 2 – MICRO-ORGANISMS

Dossier requirements

The following data will be required to support submissions.

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

- 3.7.3. Suspensibility and suspension stability
- 3.7.4. Dry sieve test and wet sieve test
- 3.7.5. Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)
- 3.7.6. Emulsifiability, re-emulsifiability, emulsion stability
- 3.7.7. Flowability, pourability (rinsability) and dustability
- 3.8. Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered
 - 3.8.1. Physical compatibility
 - 3.8.2. Chemical compatibility
 - 3.8.3. Biological compatibility
- 3.9. Summary and evaluation of physical, chemical and technical properties of the biocidal product
- 4. Analytical methods
 - 4.1. Methods for the analysis of the biocidal product
 - 4.2. Methods to determine and quantify residues
- 5. Intended use and efficacy
 - 5.1. Field of use envisaged
 - 5.2. Mode of action
 - 5.3. Details of intended use
 - 5.4. Application rate
 - 5.5. Content of micro-organism in material used (e.g. in the application device or bait)
 - 5.6. Method of application
 - 5.7. Number and timing of applications and duration of protection
 - 5.8. Necessary waiting periods or other precautions to avoid adverse effects to human and animal health and the environment
 - 5.9. Proposed instructions for use
 - 5.10. Category of users
 - 5.11. Information on the possible occurrence of the development of resistance

- 5.12. Effects on the materials or products treated with the biocidal product
- 6. Effects on human health
 - 6.1. Basic acute toxicity studies
 - 6.1.1. Acute oral toxicity
 - 6.1.2. Acute inhalation toxicity
 - 6.1.3. Acute percutaneous toxicity
 - 6.2. Additional acute toxicity studies
 - 6.2.1. Skin irritation
 - 6.2.2. Eye irritation
 - 6.2.3. Skin sensitisation
 - 6.3. Data on exposure
 - 6.4. Available toxicological data relating to non-active substances
 - 6.5. Supplementary studies for combinations of biocidal products
 - 6.6. Summary and evaluation of effects on human health
- 7. Residues in or on treated materials, food and feedingstuffs
- 8. Fate and behaviour in the environment
- 9. Effects on non-target organisms
 - 9.1. Effects on birds
 - 9.2. Effects on aquatic organisms
 - 9.3. Effects on bees
 - 9.4. Effects on arthropods other than bees
 - 9.5. Effects on earthworms
 - 9.6. Effects on soil micro-organisms
 - 9.7. Additional studies on additional species or higher tier studies such as studies on selected non-target organisms
 - 9.7.1. Terrestrial plants
 - 9.7.2. Mammals
 - 9.7.3. Other relevant species and processes

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

10. Classification, packaging and labelling

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

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

10.2. Procedures for cleaning application equipment

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

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

10.5. Measures in the case of an accident

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

10.6.1. Controlled incineration

10.6.2. Others

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

10.8. Indication on the need for biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC

11. Summary and evaluation of Sections 1 to 10 including conclusions of the risk assessment and recommendations

ANNEX IV

GENERAL RULES FOR THE ADAPTATION OF THE DATA REQUIREMENTS

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

1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY

1.1. Use of existing data

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

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

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

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

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

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

1.1.3. Historical human data

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

consequently the predictability of the effect. Criteria for assessing the adequacy of the data include:

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

In all cases adequate and reliable documentation shall be provided.

1.2. Weight of evidence

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

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

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

In all cases adequate and reliable documentation shall be provided.

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

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

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

1.4. In vitro methods

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

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

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

1.5. Grouping of substances and read-across approach

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

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

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

In all cases results should:

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

- adequate and reliable documentation of the applied method shall be provided.

2. TESTING IS TECHNICALLY NOT POSSIBLE

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

3. PRODUCT-TAILORED EXPOSURE-DRIVEN TESTING

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

ANNEX V

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

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

MAIN GROUP 1: Disinfectants and general biocidal products

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

Product-type 1: Human hygiene biocidal products

Products in this group are biocidal products used for human hygiene purposes.

Product-type 2: Private area and public health area disinfectants and other biocidal products

Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feedingstuffs contact in private, public and industrial areas, including hospitals, as well as products used as algacides.

Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil or other substrates (in playgrounds).

Product-type 3: Veterinary hygiene biocidal products

Products in this group are biocidal products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.

Product-type 4: Food and feed area disinfectants

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feedingstuffs or drink (including drinking water) for humans and animals.

Product-type 5: Drinking water disinfectants

Products used for the disinfection of drinking water (for both humans and animals).

MAIN GROUP 2: Preservatives

Product-type 6: In-can preservatives

Products used for the preservation of manufactured products, other than foodstuffs or feedingstuffs, in containers by the control of microbial deterioration to ensure their shelf life.

Product-type 7: Film preservatives

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

Product-type 8: Wood preservatives

Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms.

This product type includes both preventive and curative products.

Product-type 9: Fibre, leather, rubber and polymerised materials preservatives

Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.

Product-type 10: Masonry preservatives

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

Product-type 11: Preservatives for liquid-cooling and processing systems

Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.

Products used for the preservation of drinking water are not included in this product type.

Product-type 12: Slimicides

Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

Product-type 13: Metalworking-fluid preservatives

Products used for the preservation of metalworking fluids by the control of microbial deterioration.

MAIN GROUP 3: Pest control

Product-type 14: Rodenticides

Products used for the control of mice, rats or other rodents.

Product-type 15: Avicides

Products used for the control of birds.

Product-type 16: Molluscicides

Products used for the control of molluscs.

Product-type 17: Piscicides

Products used for the control of fish; these products exclude products for the treatment of fish diseases.

Product-type 18: Insecticides, acaricides and products to control other arthropods

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans).

Product-type 19: Repellents and attractants

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.

MAIN GROUP 4: Other biocidal products

Product-type 20: -

Product-type 21: Antifouling products

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

Product-type 22: Embalming and taxidermist fluids

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

Product-type 23: Control of other vertebrates

Products used for the control of vermin.

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

DEFINITIONS

(a) *Hazard identification*

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

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

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

(c) *Exposure assessment*

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

(d) *Risk characterisation*

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

(e) *Environment*

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

INTRODUCTION

1. This Annex lays down principles to ensure that evaluations made and decisions taken by a competent authority or the Agency, or the Commission, where relevant, concerning the authorisation of a biocidal product providing it is a chemical preparation results in a harmonised high level of protection for humans, animals and the environment in accordance with point (b) of Article 16(1).
2. In order to ensure a high and harmonised level of protection of human and animal health and of the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of any risks identified during the proposed

normal use of the biocidal product. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product.

