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from:	General Secretariat
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No. Cion prop.:	11063/09 ENV 440 MI 246 AGRI 267 CHIMIE 50 CODEC 849 - COM(2009) 267 final
Subject:	Proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products

The Annex to this note contains a revised draft of the above-mentioned Regulation incorporating further and updated Presidency suggestions, deriving from discussions within the Working Party to date and entry into force of the Treaty on the Functioning of the European Union (TFEU), and also some editorial changes and corrections.

As regards the changes to the comitology provisions contained in the Commission's proposal, Working Party has not engaged in a detailed discussion at the present time, in view of ongoing discussions on the implementation of Articles 290 and 291 of the TFEU. The provisions that refer to the advisory and regulatory procedures provided for in Decision 1999/468/EC appear between square brackets since this Decision should be replaced in the coming months by a Regulation adopted in accordance with Article 291(3) of the TFEU. All delegations therefore have a scrutiny reservation on these provisions.

All delegations also have a scrutiny reservation on those provision in the Articles that refer to the Annexes to the Regulation, since the Working Party has yet to examine these.

Underlining indicates changes to the Commission's proposal and "[...]" a deletion. Bold text indicates changes that was not already included in document 6564/10.

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 on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the Commission ¹,

Having regard to the opinion of the European Economic and Social Committee ²,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ³,

Whereas:

[Recitals omitted.]

HAVE ADOPTED THIS REGULATION:

¹ OJ C , , p. .

² OJ C , , p. .

³ OJ C , , p. .

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 and treated materials and articles within one or more Member States or the Union;
- (2) the mutual recognition of authorisations within the Union;
- (3) the establishment at Union level of a list of active substances which may be used in biocidal products.

Article 2

Scope

1. This Regulation shall apply to biocidal products as defined in point (a) of Article 3(1).
A list of the types of biocidal products covered by this Regulation and their descriptions is set out in Annex V.
2. This Regulation shall not apply to biocidal products that are within the scope of the following instruments:
 - (a) Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products ⁴;

⁴ OJ L 262, 27.9.1976, p. 169.

- (b) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ⁵;
- (c) Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production ⁶;
- (d) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁷;
- (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 feeds in the Community ⁸;
- (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 devices ⁹;
- (g) [...] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ¹⁰;
- (h) European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners ¹¹;
- (i) 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/EEC ¹²;

⁵ OJ L 213, 21.7.1982, p. 8.

⁶ OJ L 184, 15.7.1988, p. 61.

⁷ OJ L 354, 31.12.2008, p. 16.

⁸ OJ L 92, 7.4.1990, p. 42.

⁹ OJ L 7, 11.1.1994, p. 20

¹⁰ OJ L 169, 12.7.1993, p. 1

¹¹ OJ L 61, 18.3.1995, p. 1.

¹² OJ L 125, 23.5.1996, p. 35.

- (j) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices ¹³;
- (k) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ¹⁴;
- (l) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ¹⁵;
- (m) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ¹⁶;
- (n) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ¹⁷;
- (o) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ¹⁸;
- (p) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ¹⁹.

¹³ OJ L 331, 7.12.1998, p. 1.

¹⁴ OJ L 311, 28.11.2001, p. 1.

¹⁵ OJ L 311, 28.11.2001, p. 67.

¹⁶ OJ L 268, 18.10.2003, p. 29.

¹⁷ OJ L 139, 30.4.2004, p. 1.

¹⁸ OJ L 139, 30.4.2004, p. 55.

¹⁹ OJ L L 309, 24.11.2009, p. 1.

3. Subject to any explicit provision to the contrary, this Regulation shall be without prejudice to the following instruments:
- (a) Council Directive 67/548/EEC 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ²⁰;
 - (b) Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances ²¹;
 - (c) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ²²;
 - (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) ²³;
 - (e) Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ²⁴;
 - (f) Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work ²⁵;

²⁰ OJ 196, 16.8.1967, p. 1.

²¹ OJ L 33, 8.2.1979, p. 36.

²² OJ L 183, 29.6.1989, p. 1.

²³ OJ L 131, 5.5.1998, p. 11.

²⁴ OJ L 200, 30.7.1999, p. 1.

²⁵ OJ L 262, 17.10.2000, p. 21.

- (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/EC ²⁶;
- (h) Directive 2006/114/EC of 12 December 2006 of the European Parliament and of the Council concerning misleading and comparative advertising ²⁷;
- (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 chemicals ²⁸;
- (j) [...] 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 1907/2006 ²⁹;
- (k) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides ³⁰.

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 feeds that are used for biocidal purposes.

²⁶ OJ L 396, 30.12.2006, p. 1.
²⁷ OJ L 376, 27.12.2006, p. 21.
²⁸ OJ L 204, 31.7.2008, p. 1.
²⁹ OJ L 353, 31.12.2008, p. 1.
³⁰ OJ L 309, 24.11.2009, p. 71.

6. This Regulation shall not apply to processing aids that are used for biocidal purposes.
7. Where a biocidal product is intended by its manufacturer to be used for the purpose of exerting a controlling effect on any harmful organism present on medical devices and for other purposes covered by this Regulation, the relevant essential requirements of Directives 90/385/EEC, 93/42/EEC or 98/79/EC shall also be fulfilled.
8. Biocidal products which obtained the final approval under the International Convention for the Control and Management of Ships' Ballast Water and Sediments shall be considered as authorised under Chapter VII of this Regulation. Articles 38 and 57 shall apply accordingly.

Article 3

Definitions

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

- (a) 'biocidal products' means

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

A treated material or article that has a primary biocidal function shall also be considered a biocidal product;

(aa) 'primary biocidal function' means

that the main purpose of the treated material or article is to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism;

(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 or of a treated material or article for distribution or for use on the Union 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 Union;

(k) 'treated material or article' means

any substance, mixture, material or article which was treated with or incorporates one or more biocidal products [...];

(l) '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) 'Union authorisation' means

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

(n) 'authorisation' means

national authorisation or Union 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 feed' means

food as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ³¹ and feed 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 1935/2004 ³²;

(t) 'processing aid' means

any substance which:

- (i) is not consumed as a food or feed by itself;
- (ii) is intentionally used in the processing of raw materials, foods or feed 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;

³¹ OJ L 31, 1.2.2002, p. 1.

³² OJ L 338, 13.11.2004, p. 4.

(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;

(v) 'Agency' means

the European Chemicals Agency established by Regulation (EC) No 1907/2006.