3. A risk assessment on the active substance or substances present in the biocidal product is always required. This will already have been carried out for the purpose of the inclusion of the active substance into Annex I. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.
4. Additional risk assessments shall be carried out, in the same manner as described above, on any other substance of concern present in the biocidal product where relevant for the use of the biocidal product.
5. In order to carry out a risk assessment data are required. These data are detailed in Annexes II, III and IV and, recognising that there are a wide variety of product types, are flexible according to the product type and associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. Competent authorities or the Agency should take due consideration of the requirements of Article 6 and Article 19 of this Regulation in order to avoid duplication of data submissions. The minimum set of data required for an active substance in any biocidal product type, however, shall be that detailed in Annex VI to Regulation (EC) No 1907/2006; these data will already have been submitted and assessed as part of the risk assessment required for entry of the active substance into Annex I to this Regulation. Data may also be required on a substance of concern present in a biocidal product.
6. The results of the risk assessments carried out on an active substance and on a substance of concern present in the biocidal product shall be integrated to produce an overall assessment for the biocidal product itself.
7. When making evaluations and taking decisions concerning the authorisation of a biocidal product the competent authorities or the Agency shall:
 - (a) take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues;
 - (b) evaluate, where relevant, justifications submitted by the applicant for not supplying certain data.
8. It is known that many biocidal products present only minor differences in composition and this should be taken into account when evaluating dossiers. The concept of 'frame-formulations' is relevant here.
9. It is known that certain biocidal products are considered as posing only a low risk, these biocidal products, while complying with the requirements of this Annex, are subject to a simplified procedure as detailed in Article 16(3) of this Regulation.
10. The application of these common principles shall lead to the competent authorities or the Commission deciding whether or not a biocidal product can be authorised, such authorisation may include restrictions on use or other conditions. In certain cases the

competent authorities may conclude that more data are required before an authorisation decision can be made.

11. During the process of evaluation and decision-making, applicants and the competent authorities shall cooperate in order to resolve any questions on the data requirements quickly or to identify at an early stage any additional studies required, or to amend any proposed conditions for the use of the biocidal product or to modify its nature or its composition in order to ensure full compliance with the requirements of Article 16 and of this Annex. The administrative burden, especially for small and medium-sized enterprises (SMEs), shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.
12. The judgments made by the competent authorities during the evaluation and decision-making process must be based on scientific principles, preferably recognised at international level, and be made with the benefit of expert advice.

EVALUATION

General principles

13. The data submitted in support of an application for authorisation of a biocidal product shall be examined for overall scientific value by the receiving competent authorities. After acceptance of these data the competent authorities shall utilise them by carrying out a risk assessment based on the proposed use of the biocidal product.
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 either of the biocidal product itself or any material treated with it.
15. For each active substance and each substance of concern present in the biocidal product, the risk assessment shall entail a hazard identification and the establishment of appropriate no-observed-adverse-effect levels (NOAEL), where possible. It shall also include, as appropriate, a dose (concentration) - response (effect) assessment, together with an exposure assessment and a risk characterisation.
16. The results arrived at from a comparison of the exposure to the no-effect level concentrations for each of the active substances and any substances of concern shall be integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available the results of the qualitative assessments shall be integrated in a similar manner.
17. The risk assessment shall determine:
 - (a) the risk to humans and animals,
 - (b) the risk to the environment,

- (c) the measures necessary to protect humans, animals and the general environment during both the proposed normal use of the biocidal product and in a realistic worst-case situation.
18. In certain cases it may be concluded that further data are required before a risk assessment can be finalised. Any such additional data requested shall be the minimum necessary to complete such a risk assessment.

Effects on humans

19. 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.
20. The effects previously mentioned result from the properties of the active substance and any substance of concern present. They are:
- acute and chronic toxicity,
 - irritation,
 - corrosivity,
 - sensitisation,
 - repeated dose toxicity,
 - mutagenicity,
 - carcinogenicity,
 - reproduction toxicity,
 - neurotoxicity,
 - any other special properties of the active substance or substance of concern,
 - other effects due to physico-chemical properties.
21. The populations previously mentioned are:
- professional users,
 - non-professional users,
 - humans exposed indirectly via the environment.
22. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of Article 58 then dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation shall be required.

23. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not lead to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern, e.g. adverse environmental effects or unacceptable residues.
24. The competent authorities shall apply points 25 to 28 when carrying out a dose (concentration) - response (effect) assessment on an active substance or a substance of concern present in a biocidal product.
25. For repeated dose toxicity and reproductive toxicity the dose response relationship shall be assessed for each active substance or substance of concern and, where possible, the no-observed-adverse-effect level (NOAEL) identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified.
26. For acute toxicity, corrosivity and irritation, it is not usually possible to derive a NOAEL or LOAEL on the basis of tests conducted in accordance with the requirements of this Regulation. For acute toxicity, the LD50 (median lethal dose) or LC50 (median lethal concentration) value or, where the fixed dose procedure has been used, the discriminating dose shall be derived. For the other effects it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the product.
27. For mutagenicity and carcinogenicity it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product. However, if it can be demonstrated that an active substance or a substance of concern identified as a carcinogen is non-genotoxic, it will be appropriate to identify a N(L)OAEL as described in point 25.
28. With respect to skin sensitisation and respiratory sensitisation, in so far as there is no consensus on the possibility of identifying a dose/concentration below which adverse effects are unlikely to occur in a subject already sensitised to a given substance, it shall be sufficient to evaluate whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product.
29. Where toxicity data derived from observations of human exposure, e.g. information gained from manufacture, from poison centres or epidemiology surveys, are available special consideration shall be given to those data when carrying out the risk assessment.
30. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed indirectly via the environment) for which exposure to a biocidal product occurs or can reasonably be foreseen. The objective of the assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of each active substance or substance of concern to which a population is, or may be exposed during use of the biocidal product.

31. The exposure assessment shall be based on the information in the technical dossier provided in conformity with Article 6 and Article 19 and on any other available and relevant information. Particular account shall be taken, as appropriate, of:
- adequately measured exposure data,
 - the form in which the product is marketed,
 - the type of biocidal product,
 - the application method and application rate,
 - the physico-chemical properties of the product,
 - the likely routes of exposure and potential for absorption,
 - the frequency and duration of exposure,
 - the type and size of specific exposed populations where such information is available.
32. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied.

These models shall:

- make a best possible estimation of all relevant processes taking into account realistic parameters and assumptions,
- be subjected to an analysis taking into account possible elements of uncertainty,
- be reliably validated with measurements carried out under circumstances relevant for the use of the model,
- be relevant to the conditions in the area of use.

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

33. Where, for any of the effects set out in point 20 a NOAEL or LOAEL had been identified, the risk characterisation shall entail comparison of the NOAEL or LOAEL with the evaluation of the dose/concentration to which the population will be exposed. Where a NOAEL or LOAEL cannot be established a qualitative comparison shall be made.

Effects on animals

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

Effects on the environment

35. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments - air, soil and water (including sediment) - and of the biota following the use of the biocidal product.
36. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of this Regulation then dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation shall be required.
37. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not led to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern. Such grounds may derive from the properties and effects of any active substance or substance of concern in the biocidal product, in particular:
 - any indications of bioaccumulation potential,
 - the persistence characteristics,
 - the shape of the toxicity/time curve in ecotoxicity testing,
 - indications of other adverse effects on the basis of toxicity studies (e.g. classification as a mutagen),
 - data on structurally analogous substances,
 - endocrine effects.
38. A dose (concentration) - response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as the predicted no-effect concentration (PNEC). However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) - response (effect) then has to be made.
39. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Article 6 and Article 18. It shall be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g. LD50 (median lethal dose), LC50 (median lethal concentration), EC50 (median effective concentration), IC50 (concentration causing 50 % inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)).
40. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in

general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor.