2. For the purposes of this Regulation, the definitions laid down in Article 3 of Regulation (EC) No 1907/2006 shall apply for the following terms:

(a) substance;

(b) mixture;

(c) article;

(d) product and process-orientated research and development;

(e) scientific research and development.

CHAPTER II

INCLUSION OF AN ACTIVE SUBSTANCE IN ANNEX I

Article 4

Conditions for inclusion

1. An active substance shall be included in Annex I for an initial period not exceeding 10 years if **at least one representative** biocidal product containing that active substance **may be expected to meet the criteria** laid down in point (b) of Article 16(1).
2. Inclusion of an active substance in Annex I shall be restricted to those product types in Annex V for which relevant data have been submitted in accordance with Article 6.
3. **The entry for an** active substance **in Annex I** shall, where appropriate, **specify** 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.

[...]

Article 5

Exclusion criteria

1. The following active substances shall not, subject to paragraph 2, be included in Annex I:
 - (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 in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties;
 - (e) active substances which fulfil the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006;
 - (f) active substances which are persistent organic pollutants within the meaning of Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants.

2. However, [...] active substances referred to in paragraph 1 **may** be included in Annex I [...] if, **in addition to the condition laid down in Article 4(1) being met, it is shown that** at least one of the following conditions is met:
- (a) the exposure of humans or the environment to that active substance in a biocidal product, under [normal **and reasonably foreseeable**] [realistic worst case] conditions of use, is negligible, in particular where the product is used in closed systems or strictly controlled conditions;
 - (b) [...] the active substance is necessary to control a serious danger to public health or the environment;
 - (c) [...] 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 [...] there are no suitable alternative substances or technologies.

[...]

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

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

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

2. Notwithstanding paragraph 1, the applicant need not provide data required under **its points (a) and (b) where** any of the following [...] applies:
- (a) the **data** is not necessary owing to the exposure associated with the proposed uses; **or**
 - (b) it is not scientifically necessary to supply the **data**; **or**
 - (c) it is not technically possible to **generate** the **data**.
3. An applicant may propose to adapt the data required under paragraphs 1(a) and (b) 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 **advise** the applicant about the possibility of **adapting the** data requirements, the grounds on which such an adaptation can be **made and on how to prepare** a proposal.

4. **In order to ensure the harmonised application of paragraph 2(a), the Commission shall adopt delegated acts in accordance with Article 72a establishing criteria defining when the exposure associated with the proposed uses would justify adapting the data requirements of paragraph 1(a) and (b) [...].**

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 [...] Agency and inform it of the name of the competent authority of the Member State **that it proposes should** evaluate the application.

The Agency shall take a decision on which competent authority shall be the evaluating competent authority. * That competent authority (hereinafter referred to as 'the evaluating competent authority') shall be responsible for the evaluation of the application.

2. The Agency shall [...] notify the evaluating competent authority that the application is available in the Agency database.
3. Within **60 days of** receipt of an application, the Agency shall validate the application if it complies with the following requirements:
 - (a) **the data required in accordance with** 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 [...] include **a check that all the required data or justifications for the adaptation of data requirements have been submitted, but not** an assessment of the quality or the adequacy of **that** data or **such** justifications [...].

* Article 65 provides for the Biocidal Products Committee to be responsible for preparing the Agency's decision.

4. **Where** 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. **That time limit shall not normally exceed 90 days.**

The Agency shall, within **60 days of** receipt of the additional information, **validate the application if it** determines **that** the additional information submitted is sufficient to **comply with the requirements laid down in paragraph 3.**

The Agency shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant **accordingly**. In such cases, part of the fee paid 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 **second subparagraph of paragraph 1 and the third subparagraph of paragraph 4.**
6. If the Agency, on the basis of the validation made pursuant to paragraph 3 **or 4**, considers that the application is complete, it shall without delay inform the applicant and the evaluating competent authority **accordingly**.

Article 8

Evaluation of applications

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

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall provide the applicant with the opportunity to provide [...] comments on the conclusions of the evaluation within **60 days**. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

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

2. **Where** it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency **accordingly**. The **365-day** period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received. **However, the suspension shall not exceed 365 days in total.**
3. **Where** the evaluating competent authority considers that there are concerns with regard to the cumulative effects from the use of biocidal products containing the same active substance, it shall document its concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 and include this as part of its conclusions.
4. Within **180 days of** 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.

[...]

Article 8a

Inclusion of an active substance in Annex I

In order to establish at Union level a list of active substances which may be used in biocidal products, the Commission shall, on receipt of the opinion of the Agency referred to in Article 8(4), decide on the inclusion of the active substance concerned in Annex I by means of a delegated act adopted in accordance with Article 72a.

Article 9

Active substances which are candidates for substitution

1. An active substance [...] shall be considered a candidate for substitution [...] **if any of the following conditions are met:**
 - (a) it meets at least one of the exclusion criteria listed in Article 5(1) and may be included in Annex I in accordance with Article 5(2);
 - (b) its acceptable daily intake, acute reference dose or acceptable operator exposure level, **as appropriate,** is significantly lower than those of the majority of the active substances included in Annex I for the same product type and use scenario;
 - (c) it meets two of the criteria to be considered as a persistent, bio-accumulative and toxic substance as set out in Annex XIII of Regulation (EC) No 1907/2006;
 - (d) there are reasons for concern linked to the nature of the critical effects, [...] which [...] **cannot be mitigated,** even with very restrictive risk management measures;
 - (e) it contains a significant proportion of non-active isomers or impurities.

[...]

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), each renewal of the inclusion in Annex I of an active substance that is considered as a candidate for substitution shall be [...] for a period not exceeding [five] **[seven]** [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.

Article 9a

Technical guidance notes

The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter, in particular Articles 5(2) and 9(1).

CHAPTER III

RENEWAL AND REVIEW OF INCLUSION OF AN ACTIVE SUBSTANCE IN ANNEX I

Article 10

Conditions for renewal

1. The Commission shall renew the inclusion of an active substance in Annex I if the active substance still **meets the condition laid down in Article 4(1) and, where relevant, at least one of the conditions set out in Article 5(2).**
2. **In the light of scientific and technical progress, the conditions specified for the active substance referred to in Article 4(3) shall be reviewed and, where appropriate, amended.**
3. Unless otherwise specified in the decision to renew the inclusion of an active substance in Annex I, the renewal shall be for [an unlimited period of time] [**fifteen years**].

Article 11

Submission and validation of applications

1. **Applicants wishing to seek** renewal of the inclusion of an active substance in Annex I **shall submit an application** to the Agency at least **550 days** 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 the renewal **of the inclusion of the active substance in Annex I**, the applicant shall submit:

- (a) a list of all **relevant** data [...] **that it has** generated since the **initial inclusion or, as appropriate, since the previous renewal**; and
- (b) **any available information concerning the continued validity of** the conclusions of the initial **or previous** assessment of the active substance.

[...]

- 2. The Agency shall, within **30 days of** receipt of the application, notify the evaluating competent authority [...] that the application is available in the Agency database.

Unless the Agency decides otherwise, the evaluating competent authority shall be the competent authority that carried out the original evaluation. *

- 3. **Upon receipt of the fees payable under Article 70**, the Agency shall validate the application **and inform the applicant and the evaluating competent authority accordingly**.

[...]

- 4. [...] An appeal may be brought, in accordance with Article 67, against Agency decisions under the **second subparagraph of paragraph 2**.

[...]

* Article 65 provides for the Biocidal Products Committee to be responsible for preparing the Agency's decision.

Article 12

Evaluation of applications for renewal

1. On the basis of **an assessment of** the available information and **the** need to review the conclusions of the initial evaluation of the application for inclusion in Annex I **or, as appropriate, the previous renewal**, the evaluating competent authority [...] shall, within **90 days of** the validation referred to in Article 11, decide whether, **in the light of current scientific knowledge**, a full evaluation of the application for renewal is necessary.

The evaluating competent authority may at any time require the applicant to submit the data referred to in Article 11(1)(a).

2. **Where** the evaluating competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1 to **3** of Article 8. [...]

Where the evaluating competent authority decides that a full evaluation of the application is not necessary, it shall, within **180 days**, prepare and submit to the Agency a recommendation on the renewal of the inclusion of the active substance in Annex I.

[...]

3. **Within 270 days of** receipt of a recommendation from the evaluating competent authority, the Agency shall **prepare and submit to the Commission an opinion on the inclusion of the active substance in Annex I.**

[...]

- 4.** In order to keep the list of active substances which may be used in biocidal products up-to-date, the Commission shall, [...] on receipt of the opinion of the Agency, decide on renewal of the inclusion of the active substance concerned in Annex I by means of a delegated act adopted [...] in accordance with [...] Article 72a.
- 5.** 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 advisory 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.
- 6.** 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 [...] placing on the market and an additional maximum of twelve months for [...] disposal, storage, and use of existing stocks of [...] 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 **condition laid down** in Article 4(1) **is** no longer **met**. Where those indications are confirmed the Commission shall, in order to keep the list of active substances which may be used in biocidal products up-to-date, adopt a delegated act amending the inclusion of an active substance in Annex I or removing it from that Annex in accordance with Article 72a.

[...] On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 72d.

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 **270 days of** the request, prepare an opinion and submit it to the Commission.
3. Where the Commission removes the entry for 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 [...] placing on the market and an additional maximum of twelve months for [...] disposal, storage, and use of existing stocks of [...] biocidal products containing that active substance.

Article 14

Implementing measures

The Commission may adopt detailed measures for the implementation of Articles 10 to 13 further specifying the procedures **for** the renewal and review of **the** inclusion of an active substance in Annex I [in accordance with the regulatory procedure [...] referred to in Article 72(3)].

CHAPTER IV

GENERAL PRINCIPLES CONCERNING THE AUTHORISATION OF BIOCIDAL PRODUCTS

Article 15

Placing on the market and use of biocidal products

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

2. Applications for authorisation shall be made by, or on behalf of, **the prospective authorisation holder** (the person **who would be** responsible for the placing on the market of the biocidal product in a particular Member State or in the Union).

Applications 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').

Applications for Union authorisation shall be submitted to the Agency.

The authorisation holder shall have a permanent office within the Union.

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 **and packaging** 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) **for biocidal products other than low-risk biocidal products**, the active substances included therein are listed in Annex I and any conditions **specified** in that Annex **for** those active substances are **met**;
 - (b) it is established according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI, that the biocidal product, when used as authorised and having regard to the factors referred to in paragraph 2, 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 **a** biocidal product **against** the criteria set out in point (b) of paragraph 1 shall take into account the following factors:

- (a) all [normal **and reasonably foreseeable**] [**realistic worst case**] 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. [...] A biocidal product shall only be authorised for uses for which relevant information has been submitted in accordance with Article 18.

- 4.** A biocidal product shall not be authorised for placing on the market **for** 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) [...] 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.
- 5.** 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.
- 6. Where appropriate, maximum residue limits shall be established with respect to active substances contained in a biocidal product in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council³³ and Regulation (EC) No 470/2009 of the European Parliament and of the Council³⁴.**

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;

³³ OJ L 70, 16.3.2005, p. 1.

³⁴ OJ L 152, 16.6.2009, p. 11.

- (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.

2. 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.

3. Notwithstanding paragraphs 1 and 2, 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.

[...]

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

Requirements for applications 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 proposed **ed** summary of biocidal product characteristics **including** 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 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.

Article 19

Waiving of data requirements

1. Notwithstanding Article 18, the applicant need not provide data required under that Article **where** any of the following [...] applies:
 - (a) the **data** is not necessary owing to the exposure associated with the proposed uses; **or**
 - (b) it is not scientifically necessary to supply the **data**; **or**
 - (c) it is not technically possible to **generate** the **data**.
2. The applicant may propose to adapt the data 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 **advise** the applicant about the possibility of **adapting the** data requirements, the grounds on which such an adaptation can be **made and on how to prepare** a proposal.

3. In order to ensure the harmonised application of paragraph 1(a), the Commission shall adopt delegated acts in accordance with Article 72a establishing criteria defining when the exposure associated with the proposed uses would justify adapting the data requirements of Article 18 [...].