The specifications for the assessment factors shall be elaborated in the notes for technical guidance which, to this end, shall be based particularly on the indications given in point 3.3.1 of Annex I to Regulation (EC) No. 1907/2006.

41. For each environmental compartment an exposure assessment shall be carried out in order to predict the concentration likely to be found of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.
42. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions including any relevant contribution from material treated with biocidal products are known or are reasonably foreseeable.
43. The PEC, or qualitative estimation of exposure, shall be determined taking account of, in particular, and if appropriate:
 - adequately measured exposure data,
 - the form in which the product is marketed,
 - the type of biocidal product,
 - the application method and application rate,
 - the physico-chemical properties,
 - breakdown/transformation products,
 - likely pathways to environmental compartments and potential for adsorption/desorption and degradation,
 - the frequency and duration of exposure.
44. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in point 32. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.
45. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.

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

Unacceptable effects

47. Data shall be submitted to and evaluated by the competent authorities to assess whether the biocidal product does not cause unnecessary suffering 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.
48. The competent authorities shall, where relevant, evaluate the possibility of the development of resistance to an active substance in the biocidal product by the target organism.
49. If there are indications that any other unacceptable effects may occur the competent authorities shall evaluate the possibility of such effects occurring. An example of such an unacceptable effect would be an adverse reaction to fastenings and fittings used in wood following the application of a wood preservative.

Efficacy

50. Data shall be submitted and evaluated to ascertain if the efficacy claims of the biocidal product can be substantiated. Data submitted by the applicant or held by the competent authorities or the Agency must be able to demonstrate the efficacy of the biocidal product against the target organism when used normally in accordance with the conditions of authorisation.
51. Testing should be carried out according to Community guidelines if these are available and applicable. Where appropriate, other methods can be used as shown in the list below. If relevant acceptable field data exist, these can be used.
- ISO, CEN or other international standard method
 - national standard method
 - industry standard method (accepted by competent authorities or the Agency)
 - individual producer standard method (accepted by competent authorities or the Agency)
 - data from the actual development of the biocidal product (accepted by competent authorities or the Agency).

Summary

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

the active substance together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This should take account of any likely synergistic effects of the active substance(s) and substances of concern in the biocidal product.

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

DECISION MAKING

General principles

54. Subject to point 90, the competent authorities or the Commission shall come to a decision regarding the authorisation for use of a biocidal product as a result of the integration of the risks arising from each active substance together with the risks from each substance of concern present in the biocidal product. The risk assessments shall cover normal use of the biocidal product together with a realistic worst-case scenario including any relevant disposal issue either of the biocidal product itself or any material treated with it.
55. In making a decision concerning authorisation, the competent authorities or the Commission shall arrive at one of the following conclusions for each product type and for each area of use of the biocidal product for which application has been made:
- (1) the biocidal product cannot be authorised;
 - (2) the biocidal product can be authorised subject to specific conditions/restrictions;
 - (3) more data is required before a decision on authorisation can be made.
56. If the conclusion arrived at by the competent authorities or the Commission is that additional information or data are required before an authorisation decision can be made, then the need for any such information or data shall be justified. This additional information or data shall be the minimum necessary to carry out a further appropriate risk assessment.
57. The competent authorities or the Commission shall only grant authorisation to those biocidal products which, when used according to their conditions of authorisation, do not present an unacceptable risk to humans, animals or the environment, are efficacious and which contain active substances permitted at Community level to be used in such biocidal products.
58. The competent authorities or the Commission shall impose, where appropriate, conditions or restrictions when giving authorisations. The nature and severity of these shall be selected on the basis of, and be appropriate to, the nature and extent of the expected advantages and the risks likely to arise from the use of the biocidal product.
59. In the decision-making process the competent authorities or the Commission shall take into consideration the following:

- the results of the risk assessment, in particular the relationship between exposure and effect,
 - the nature and severity of the effect,
 - the risk management which can be applied,
 - the field of use of the biocidal product,
 - the efficacy of the biocidal product,
 - the physical properties of the biocidal product,
 - the benefits of using the biocidal product.
60. The competent authorities or the Commission shall, when taking a decision concerning the authorisation of a biocidal product, take into account the uncertainty arising from the variability in the data used in the evaluation and decision-making process.
61. The competent authorities or the Commission shall prescribe that biocidal products shall be used properly. Proper use shall include application at an efficacious dose and minimisation of use of biocidal products where possible.

Effects on humans

62. The competent authorities or the Commission shall not authorise a biocidal product if the risk assessment confirms that, in foreseeable application including a realistic worst possible scenario, the product presents an unacceptable risk to humans.
63. The competent authorities or the Commission shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environment when making a decision on the authorisation of a biocidal product.
64. The competent authorities or the Commission shall examine the relationship between the exposure and the effect, and use this in the decision-making process. A number of factors need to be considered when examining this relationship and one of the most important is the nature of the adverse effect of the substance. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, reproduction toxicity together with physico-chemical properties, and any other adverse properties of the active substance or substance of concern.
65. The competent authorities or the Commission shall, where possible, compare the results obtained with those obtained from previous risk assessments for an identical or similar adverse effect and decide on an appropriate margin of safety (MOS) when making an authorisation decision.
66. An appropriate MOS is typically 100 but an MOS higher or lower than this may be appropriate depending on, among other things, the nature of the critical toxicological effect.

67. The competent authorities or the Commission shall, if appropriate, impose, as a condition of authorisation, the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles in order to reduce exposure for professional operators. Such equipment must be readily available to them.
68. If for non-professional users the wearing of personal protective equipment would be the only possible method for reducing exposure, the product shall not normally be authorised.
69. If the relationship between the exposure and the effect cannot be reduced to an acceptable level then no authorisation can be given by the competent authorities or the Commission for the biocidal product.

Effects on animals

70. The competent authorities or the Commission shall not authorise a biocidal product if the risk assessment confirms that, in normal use, the biocidal product presents an unacceptable risk to non-target animals.
71. Using the same relevant criteria as described in the section dealing with effects on humans, the competent authorities or the Commission shall consider the risks posed to animals from the biocidal product when making an authorisation decision.

Effects on the environment

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

In considering whether there is an unacceptable risk competent authorities or the Commission shall, when coming to a final decision in accordance with point 90, take into account the criteria in points 75 to 85.

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

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

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

If the PEC/PNEC ratio is greater than 1 the competent authorities or the Commission shall judge, on the basis of the size of that ratio and on other relevant factors, if further information and/or testing are required to clarify the concern or if risk

reduction measures are necessary or if the product cannot be given an authorisation at all. Relevant factors to be considered are those previously mentioned in point 37.

Water

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

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

- the maximum permissible concentration laid down by Directive 80/778/EEC relating to the quality of water intended for human consumption⁶⁰, or
- the maximum concentration as laid down following the procedure for including the active substance in Annex I to this Regulation, on the basis of appropriate data, in particular toxicological data

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

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

- exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by
 - Council Directive 75/440/EEC concerning the quality required of surface water intended for the abstraction of drinking water in the Member States⁶¹,
 - Directive 80/778/EEC or
- has an impact deemed unacceptable on non-target species

unless it is scientifically demonstrated that under relevant field conditions this concentration is not exceeded.

⁶⁰ OJ L 229, 30.8.1980, p. 11.