Article 20

Content of authorisation

1. An authorisation shall stipulate the terms and conditions relating to the placing on the market and use of the biocidal product.
2. An authorisation shall include a summary of 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;
- (p) shelf-life of the biocidal product.**

3. In addition to **the information mentioned in** 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 that reference biocidal product expressed in percentage of the non-active substances contained in biocidal products **belonging** to that frame formulation;
- (c) **alternative** non-active substances that may be **included in** 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 Union authorisation, the evaluating competent authority, shall perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 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 Union authorisation, also to the Commission.
3. The receiving competent authority or, in the case of a decision on an application for a Union authorisation, the Commission shall prohibit or restrict the placing on the market or use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment weighing up the risks and benefits in accordance with Annex VI demonstrates that all the following criteria are met:
 - (a) for the uses specified in the application, 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 **and no** [...] significant economic or practical disadvantages;

- (b) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.
4. By way of derogation from paragraph 1, a biocidal product containing an active substance that is a candidate for substitution may be authorised without comparative assessment in exceptional cases where it is necessary to acquire experience first through using that product in practice.
5. Where the comparative assessment involves a question which, by reason of its scale or consequences, would be better addressed at the Union level, in particular where it is relevant to two or more competent authorities, the receiving competent authority may refer the question to the Commission for a decision. The Commission shall adopt the decision [in accordance with the regulatory procedure referred to in Article 72(3)].

The Commission shall adopt implementing rules specifying the procedures related to comparative assessments involving questions of Union interest [...] [in accordance with the regulatory procedure [...] referred to in Article 72(3)].

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 [three] [five] years after that decision. However, where the inclusion in Annex I of the active substance which is a candidate for substitution expires on an earlier date, the cancellation of the authorisation shall take effect on that earlier date.

Article 21a

Technical guidance notes

The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter and, in particular, Articles 18(1)(d) and 21(3).

CHAPTER V

NATIONAL AUTHORISATIONS OF BIOCIDAL PRODUCTS

Article 22

Submission and validation of applications

1. Within **45 days of** receipt of an application for a national authorisation **in accordance with** Article 15, the receiving competent authority shall validate the application if it complies with the following requirements:
 - (a) the **relevant** information referred to in Article 18 has been submitted;
 - (b) **the applicant states that it has not applied to any other competent authority for a national authorisation for the same biocidal product;**
 - (c) **the application** is accompanied by the fees payable under Article 70.

The validation shall [...] include **a check that all the required data or justifications for the adaptation of data requirements have been submitted, but not** an assessment of the quality or the adequacy of **that** data or **such** justifications [...].

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

The receiving competent authority shall, within **45 days of** receipt of the additional information, **validate the application if it** determines **that** the additional information submitted is sufficient to **comply with the requirements laid down in paragraph 1.**

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

3. **Where the *Union Register of Biocidal Products* shows that the competent authority of another Member State is examining an application relating to the same biocidal product or has already authorised the same biocidal product, the receiving competent authority shall decline to evaluate the application. In that event, it shall inform the applicant that it may seek mutual recognition in accordance with Article 25 or 26.**

4. If **paragraph 3 does not apply and** the receiving competent authority, on the basis of the validation made pursuant to paragraph 1 **or 2**, considers that the application is complete, it shall without delay inform the applicant **accordingly**.

Article 23

Evaluation of application

1. The receiving competent authority shall, within **365 days of** the validation **of an application in accordance with** Article 22, decide **whether to grant an authorisation** in accordance with Article 16.

[...]

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

- 3.** The receiving competent authority shall draft a report summarising the conclusions of its assessment and the reasons for authorising **the** biocidal product or for refusing to grant an authorisation (**hereinafter referred to as the 'assessment report'**). The receiving competent authority shall send the draft assessment report to the applicant **and provide it** with the opportunity to submit [...] comments within **30 days**. The receiving competent authority shall take due account of those comments when finalising its assessment. [...] It shall **provide** the applicant **with** a copy of the final assessment report.
- 4.** As soon as the receiving competent authority has **decided whether to grant an authorisation** it shall enter the following information in the *Union Register of Biocidal Products*:
- (a) the **approved** summary of biocidal product characteristics;
 - (b) the **final assessment report**;
 - (c) **any terms or conditions imposed on the placing on the market or use of the biocidal product**.

Article 24

Renewal of a national authorisation

1. **An application by or on behalf of an** authorisation holder [...] **wishing to seek the** renewal of a national authorisation **shall be submitted** to the receiving competent authority at least **550 days** 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) a list of all **relevant** data [...] that **it has** generated since the **initial** authorisation **or, as appropriate, previous renewal**; and
 - (b) **any available information concerning the continued validity of** the conclusions of the initial **or previous** assessment of the biocidal product [...].
- [...]
4. [...] **Upon receipt of the fees payable under Article 70**, the receiving competent shall validate the application **and** [...] inform the applicant **accordingly**.
5. The decision **whether to renew** the national authorisation shall be taken within **180 days of** the validation.
6. **Where**, when the application for renewal is evaluated, it appears that additional information is necessary to carry out **the** evaluation [...], the receiving competent authority shall ask the applicant to submit such information **within a specified time limit**. The **180-day period** referred to in paragraph 6 shall be suspended from the date of the request until the date the information is received. **However, the suspension shall not exceed 180 days in total.**
- The receiving competent authority may at any time require the applicant to submit the data referred to in paragraph 3(a).**
7. Where, for reasons beyond the control of the holder of **a** national authorisation, no decision is taken on the renewal of **that** authorisation before its expiry, the receiving competent authority shall grant **a** renewal [...] for the period necessary to complete the evaluation.
8. As soon as the competent authority has taken a decision **on whether to grant a** renewal of a national authorisation, it shall **update** the information referred to in Article 23(4) in the *Union Register of Biocidal Products*.

CHAPTER VI

MUTUAL RECOGNITION PROCEDURES

Article 24a

Authorisation through mutual recognition

1. **Applications for mutual recognition of a national authorisation shall be made by, or on behalf of, the prospective authorisation holder in accordance with the procedures set out in Articles 25 (mutual recognition in sequence) and 26 (mutual recognition in parallel).**

2. **Without prejudice to Article 29, all Member States receiving such applications shall, in accordance with and subject to the procedures set out in this Chapter, authorise a biocidal product under the same terms and conditions.**

Article 25

Mutual recognition [...] in sequence

1. **Applicants wishing to seek the mutual recognition in sequence in one or more Member States (for the purposes of this Article, 'the Member States concerned') of the national authorisation of a biocidal product already granted in another Member State in accordance with Article 15 (hereinafter referred to as 'the reference Member State') shall submit an application to the competent authorities of the Member States concerned containing:**
 - (a) **[...] translations, into such official languages of the Member States concerned as they may require, of the national authorisation granted by the reference Member State;**
 - (b) an electronic summary of the dossier satisfying the requirements set out in Annex III;
[...] and

(c) the summary of biocidal product characteristics referred to in Article 20(2) in such official languages of the Member States concerned as they may require.

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

2. **Within 15 days of receipt of the documents referred to in paragraph 1, the Member States concerned shall validate the application and inform the applicant accordingly.**

Within 90 days of validating the application, and subject to Articles 27, 28 and 29, the Member States concerned shall approve the assessment report and the summary of product characteristics and shall record their approval in the *Union Register of Biocidal Products*.

3. **The procedure shall be closed after all the Member States concerned have recorded their approval in the *Union Register of Biocidal Products*.**

4. Upon closure of the procedure, each of the concerned Member States shall adopt a decision in conformity with the approved assessment report and summary of product characteristics within 30 days.

[...]

Article 26

Mutual recognition [...] in parallel

1. **Applicants wishing to seek the mutual recognition in parallel of a biocidal product not authorised in accordance with Article 15 in any Member State [...]** shall submit to the competent authority of the Member State of its choice (hereinafter referred to as 'the reference Member State') an application containing:
 - (a) the information referred to in Article 18;
 - (b) a list of all other Member States where a national authorisation is sought (**for the purposes of this Article**, 'the Member States concerned').

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

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

2. The applicant shall **at the same time** submit to the competent authorities of **each of the Member States concerned** an application for mutual recognition of the authorisation for which it has applied to the reference Member State. This application shall contain:
 - (a) an electronic summary of the dossier as required in Annex III;
 - (b) the names of the reference Member State and of the Member States concerned;
 - (c) **the proposed summary of biocidal product characteristics referred to in Article 18(1)(b) in such official languages of the Member States concerned as they may require.**

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

3. The reference Member State shall [...] validate the application in accordance with Article 22.

Within 15 days of receipt of the documents referred to in paragraph 2, the Member States concerned shall validate the application and inform the applicant accordingly.

4. Within 365 days of **validating an** application, the reference Member State shall **evaluate the application and draft an assessment report in accordance with paragraphs 2 and 3 of Article 23 and shall send its** assessment report and the summary of biocidal product characteristics to the Member States concerned and to the applicant.

5. Within 90 days of receipt of the **documents referred to in the paragraph 4, and subject to Articles 27, 28 and 29,** the [...] Member States concerned shall approve the assessment report and the summary of product characteristics, **and shall record their approval in the** *Union Register of Biocidal Products*.

6. **The procedure shall be closed after all the Member States concerned have recorded their approval in the *Union Register of Biocidal Products*.**

7. Upon closure of the procedure, **the reference Member State and each Member State concerned** shall adopt a decision in conformity with the approved assessment report and summary of product characteristics within 30 days.

[...]

Article 27

Referral of objections to the coordination group

1. **A coordination group shall be set up to examine any question, other than matters referred to in Article 29, relating to whether a biocidal product for which an application for mutual recognition has been made in accordance with Article 25 or 26 meets the conditions for granting an authorisation laid down in Article 16.**

All Member States shall be entitled to participate in the work of the coordination group.

The coordination group shall establish its rules of procedure.

2. If, within the 90-day period laid down in Articles 25(2) and 26(6), any of the Member States concerned considers that a biocidal product authorised by the reference Member State does not meet the conditions laid down in Article 16, they shall send a detailed explanation of the points of disagreement and the reasons for their position to the reference Member State, the other Member States concerned, the applicant, and, where applicable, the authorisation holder. The points of disagreement shall be referred without delay to the coordination group.
3. Within the coordination group, all Member States referred to in paragraph 2 shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known. Where they reach agreement within 60 days of the communication referred to in paragraph 2, the reference Member State shall record the agreement in the *Union Register of Biocidal Products*. The procedure shall then be considered to be closed and Article 25(4) or 26(7) shall apply as appropriate.

Article 28

Referral of unresolved objections to the Commission

1. If Member States fail to reach agreement within the 60-day period laid down in Article 27(3), the reference Member State shall immediately inform the Commission, and provide it with a detailed statement of the matters on which Member States have been unable to reach agreement and the reasons for their disagreement. A copy shall be forwarded to the Member States concerned, the applicant and, where applicable, the authorisation holder.
2. The Commission shall consider and adopt a decision on the matter referred to it [in accordance with the regulatory procedure referred to in Article 72(3)].

3. The Commission may ask the Agency for an opinion on scientific or technical questions raised by Member States.
4. The decision referred to in paragraph 2 shall be addressed to all Member States and reported for information to the applicant and, where applicable, the authorisation holder. The Member States concerned and the reference Member State shall, within 30 days of notification of the decision, either grant or revoke the authorisation, or vary its terms and conditions as necessary to comply with the decision.

Article 29

Derogations from mutual recognition

1. By way of derogation from Article 24a(2), any of the Member States concerned may propose to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of:
 - (a) the protection of the environment;
 - (b) public policy or public security;
 - (c) the protection of health and life of humans, animals or plants; or
 - (d) the protection of national treasures possessing artistic, historic or archaeological value.
2. The Member State concerned shall communicate to the applicant a detailed statement of the grounds for seeking a derogation on the grounds referred to in paragraph 1. A copy shall be forwarded to the Commission.

If, within 60 days of that communication, an agreement on the proposed derogation is not reached between the applicant and the Member State concerned, that Member State shall without delay inform the Commission **accordingly**.

The Commission shall adopt a decision on the derogation [in accordance with the regulatory procedure referred to in Article 72(3)].

The Commission may ask the Agency for an opinion on scientific or technical questions raised by the applicant or the Member State concerned.

The decision shall be addressed to the Member State concerned and reported for information to the applicant.

The Member State concerned shall take necessary measures to comply with the decision within 30 days following its notification.

- 3.** By way of derogation from Articles 16 and 24a(2), a Member State may refuse to grant authorisations for product types 15, 17 and 23 of Annex V on grounds of animal welfare. Member States shall without delay inform other Member States and the Commission of any decision taken in this respect and its justification.

Article 30

Opinion of the Agency

1. If so requested by the Commission pursuant to Article 28(3) or 29(1), the Agency shall issue an opinion within 180 days from the date on which the matter was referred to it.
2. Before issuing its opinion, the Agency shall provide the applicant and, where applicable, the authorisation holder with an opportunity to present [...] explanations within a specified time limit not exceeding 30 days.