⁶¹ OJ L 194, 25.7.1975, p. 26.

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

Soil

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

- during tests in the field, persists in soil for more than one year, or
- during laboratory tests, forms non-extractable residues in amounts exceeding 70 % of the initial dose after 100 days with a mineralisation rate of less than 5 % in 100 days,
- has unacceptable consequences or effects on non-target organisms,

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

Air

80. The competent authorities or the Commission shall not authorise a biocidal product where there is a foreseeable possibility of unacceptable effects on the air compartment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Effects on non-target organisms

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

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

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

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

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

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

Unacceptable effects

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

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

- death is synchronous with the extinction of consciousness, or,
- death occurs immediately, or,
- vital functions are reduced gradually without signs of obvious suffering.

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

Efficacy

86. Competent authorities or the Commission shall not authorise a biocidal product which does not possess acceptable efficacy when used in accordance with the conditions specified on the proposed label or with other conditions of authorisation.

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

Summary

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

The result shall be:

- a summary of the effects of the biocidal product on humans,
- a summary of the effects of the biocidal product on animals,
- a summary of the effects of the biocidal product on the environment,
- a summary of the efficacy assessment,
- a summary of the unacceptable effects.

OVERALL INTEGRATION OF CONCLUSIONS

89. The competent authorities or the Commission shall combine the individual conclusions arrived at with regard to effects of the biocidal product on the three sectors namely, humans, animals and the environment to arrive at an overall conclusion for the global effect of the biocidal product.
90. The competent authorities or the Commission shall then take due consideration of any relevant unacceptable effects, the efficacy of the biocidal product and the benefits of using the biocidal product before taking an authorisation decision on the biocidal product.
91. The competent authorities or the Commission shall ultimately decide whether or not the biocidal product can be authorised and whether this authorisation shall be subject to any restrictions or conditions in conformity with this Annex and this Regulation.

APPENDIX 1

CORRELATION TABLE

This Regulation	Directive 98/8/EC
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16.4 16.5 16.6	Article 5.2 Article 2.1.j
Article 17 17.1 17.2 17.3 17.4	Article 2.1.b
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APPENDIX 2

LEGISLATIVE FINANCIAL STATEMENT

1. NAME OF THE PROPOSAL:

Proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products.

2. ABM / ABB FRAMEWORK

Policy area: 07 Environment

Activity Code 07 03: Implementation of Community environmental policy and legislation

3. BUDGET LINES

3.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B..A lines)) including headings:

NEW BUDGET LINE TO BE CREATED UNDER TITLE 07 ENVIRONMENT – Chemicals Agency – activities in the field of the Legislation on Biocidal Products — Subsidy under Titles 1 &2

NEW BUDGET LINE TO BE CREATED UNDER TITLE 07 ENVIRONMENT – Chemicals Agency – activities in the field of the Legislation on Biocidal Products — Subsidy under Title 3

The new budget lines to be created will cover ECHA's staff and administrative expenditure (titles 1 and 2) and ECHA's operating expenditure (title 3) for the activities to be carried out in the field of biocidal products in accordance with this Regulation, as part of the annual subsidy to the European Chemicals Agency (ECHA) from the Community budget (in addition to the appropriations under budget items 02 03 03 01 and 02 03 03 02 to finance the activities of the REACH Regulation⁶²).

3.2. Duration of the action and of the financial impact:

The duration of the action is not limited in time as the proposal establishes the rules applicable to the placing on the market of biocidal products. The financial impact is, however, expected to be limited to supporting the European Chemicals Agency (ECHA) in taking up the additional tasks related to the assessment of active substances used in biocidal products and of certain biocidal products. ECHA will indeed receive from industry specific fees for certain of these activities as well as an annual fee for products authorised by the Community.

⁶² Regulation (EC) N° 1907/2006

It is expected that ECHA will be involved in these tasks from the year 2012. As 2013 is the last year of the current financial programming, estimates of the commitment and payment appropriations have been limited to that of 2012 and 2013 in this financial statement.

A detailed analysis of the ECHA budget for these additional tasks is provided in annexes to the financial statement for the years 2012 and 2013 as well as for the next 8 following years (i.e. until 2021), in order to match the timetable attached to the REACH revised legislative Financial Statement (SEC(2006)924).

3.3. Budgetary characteristics:

Budget line	Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
NEW	Non-comp	Diff	YES	YES	NO	No 2
NEW	Non-comp	Diff	YES	YES	NO	No 2

4. SUMMARY OF RESOURCES

4.1. Financial Resources

4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Section no.		2012	2013	2014 ⁶³	2015	2016	2017 and later	Total
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Operational expenditure

Commitment Appropriations (CA)	8.1.	a	1,023	2,280					3,303
Payment Appropriations (PA)		b	1,023	2,280					3,303

Administrative expenditure within reference amount

Technical & administrative assistance (NDA)	8.2.4.	c	-	-	-	-	-	-	-
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TOTAL REFERENCE AMOUNT

Commitment Appropriations		a+c	1,023	2,280					3,303
Payment Appropriations		b+c	1,023	2,280					3,303

Administrative expenditure not included in reference amount

Human resources and associated expenditure (NDA)	8.2.5.	d	-	-	-	-	-	-	-
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	8.2.6.	e	0,204	0,204	-	-	-	-	0,408

Total indicative financial cost of intervention

TOTAL CA including cost of Human Resources		a+c+d+e	1,227	2,484					3,711
TOTAL PA including cost of Human Resources		b+c+d+e	1,227	2,484					3,711

⁶³ Estimates of the commitment and payment appropriations are limited to the current financial programming running until 2013.

4.1.2. *Compatibility with Financial Programming*

- Proposal is compatible with existing financial programming.
- Proposal will entail reprogramming of the relevant heading in the financial perspective (1,227M€ in 2012 and 2,484M€ in 2013).
- Proposal may require application of the provisions of the Interinstitutional Agreement⁶⁴ (i.e. flexibility instrument or revision of the financial perspective).

4.1.3. *Financial impact on Revenue*

- Proposal has no financial implications on revenue

There is no impact on the revenue side of the Community budget. ECHA's budget foresees its own revenues consisting of the fees paid by industry, which ECHA is authorised to collect by virtue of the tasks entrusted to it under this Regulation and a balancing subsidy from the Community budget.

For tasks related to biocidal products, the proposal foresees that ECHA would charge fees for the inclusion and renewal of inclusion of active substances in Annex I, for the evaluation of application for the authorisation, modification of authorisation and renewal of authorisation of certain biocidal products at the Community level, as well as an annual fee to be paid by holders of Community authorisations.

Although the activities relating to inclusion of active substances and authorisation of biocidal products are expected to be self-financed after a few years, a balancing subsidy from the Community budget could still be necessary, if the fee structure does not cover the expenses. The present financial fiche has been established with the hypothesis that some tasks would not be covered by the fees:

- Preparation of opinions on questions referred to ECHA by virtue of Article 30 of the proposal, in case of disagreement between Member States during a mutual recognition procedure
- Tasks related to data sharing and confidentiality
- Development of general and specific guidance documents
- Completion of Review Programme for existing substances
- Reductions for SMEs (as proposed in point (a) of Article 70(2))
- Other tasks of Community interest not covered by fees

Also, Article 68 of the proposal requires a clear separation of ECHA's budget between activities to be carried out in accordance with the provisions of the REACH Regulation and the new and additional tasks derived from this proposal. As a consequence, expenditures and revenues under these additional tasks have to be clearly identified by the accounting system of the agency.