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

Article 31

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, **under the mutual recognition procedure provided for in Article 25 and** with the consent of the authorisation holder in **the other** Member State, for a national authorisation for the same biocidal product, **with** the same use and the same conditions for use **as** in that Member State.

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

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

2. [...] If the competent authority of the Member State concerned considers that the biocidal product fulfils the conditions referred to in Article 16 and the conditions under this Article are met, the competent authority shall authorise the placing on the market and use of the biocidal product. [...]

CHAPTER VII

UNION AUTHORISATIONS OF BIOCIDAL PRODUCTS

Section 1

Granting of Union authorisations

Article 32

Union authorisation

A Union authorisation issued by the Commission in accordance with this Section shall be valid throughout the Union unless otherwise specified. It shall confer the same rights and obligations in each Member State as a national authorisation. For those categories of biocidal products referred to in Article 33(1), the applicant may decide to apply for Union authorisation as an alternative to applying for a national authorisation and mutual recognition.

Article 33

Biocidal products for which Union authorisation may be granted

1. Applicants may apply for Union authorisation for following categories of biocidal products:
 - (a) [biocidal products containing one or more new active substances];
 - (b) [low-risk biocidal products];
 - (c) [product types 6 (in can preservatives) and 13 (metalworking-fluid preservatives) of Annex V.]

2. [...] In order to extend the option of Union authorisations to other categories of biocidal products, the Commission may adopt a delegated act in accordance with Article 72a adding some or all of the following categories of biocidal products to paragraph 1 of this Article [...]:

- (a) ...
- (b) ...
- (c) ...*

Article 34

Submission and validation of application

1. Applicants deciding to apply for Union authorisation in accordance with Article 33(1) shall submit an application to the Agency and inform it of the name of the competent authority of the Member State **that it proposes should evaluate** the application.

The Agency shall take a decision on which competent authority shall be the evaluating competent authority. ** **That competent authority** (hereinafter referred to as 'the evaluating competent authority') shall be responsible for the evaluation of the application.

2. The Agency shall [...] notify the evaluating competent authority that the application is available in the Agency database.

3. Within **60 days of** receipt of an application, the Agency shall validate the application if it complies with the following requirements:

- (a) the **relevant** information referred to in Article 18 has been submitted;
- (b) it is accompanied by the fees payable under Article 70.

* The Presidency has not suggested categories of biocidal products to which the centralised procedure could be extended at this stage.

** Article 65 provides for the Biocidal Products Committee to be responsible for preparing the Agency's decision.

The validation shall [...] include **a check that all the required data or justifications for the adaptation of data requirements have been submitted, but not** an assessment of the quality or the adequacy of **that** data or **such** justifications [...].

- 4.** **Where** 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. **That time limit shall not normally exceed 90 days.**

The Agency shall, within **60 days of** receipt of the additional information, **validate the application if it** determines **that** the additional information submitted is sufficient to **comply with the requirements laid down in paragraph 3.**

The Agency shall reject the application if the applicant fails to **submit the requested information** within the deadline and **shall** inform the applicant and the evaluating competent authority **accordingly**. In such cases, 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 **second subparagraph of paragraph 1 and the** third subparagraph of paragraph **4.**
- 6.** If the Agency, on the basis of the validation made pursuant to paragraph **3 or 4,** considers that the application is complete, it shall without delay inform the applicant and the evaluating competent authority **accordingly.**

Article 35

Evaluation of applications

1. The evaluating competent authority shall, within **365 days of** the validation **of an application**, evaluate **it** in accordance with Article 16 including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 19(2).

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

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

2. **Where** it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency **accordingly**. The **365-day** period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received. **However, the suspension shall not exceed 365 days in total.**
3. Within **270 days of** receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product.

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

- (a) a statement on whether the conditions of points (b), (c) and (d) of Article 16(1) are fulfilled, and a draft summary of biocidal product characteristics, as referred to in Article 20(2);

- (b) where relevant, details of any terms or conditions which should be imposed on the placing on the market or use of the biocidal product;
 - (c) the final assessment report on the biocidal product.
4. On receipt of the opinion of the Agency, the Commission shall adopt a decision on the Union authorisation of the biocidal product [in accordance with the regulatory procedure referred to in Article 72(3)]. As soon as the Commission has taken a decision to grant a Union authorisation, it shall enter the information referred to in Article 23(4) in the *Union Register of Biocidal Products*.

The Commission may, **at** the request of a Member State, decide that the Union 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, **at** the request of a Member State, decide that certain conditions of the Union 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 Union authorisation to a biocidal product because it does not fulfil the criteria for a low-risk biocidal product in accordance with Article 17, the applicant may apply, if relevant, for a Union authorisation in accordance with point (a) of Article 33(1) or a national authorisation in accordance with Chapter V.

[...]

Section 2

Renewal of Union authorisations

Article 36

Submission and validation of applications

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

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

2. The Agency shall, within **30 days of** receipt of the application, notify the evaluating competent authority [...] that the application is available in the Agency database.

Unless the Agency decides otherwise, the evaluating competent authority shall be the competent authority that carried out the original evaluation. *

3. The Commission shall renew a Union authorisation, provided that the conditions set out in Article 16 are still satisfied.
4. When applying for renewal, the applicant shall submit:
 - (a) a list of all **relevant** data [...] that **it has** generated since the **initial** authorisation **or, as appropriate, previous renewal;** and
 - (b) **any available information concerning the continued validity of** the conclusions of the initial **or previous** assessment of the biocidal product [...].

[...]

* Article 65 provides for the Biocidal Products Committee to be responsible for preparing the Agency's decision.

5. **Upon receipt of the fees payable under Article 70, the Agency shall validate the application and inform the applicant and the evaluating competent authority accordingly.**

[...]

6. [...] An appeal may be brought, in accordance with Article 67, against Agency decisions under the **second** subparagraph of paragraph **2**.

[...]

Article 37

Evaluation of applications for renewal

1. On the basis of **an assessment of** the available information and **the** need to review the conclusions of the initial assessment of the application for Union authorisation **or, as appropriate, the previous renewal,** the evaluating competent authority [...] shall, within **30 days of** the validation referred to in Article 36(5), decide whether, **in the light of current scientific knowledge,** a full evaluation of the application for renewal is necessary

The evaluating competent authority may at any time require the applicant to submit the data referred to in Article 36(4)(a).

2. **Where** the evaluating competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1 to 3 of Article 35. [...]

Where the evaluating competent authority [...] decides that a full evaluation of the application is not necessary, it shall, within **365 days of** the validation, prepare and submit to the Agency a recommendation on the renewal of the authorisation.

[...]

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 **90 days** during which they may submit written comments [...].
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 **180 days of** the date on which the matter was referred to it.
5. At the end of the period referred to in paragraph 3 or on receipt of the opinion of the Agency, the Commission shall adopt a decision to renew, or to refuse to renew, the Union authorisation [in accordance with the regulatory 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(4) in the Union Register of Biocidal Products.
6. Where, for reasons beyond the control of the holder of the Union authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Commission shall grant the renewal of the Union authorisation for the period necessary to complete the evaluation [in accordance with the advisory procedure referred to in Article 72(2)].

CHAPTER VIII

CANCELLATION, REVIEW AND AMENDMENTS OF AUTHORISATIONS

Article 38

Obligation for notification of new information

1. On becoming aware of information concerning the authorised biocidal product, or the active substance(s) it contains, which may affect the authorisation the holder of an authorisation shall without delay notify the competent authority that granted the national authorisation and the Agency or, in the case of a Union authorisation, the Commission and the Agency. In particular, the following shall be notified:
 - (a) new 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 Union authorisation, the Agency, shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 39.

3. The competent authority that granted the national authorisation or in the case of a Union authorisation, the Agency, shall without delay notify competent authorities of other Member States and, where appropriate, the Commission of any such information it received.

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

Article 39

Cancellation or amendment of an authorisation

1. The competent authority of a Member State or, in the case of a Union authorisation, the Commission, may at any time cancel or amend an authorisation it has granted in the following cases:
 - (a) 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 its obligations resulting from this Regulation.
2. Where the competent authority or, in the case of a Union authorisation, the Commission, intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give 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 those comments when finalising its decision.

3. Where the competent authority or, in the case of a Union authorisation, the Commission, cancels or amends an authorisation in accordance with paragraph 1, it shall without delay notify the authorisation holder, the competent authorities of other Member States and, where relevant, the Commission.

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

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

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

Article 40

Cancellation of an authorisation at the request of the authorisation holder

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

As soon as the competent authority, or the Commission in the case of a Union authorisation, has taken a decision to cancel an authorisation, it shall update the information referred to in Article 23(5) relating to the biocidal product concerned in the *Union 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 previously authorised the biocidal product concerned, or in the case of a Union authorisation, by the Commission.
2. An application by an authorisation holder to amend the terms and conditions of an authorisation shall be submitted to the competent authorities of all Member States which had previously authorised the biocidal product concerned, or in the case of a Union authorisation, to the Agency.

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

Article 42

Detailed rules

In order to ensure the harmonised approach to the cancellation and amendment of authorisations, the Commission shall adopt a delegated act in accordance with Article 72a specifying the criteria and procedures for the application of Articles 39 to 41, including a dispute settlement mechanism [...].

Article 43

Period of grace

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

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

Article 44

Parallel trade

1. A competent authority of a Member State (hereinafter 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 only if all the following conditions are 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; and
 - (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 *Union Register of Biocidal Products*.

CHAPTER IX

DEROGATIONS

Article 45

Derogation from the requirements

1. By way of derogation from Articles 15 and 16, a competent authority may authorise, for a period not exceeding 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 the 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 regulatory 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 Union 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 *Union 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. In order to ensure a harmonised approach, the Commission shall adopt delegated acts in accordance with Article 72a 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.

[...]

CHAPTER X

TREATED ARTICLES OR MATERIALS

Article 47

Placing on the market of treated articles or materials

1. A treated material or article shall not be placed on the market unless the biocidal product(s) that it was treated with or incorporates are authorised for that use in the Union or in at least one Member State.

2. The treated material or article shall be labelled with the following information:
 - (a) the name of all active substances that the material or article was treated with or incorporates;

 - (b) where relevant, the biocidal property attributed to the treated material or article;

 - (c) the authorisation number of all biocidal products that the material or article was treated with or incorporates;

 - (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 material or article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty [...].

CHAPTER XI

DATA PROTECTION AND DATA-SHARING

Article 48

Protection of information held by competent authorities or the Agency

1. Information submitted pursuant to the data requirements of Articles 6 and 18 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, to the use that information;
 - (b) the relevant time limit for data protection has expired; and
 - (c) sharing, pursuant to Articles 51 and 52, of information resulting from animal testing.

2. When [...] submitting information to a competent authority or to the Agency in accordance with Article 6 or 18, the applicant shall also provide a list of all the information submitted. In the list it shall specify whether it is the owner of the information or whether it only holds a letter of access to that information. In the former case, the applicant shall indicate whether it claims data protection for the information submitted, whether it has previously been protected anywhere in the Union and, if so, when any data protection period expires. 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. This shall include:
- (a) the name and contact details of the owner of the information;
 - (b) a description of the protected information;
 - (c) the date on which the information was generated.
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 environment ³⁵ and the competent authorities shall have access to the information referred to in paragraph 1. The information referred to in paragraph 4(b) and (c) shall be made publicly available.

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

³⁵ OJ L 66, 4.3.2004, p. 45.

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

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

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

The protection period for information submitted with a view to 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. The letter of access shall be signed by the data owner;
 - (b) name of the active substance or biocidal product for which access to the data is authorised;
 - (c) date on which the letter of access takes effect [...];
 - (d) a list of the submitted information to which the letter of access grants citation rights;
 - (e) the address of the manufacturing facility where the active substance or biocidal product is produced.

[...]
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 data sharing

1. In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. Testing on vertebrate animals shall not be repeated for the purposes of this Regulation.

2. Any person intending to perform tests or studies involving vertebrate animals or non-vertebrate animals, 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, [...] the prospective applicant:

(a) shall, in the case of information involving tests on vertebrate animals; and

(b) may, in the case of information not involving tests on vertebrate animals,

request from the owner of the information the right to refer to the tests or studies.

[...]

Article 52

Compensation for mandatory data 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 a formal and binding arbitration procedure administered under national law.

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) with respect to information involving tests on vertebrate animals, 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 those tests or studies [...]. [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, having regard to the guidance established by the Agency.³⁶ The prospective applicant shall be required to share only in the costs of information that it is required to submit to meet the authorisation requirements.
5. An appeal may be brought, in accordance with Article 67, against Agency decisions under paragraph 3 of this Article.