⁶⁴ See points 19 and 24 of the Interinstitutional agreement.

4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.

Annual requirements	2012	2013	2014	2015	2016	2017 and later
Total number of human resources	-	-	-	-	-	-

5. CHARACTERISTICS AND OBJECTIVES

5.1. Needs to be met in the short or long term

Before any substance can be authorised for use in a biocidal product, it must be assessed whether its use poses any unacceptable risk for the environment or public health. This assessment is done by Member State competent authorities followed by a peer review organised at the Community level, before a decision is taken by the Commission.

In addition, to improve the authorisation process of biocidal products as well as to promote innovation and the development of new products with better health or environmental profile, it is proposed that certain products – those containing new active substances or those presenting a low risk – will be authorised directly at the Community level at the choice of the applicant. Other categories of biocidal products will continue being authorised at Member State level.

Also, for biocidal products to be authorised by the Member States, through the mutual recognition procedure, divergence of opinions between Member States will need to be addressed through an ad hoc conflict resolution procedure. Most of these divergences of opinions are expected to be of a scientific or a technical nature.

Last, genuine scientific and technical support for the implementation of the Regulation will need to be provided.

5.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy

Until today the Commission Joint Research Centre provides a significant input to the review programme of existing active substances⁶⁵. However, with the downsizing of its activities in

⁶⁵ The current Directive 98/8/EC provides for the systematic evaluation of active substances, which were already on the market on 14 May 2000, when that Directive came into force. This evaluation is carried out by Member States, which have all been allocated a number of substances for which they have to produce assessment reports. These assessment reports are then peer reviewed by the other Member States and discussed at different meetings organised by the Commission JRC for the scientific and technical issues and then by DG Environment for the final discussions before the final steps of the decision-making process are taken (Comitology procedure). The scientific and technical discussions and the preparatory work they entail to read the reports and analyse the different issues require

the field of chemical substances due to the transfer of many of these activities to ECHA, the Commission JRC already announced that it would also stop its activities in the field of biocidal products at the end of 2013 and would then concentrate on other priorities.

As the Commission services will then no longer have the expertise and resources to address issues of scientific or technical nature linked to the evaluation of active substances and the authorisation of biocidal products, it was considered most appropriate to seek advice and support from an external body.

Relying on an external body to carry out the risk assessment is also in line with the approach adopted in other sectors such as medicinal products, plant protection products, food, where there is a clear separation between risk assessment (carried out by scientific bodies) and risk management (carried out by the Commission).

Having excluded the possibility of establishing a specific body to be in charge of the risk assessment of active substances and biocidal products, three existing bodies were considered as possible candidates to provide this scientific and technical support in the field of biocides:

- The European Agency for the Evaluation of Medicinal Products (EMA), because the proposal to authorise certain biocidal products at the Community level is modelled upon the lines and principles of what already exist since 1995 for medicinal products for veterinary and human use;
- The European Food Safety Authority (EFSA), because Directive 98/8/EC is often referred to as the sister Directive of Directive 91/414/EEC regulating the placing on the market of plant protection products and where EFSA is the official scientific body in charge of preparing opinions for the Commission; and
- The European Chemicals Agency (ECHA).

Limited synergies can however be expected from the first two options. On the other hand, the choice of ECHA is expected to create significant synergies, on the basis of the following considerations:

- First and foremost, the evaluation of active substances used in biocidal products follows many of the methodologies and principles that also apply to chemical substances. Data requirements are similar and the risk assessment of these substances, notably when they have certain hazardous properties, is even of the direct competence of ECHA.
- In addition, the proposal includes rules concerning data sharing for biocidal products, which have now been aligned on those of REACH and make mandatory the sharing of data involving testing on vertebrate animals. Only REACH and ECHA have already set up the mechanisms and the databases to make such sharing possible.
- Last but not least, producers, downstream users of biocidal products and even the Commission already have a number of obligations under REACH. Notably, the data held by the Commission JRC relating to active substances under evaluation in the

significant resources, which are currently provided by the Commission JRC and financed under the LIFE + programme under budget line 07 03 07.

review programme shall be made available to ECHA, in accordance with the provision of Article 16 of the REACH Regulation.

- Another important element of choice is that many of the ECHA scientific staff is already familiar with biocidal products, through previous work at the Commission JRC, in Member States Competent Authorities as well as in industry.

For these reasons, it is felt that the ECHA, amongst the other options at hand - a new agency, the Commission JRC, the EMEA or EFSA - considered at an early stage of the process is the most effective one in terms of possible synergies.

In addition, with the phasing out of the Commission JRC support concerning the review programme of existing active substances announced for the end of 2013, ECHA is expected to take over that role from 2014 onwards.

The legislative proposal therefore relies on the assumption that a number of tasks of a scientific and technical nature related to the assessment of active substances used in biocidal products and of certain biocidal products will be given to ECHA.

To this end, financial resources are needed to ensure that ECHA has the appropriate level of staff and is able to convene as many meetings as necessary to deliver its opinions to the Commission.

5.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework

The objectives of the proposal are to ensure a high level of protection of public health and the environment as well as the harmonisation of the internal market for biocidal products, while enhancing competitiveness and innovation.

To achieve these objectives it is necessary that the hazards and risks from active substances and biocidal products are fully known before they are placed on the market.

To ensure the efficient implementation of the proposal it is appropriate to rely on the existing European Chemicals Agency, which will receive and deliver opinions on data submitted by industry, for example, for the evaluation of active substances or certain biocidal products, and will be the focal point for providing scientific advice and assistance to the Commission, to Member State competent authorities, to enterprises, especially SMEs, and for making relevant information available to the public.

The harmonisation of the internal market for biocidal products and the enhancement of competitiveness and innovation will be strengthened by having a coherent approach to the treatment of applications submitted by industry, by simplifying procedures for the authorisation of products, and by encouraging the development of ‘new’ substances and products having a better public health or environmental profile, so as to enable Europe to compete better with its international competitors, and bring about the greater availability of substances or products with lower risks.

The objectives and indicators identified to date are as follows:

Objectives	Indicators for the policy
Assessment of new active substances in view of their inclusion in Annex I of the Regulation	Number of opinions delivered. Time from reception of a valid application to transmission of opinion to the Commission.
Renewal of Annex I inclusion	Number of opinions delivered. Time from reception of a valid application to transmission of opinion to the Commission.
Authorisations of low-risk products	Number of opinions delivered. Time from reception of a valid application to transmission of opinion to the Commission.
Authorisations of products containing new active substances	Number of opinions delivered. Time from reception of a valid application to transmission of opinion to the Commission.
Opinion in case of disagreement during mutual recognition procedures	Number of opinions delivered. Time from reception of a Commission request to transmission of opinion to the Commission.
Tasks related to data sharing and confidentiality	Number of searches in the database. Number of request for information for non-confidential data.
Development of general and specific guidance documents	Number of guidance documents developed.

Maintenance of Community register on biocidal products	Number of searches in the database
Completion of the review programme of existing substances	Number of opinions delivered. Time from reception of a draft Competent authority report to finalisation of Competent authority report.

5.4. Method of Implementation (indicative)

X *Centralised Management*

X directly by the Commission

X indirectly by delegation to:

executive Agencies

X bodies set up by the Communities as referred to in art. 185 of the Financial Regulation

national public-sector bodies/bodies with public-service mission

Shared or decentralised management

with Member states

with Third countries

Joint management with international organisations (please specify)

Relevant comments:

The overall responsibility for the implementation and enforcement of the proposed legislation will rest with the Commission services. However, the scientific and technical support will be provided by the European Chemicals Agency. ECHA will in particular have to provide opinions on the level of risk presented by active substances used in biocidal products as well as on the authorisations of certain biocidal products. ECHA will only provide opinions on the basis of which the Commission will take decisions (comitology procedure).

6. MONITORING AND EVALUATION

6.1. Monitoring system

In order to evaluate the progress of implementation and effects of the new policy, the indicators as set out in 5.3 will be gathered and monitored at regular intervals. For the most part, this will be done as part of the normal activity of ECHA on an annual basis.

In addition to this, Member States shall submit to the Commission every three years a report on enforcement and control measures and results of these measures. The Commission shall also

draw up a report on the implementation of the Regulation and in particular on the functioning of the Community authorisation procedure and mutual recognition.

6.2. Evaluation

6.2.1. Ex-ante evaluation

The Impact Assessment carried out by the Commission addresses five policy issues that require action: the extension of the scope of the Regulation to include articles and materials treated with biocidal products; the improvement of procedures for product authorisation with the possibility to authorise certain products at the Community level; the introduction of mandatory data-sharing at product authorisation and active substance approval stage along the principles of the REACH Regulation; a clarification on data requirements with a combination of data waiving with the use of existing information and a new approach for low-risk biocidal products; a partial harmonisation of fee structure to encourage the development of more new active substances and the retention of more existing active substances.

6.2.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)

The proposal is also based on the conclusions of a study carried out in 2007 to analyse the deficiencies of the current Directive. The results of this study (available at <http://ec.europa.eu/environment/biocides/study.htm>) were incorporated in the Commission report on the impacts of the implementation of Directive 98/8/EC (available at http://ec.europa.eu/environment/biocides/impl_report.htm).

6.2.3. Terms and frequency of future evaluation

As indicated in Section 6.1 a general report will be prepared by ECHA and submitted to the Commission. This information will be used by the Commission in order to prepare the report on the implementation of the Regulation.

7. ANTI-FRAUD MEASURES

The European Chemicals Agency has specific budgetary control mechanisms and procedures. These are however based on Regulation (EC, Euratom) No 2343/2002.

The Management Board of ECHA, which comprises representatives of the Member States, the Commission and the European Parliament (Article 79(1) of the REACH Regulation), produces an estimate of the revenue and expenditure of ECHA (Article 96(5)) and adopts the final budget (Article 96(9)). Each year, the provisional and final accounts are sent to the European Court of Auditors (paragraphs 4 and 7 of Article 97). The European Parliament gives a discharge to the Director of ECHA regarding the implementation of the budget (Article 97(10)).

In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) apply without restrictions to ECHA, in accordance with Article 98(1) of Regulation (EC) No 1907/2006.

In accordance with Article 98(2), ECHA is also bound by the Interinstitutional Agreement of May 25, 1999 concerning internal investigations by the European Anti-Fraud Office (OLAF).

8. DETAILS OF RESOURCES

8.1. Objectives of the proposal in terms of their financial cost

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	Type of output	Av. cost	Year 2012		Year 2013		Year 2014		Year 2015		Year 2016		Year 2017 and later		TOTAL	
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost
OPERATIONAL OBJECTIVE No.1 ⁴ ECHA scientific and technical support	Please refer to Annex 1 for a detailed breakdown of ECHA's costs and to Annex 2 for the main underlying assumptions.															
TOTAL COST				1,023		2,280										

8.2. Administrative Expenditure

8.2.1. Number and type of human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources (number of posts/FTEs)					
		Year 2012	Year 2013	Year 2014	Year 2015	Year 2016	Year 2017
Officials or temporary staff ⁶⁶ (XX 01 01)	A*/AD	-	-	-	-	-	-
	B*, C*/AST	-	-	-	-	-	-
Staff financed ⁶⁷ by art. XX 01 02		-	-	-	-	-	-
Other staff ⁶⁸ financed by art. XX 01 04/05		-	-	-	-	-	-
TOTAL		-	-	-	-	-	-

No additional staff will be necessary. Additional resources will however be required to cover participation in meetings held in ECHA and for the organisation of an increased number of meetings of the Standing Committee on Biocidal Products (see 8.2.6).

8.2.2. Description of tasks deriving from the action

Not applicable.

8.2.3. Sources of human resources (statutory)

- Posts currently allocated to the management of the programme to be replaced or extended
- Posts pre-allocated within the APS/PDB exercise for year n
- Posts to be requested in the next APS/PDB procedure
- Posts to be redeployed using existing resources within the managing service (internal redeployment)
- Posts required for year n although not foreseen in the APS/PDB exercise of the year in question

⁶⁶ Cost of which is NOT covered by the reference amount

⁶⁷ Cost of which is NOT covered by the reference amount

⁶⁸ Cost of which is included within the reference amount

8.2.4. *Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management)*

EUR million (to 3 decimal places)

Budget line (number and heading)	Year 2012	Year 2013	Year 2014	Year 2015	Year 2016	Year 2017 and later	TOTAL
1 Technical and administrative assistance (including related staff costs)	-	-	-	-	-	-	-
Executive agencies	-	-	-	-	-	-	-
Other technical and administrative assistance	-	-	-	-	-	-	-
- <i>intra muros</i>	-	-	-	-	-	-	-
- <i>extra muros</i>	-	-	-	-	-	-	-
Total Technical and administrative assistance	-	-	-	-	-	-	-

8.2.5. *Financial cost of human resources and associated costs not included in the reference amount*

EUR million (to 3 decimal places)

Type of human resources	Year 2012	Year 2013	Year 2014	Year 2015	Year 2016	Year 2017 and later
Officials and temporary staff (XX 01 01)	-	-	-	-	-	-
Staff financed by Art XX 01 02 (auxiliary, END, contract staff, etc.) (specify budget line)	-	-	-	-	-	-
Total cost of Human Resources and associated costs (NOT in reference amount)	-	-	-	-	-	-

8.2.6. Other administrative expenditure not included in reference amount

EUR million (to 3 decimal places)

	Year 2012	Year 2013	Year 2014	Year 2015	Year 2016	Year 2017 and later	TOTAL
07 01 02 11 01 – Missions	0,024	0,024					0,048
07 01 02 11 02 – Meetings & Conferences	-	0	-	-	-	-	0
07 01 02 11 03 – Committees	0,180	0,180	-	-	-	-	0,360
07 01 02 11 04 – Studies & consultations	-	0	-	-	-	-	
07 01 02 11 05 - Information systems	-	0	-	-	-	-	
2 Total Other Management Expenditure (XX 01 02 11)	0,204	0,204	-	-	-	-	0,408
3 Other expenditure of an administrative nature (specify including reference to budget line)	-	0	-	-	-	-	0
Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)	0,204	0,204	-	-	-	-	0,408

Calculation - *Other administrative expenditure not included in reference amount*

20 2-day missions to Agency per year at 1200 EUR per mission

Standing Committee on Biocidal Products: 6 one-day meetings per year at 30.000 EUR/meeting

The needs for human and administrative resources shall be covered within the allocation that can be granted to the managing DG in the framework of the annual allocation procedure in the light of budgetary constraints.

ANNEX 1

Draft Budget for the European Chemicals Agency (in Euros)

Tasks related to biocidal products

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Expenditure										
Title 1										
Salaries & allocations	578,600	1,959,800	3,680,700	4,240,600	4,157,700	4,157,700	4,032,400	4,320,800	4,358,000	4,285,900
Other personnel costs	19,300	157,200	315,700	362,900	362,900	362,900	362,900	377,300	384,600	384,600
Total Title 1	597,900	2,117,000	3,996,400	4,603,500	4,520,600	4,520,600	4,395,300	4,698,100	4,742,600	4,670,500
Title 2										
Rental of building and associated costs	69,200	234,500	440,500	507,500	497,500	497,500	482,600	517,100	521,500	512,900
Information & communication technology	23,800	80,700	151,500	174,500	171,100	171,100	166,000	177,800	179,400	176,400
Movable property and associated costs	4,900	16,700	31,300	36,100	35,400	35,400	34,300	36,800	37,100	36,500
Current administrative expenditure	4,900	16,500	30,900	35,600	34,900	34,900	33,900	36,300	36,600	36,000
Postal charges and telecommunication	2,900	9,700	18,200	21,000	20,600	20,600	19,900	21,400	21,500	21,200
Expenditure on meetings other than those covered under Title 3	400	1,400	2,600	3,000	2,900	2,900	2,800	3,100	3,100	3,000
Total Title 2	106,100	359,500	675,000	777,700	762,400	762,400	739,500	792,500	799,200	786,000
Title 3										
Development of databases and software tools related to the operation of biocidal products related activities	300,000	300,000	83,700	96,000	93,500	93,500	91,000	95,100	93,500	91,900
Evaluation activities	2,100	7,900	15,200	17,500	17,000	17,000	16,600	17,300	17,000	16,700
Information and publications	1,400	5,300	10,300	11,800	11,500	11,500	11,200	11,700	11,500	11,300
Helpdesk services	8,000	29,600	57,100	65,500	63,800	63,800	62,000	64,800	63,700	62,700
Studies and Consultants	1,600	5,900	11,400	13,100	12,800	12,800	12,400	13,000	12,700	12,500
Mission expenses	3,500	12,800	24,700	28,300	27,600	27,600	26,900	28,100	27,600	27,100
Technical training of staff and stakeholders	2,400	8,900	17,100	19,600	19,100	19,100	18,600	19,400	19,100	18,800
Meetings of the Committee on biocidal products and subgroups	0	707,200	707,200	707,200	707,200	707,200	707,200	707,200	707,200	707,200
Fees paid back to Evaluating Member State	0	2,520,000	2,758,600	2,877,300	3,115,900	3,373,700	3,631,500	4,215,800	4,646,400	4,885,000
Fees paid back to rapporteurs	0	326,000	328,400	324,800	327,200	330,400	333,600	350,400	360,800	363,200
Total Title 3	319,000	3,923,600	4,013,700	4,161,100	4,395,600	4,656,600	4,911,000	5,522,800	5,959,500	6,196,400
Total	1,023,000	6,400,100	8,685,100	9,542,300	9,678,600	9,939,600	10,045,800	11,013,400	11,501,300	11,652,900
Revenues										
Community subvention	1,023,000	2,280,100	3,941,100	4,294,300	3,806,600	3,411,600	2,861,800	2,629,400	2,173,300	1,700,900
Fee income of agency	0	4,120,000	4,744,000	5,248,000	5,872,000	6,528,000	7,184,000	8,384,000	9,328,000	9,952,000
Over income to next year	0	0	0	0	0	0	0	0	0	0
Total	1,023,000	6,400,100	8,685,100	9,542,300	9,678,600	9,939,600	10,045,800	11,013,400	11,501,300	11,652,900

ANNEX 2

Applied methodology and main underlying assumptions for the financial model of the European Chemicals Agency for activities relating to biocides

Computation of staff costs

Due to the fact that the Commission JRC in Ispra currently has a major role in operating the review programme of substances used in biocidal products established by Directive 98/8/EC, significant experience exists with regard to how long certain tasks take and what kind of resources are needed in order to carry them out (differentiation between different categories of staff).

Based on this experience and on the model developed for the operation of REACH, a staff model has been developed for the operation of the activities related to biocides. The output of this staff model is how many staff (by grade) are required in a given year to fulfil the tasks of ECHA (operational tasks of the biocides legislation).

To these staff numbers additional resource requirements have been added for the management and training of these resources, taking into account economies of scale that can be achieved in particular in support tasks and staff from existing arrangements set up for the implementation of the REACH Regulation (e.g. for international relations, for external communication, helpdesk services, the Legal Department, Audit and Internal Control, Human Resources (HR), Finance, Information Technology (IT) Building Management). Based on the current ECHA staff ratio, these additional resources amount to 20% of those required for the operational tasks related to the biocidal legislation.

For the scientific staff, the ratio in % of AD and AST grades is in compliance with the REACH staff model. As is the case for staff carrying out REACH related tasks, a higher number of AD than AST staff is justified because of the complexity of the scientific tasks.

For 2012, it is proposed that ECHA should be able to recruit staff to prepare the grounds before the date when ECHA tasks relating to biocidal products come into operation.

From 2013, ECHA would then be responsible for the different tasks set out in the proposal.

From 2014, the responsibility of coordinating the review programme of existing substances would be transferred from the Commission JRC to ECHA (cf. Article 71 of the proposal). ECHA would therefore need extra resources to carry out this additional task. Based on the current assumptions, ECHA would require 10 additional scientific officers to carry that task (3 of whom could already be recruited in the last quarter of 2013 to prepare the activities and ensure a smooth hand-over). However, as the review programme is expected to be completed within 4 to 5 years afterwards, this additional task could be carried out in part via contractual staff to limit the impact on the establishment plan.

Annex 3 sets out the proposed establishment plan related to this proposal. The budget set out in Annex 1 takes into account permanent / temporary staff (i.e. that appear in establishment plan) and contract agents (count for staff costs but do not appear in establishment plan).

All the resources computed have been multiplied by the average annual cost by grade and that has led to the total staff costs. In addition, the weighting factor for Helsinki (119.8% – cost of living adjustment applicable to all staff) has been applied.

The other personnel costs in Title 1 have been assumed to represent 10% of salary costs of permanent / temporary staff.

Applied average costs for permanent/temporary staff by grade per annum (source ECHA)

Grade	Salary
AD 13	187,472
AD 12	175,575
AD 5-11	114,264
AST 7-11	103,973
AST 1-6	112,189

Applied average costs for contract agents by function group per annum (source ECHA)

Grade	Salary
FG IV	72,139
FG III	52,674
FG II	39,836
FG I	34,747

For the purpose of the computation of the staff required it has been assumed that per year the following resources would be needed:

- a desk officer per 10 applications for product authorisation;
- a desk officer per 10 applications for substance evaluation
- a desk officer per 30 applications to amend an existing product authorisation
- a desk officer per 20 opinions requested in case of disagreement during Mutual Recognition

Computation of building, equipment and miscellaneous operating expenditure:

All building, equipment, furniture, IT and other administrative expenditure have been computed based on the number of required staff multiplied by average cost figures per person based on the current Agency budget.

Operating expenditure:

Major cost items in this area are general operating expenditures and all expenditure related to the Committee for Biocidal Products.

The major cost driver for the general operating expenditure is the expenditure for the Committee for Biocidal Products and the fees paid back to the Competent Authorities in charge of the scientific evaluation.

For the Committee for Biocidal Products and its experts groups, the costs include the reimbursement of travel, hotel, daily allowances according to currently applicable Commission rates.

It has also been assumed for the purpose of the computation of ECHA expenses, that 60% and 5% of the fee paid to ECHA would be paid back to the Competent Authorities and the Rapporteur in charge of the scientific evaluation respectively.

This represents only an hypothesis and is therefore provisional and without prejudice to ECHA's decision in this matter.

Computation of expected fee income:

It is assumed that ECHA will have a very simple fee structure for tasks related to biocidal products.

For the purpose of the computation of the expected fee income it has been assumed that:

- Fees for inclusion of an active substance in Annex I amount to EUR 400,000
- Fees for renewal of Annex I inclusion amount to EUR 40,000 when a thorough evaluation is required but can be reduced to 10,000 when this is not the case.
- Fees for product authorisation amount to EUR 100,000 for products containing new active substances, to EUR 80,000 for low-risk products.
- Annual fees amount to EUR 20,000

The amounts of fees above were calculated on the basis of the average value of the fees charged by the Member States.

As noted in the impact assessment, there are however differences in the structure and level of fees from one Member State to another:

Fees charged for the evaluation of active substances vary from €10,000 to €356,000 per substance (Figure 1)

Fees for the authorisation of biocidal products range from €626 to €85,500 per biocidal product (Figure 2).

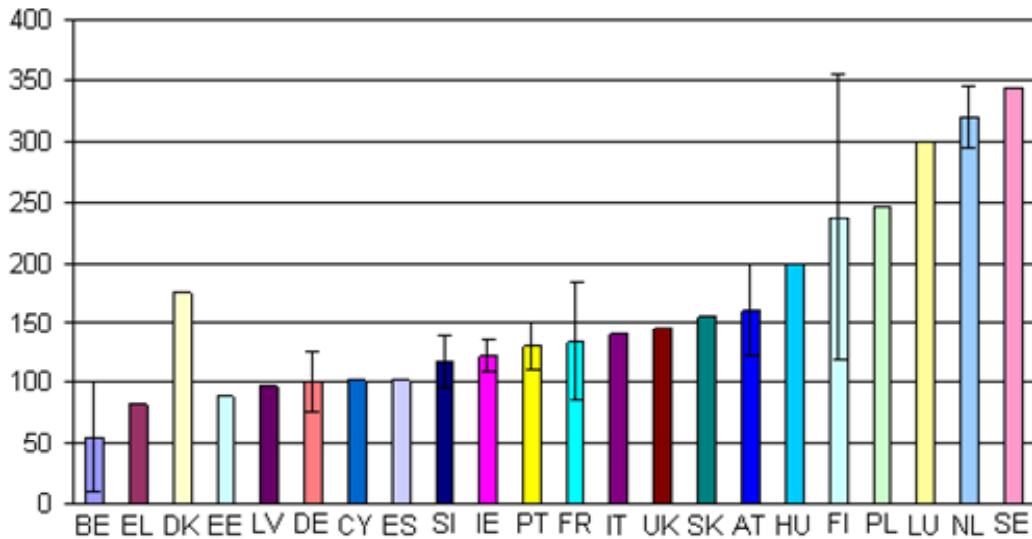


Figure 1: Member States Fees and Fee Ranges for Active Substance Evaluation (Fee in Thousand EURO – Vertical lines indicate Member State Fee Ranges)

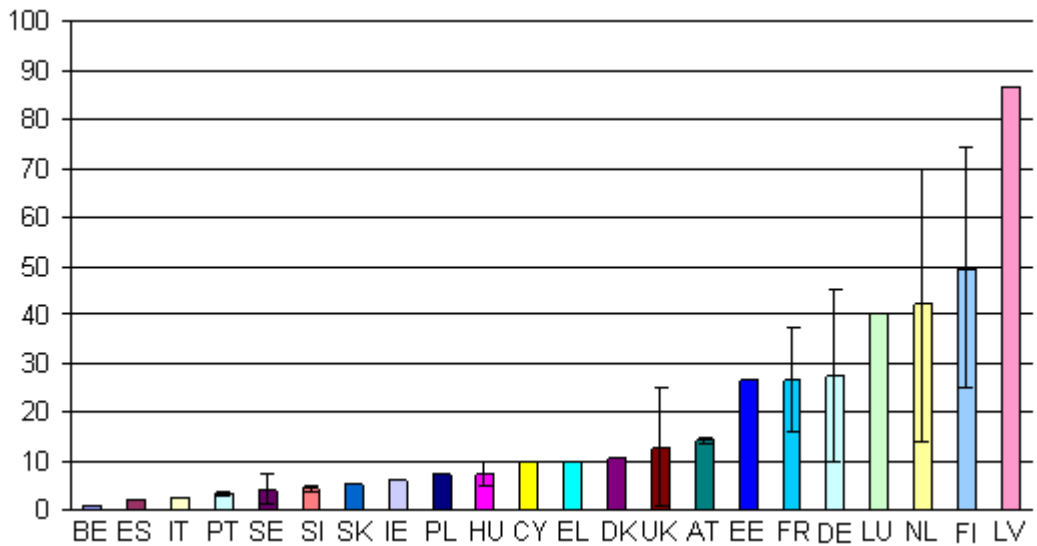


Figure 2: Member States Fees and Fee Ranges for Product Authorisation (Fee in Thousand EURO – Vertical lines indicate Member State Fee Ranges)

These fees will however have to be established by a separate Fee Regulation (Commission Regulation). In that context it will be necessary to establish the fee structure that allows certain reduction for SMEs as foreseen in the proposal.

The rates of fees and the structure outlined above represent only one hypothesis and are therefore provisional and without prejudice to the Commission’s decision in this matter.

The corresponding revenues were calculated based on a certain number of procedures per year.

- Evaluation of new active substances: 5/year
- Authorisation of products based on new active substances: 4/year

- Authorisation of low risk biocidal products: 20/year
- Amendments of Community authorisations: 0,5/year/product authorised.

ANNEX 3

ESTABLISHMENT PLAN

Additional staff to carry out activities related to biocidal products

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
AD 13	0	1	1	1	1	1	1	1	1	1
AD 12	1	2	3	3	3	3	3	3	3	3
AD 5-11	1	8	15	15	15	15	15	15	15	15
AST 7-11	0	3	4	4	4	4	4	5	5	5
AST 1-6	0	4	7	7	7	7	7	8	8	8
Overall	2	18	30	30	30	30	30	32	32	32