³⁶ Chapter 7 of the guidance on data sharing established in accordance with Regulation (EC) 1907/2006.

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 the same as the one authorised in the first place, or the differences between them both are not significant in relation to the risk assessment. In the same way, it should be proved that [...] 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) [...] (d) the data needed to demonstrate the comparability of the risk from and efficacy of the biocidal product to that of 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 339/93 ³⁷ 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.

³⁷ OJ L 218, 13.8.2008, p. 30.

4. The Commission shall draw up a report on the implementation of this Regulation and, in particular, on the functioning of the Union authorisation procedure and mutual recognition, by 1 January 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 documents³⁸ 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;
 - (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.

³⁸ OJ L 145, 31.5.2001, p. 43.

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 their 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 publicly available free of charge:
 - (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 publicly 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 regulatory 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 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 feeds 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

Union Register of Biocidal Products

1. A Union Register of Biocidal Products shall be established and maintained by the Commission.
2. The Union Register of Biocidal Products shall be used for the exchange of information between competent authorities, the Agency and the Commission.
3. Applicants shall use the Union Register of Biocidal Products to generate the application form for all procedures relating to the authorisation of biocidal products, the mutual recognition and the parallel trade permit.

4. Competent authorities shall update in the *Union Register of Biocidal Products* the information relating to biocidal products which have been authorised within their territory or for which a national authorisation has been refused, amended, renewed or cancelled. The Commission shall update the information relating to biocidal products which have been authorised in the Union or for which a Union authorisation has been refused, amended, renewed or cancelled.
5. The Commission may adopt detailed rules on the types of information to be entered in the *Union Register of Biocidal Products* and the procedures related to it, [in accordance with the advisory 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 be accessible only 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 Union authorisation of biocidal products and for renewal, cancellation and amendments of Union authorisation;
- (e) scientific and technical matters in the case of objections to mutual recognition;
- (f) any other questions that arise from the operation of this Regulation relating to risks to human health or the environment.

The Biocidal Products Committee shall also be responsible for preparing decisions of the Agency on which competent authority shall be the evaluating competent authority pursuant to Articles 7(1), 11(2), 34(1) and 36(2).

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.] [Each Member State may appoint one member 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 Union authorisation;
 - (e) preparing explanatory information on this Regulation;
 - (f) establishing and maintaining database(s) with information on active substances and biocidal products;
 - (g) at the request of the Commission, providing technical and scientific support to improve cooperation between the Union, 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(1) and (4), 11(2), 34(1) and (4), 36(2), 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 Union, 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 adopt delegated acts in accordance with Article 72a establishing rules concerning:
 - (a) the system of fees payable to the Agency; and
 - (b) a harmonised structure of fees and conditions of payment for fees payable to the Agency or to Member States' competent authorities.

[...]

2. The harmonised structure of fees and conditions of payment referred to in paragraph 1(b) shall be based on the following principles:
 - (a) a proportion of the fee paid to the Agency shall be transferred to the competent authority of the evaluating Member State;
 - (b) partial reimbursement of the fee if the applicant fails to submit the information requested within the deadline during validation of the application;
 - (c) 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 enterprises ³⁹;

³⁹ OJ L 124 of 20.5.2003, p. 36.

- (d) the fee structure shall take into account whether information has been submitted jointly or separately;
 - (e) in duly justified circumstances and where it is accepted by the competent authority or the Agency, it shall be possible to waive the fee;
 - (f) an annual fee shall be paid by persons placing biocidal products on the market; and
 - (g) 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 Member States' competent authorities and shall be fixed at such a level as to ensure that the revenue derived from the fees when combined with other sources of the Agency's revenue pursuant to this Regulation is sufficient to cover the cost of the services delivered by the Agency or Member States' competent authorities.
3. Member States shall oblige those who have placed or are seeking to place biocidal products on the market and those supporting inclusion of active substances in Annex I to pay fees in accordance with the harmonised structure of fees and conditions of payment to be adopted in accordance with paragraph 1.
4. In accordance with the rules referred to in paragraph 1, the Agency shall oblige those who have placed or are seeking to place biocidal products on the market and those supporting inclusion of active substances in Annex I to pay fees. The structure and the amount of fees payable to the Agency shall be determined in accordance with paragraph 1.
The Agency may collect charges for other services it provides.

Article 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.]

[...]

Article 72a

Exercise of the delegation

1. The power to adopt the delegated acts referred to in Articles 6(4), 8a, 12(5), 13(1), 19(3), 33(2), 42, 46, 70(1), 74 and 77(1) shall be conferred on the Commission for a period of five years following the entry into force of this Regulation. The Commission shall make a report in respect of the delegated powers at the latest six months before the end of the five year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 72b.
2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 72b and 72c. Where imperative grounds of urgency so require, Article 72d shall apply.

Article 72b

Revocation of the delegation

1. The delegation of power referred to in Article 72a(1) may be revoked at any time by the European Parliament or by the Council.
2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall inform the other institution and the Commission at the latest one month before the final decision is taken, stating the delegated powers which could be subject to revocation and the reasons for a revocation.
3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the Official Journal of the European Union.

Article 72c

Objections to delegated acts

1. The European Parliament or the Council may object to the delegated act within a period of three months from the date of notification.
2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, or if, before that date, the European Parliament and the Council have both informed the Commission that they have decided not to raise objections, the delegated act shall enter into force at the date stated therein.
3. If the European Parliament or the Council objects to the delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 72d

Urgency procedure

1. A delegated act adopted under the urgency procedure shall enter into force without delay and apply as long as no objection is expressed in accordance with paragraph 2. The notification of the act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
2. The European Parliament and the Council may within a period of six weeks from the date of notification object to the delegated act. In such a case, the act shall cease to be applicable. The institution which objects shall state the reasons for objecting to the delegated act.

Article 73

Adaptation to scientific and technical progress

In order to allow the provisions of this Regulation to be adapted to scientific and technical progress, the Commission shall adopt delegated acts in accordance with Article 72a as regards the adaptation of the Annexes to such scientific and technical progress.

Article 74

Updating of Annex I

In order to facilitate a smooth transition from Directive 98/8/EC to this Regulation, the Commission shall, by 1 January 2013, adopt a delegated act in accordance with [...] Article 72a to 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 regulatory 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. To that end, the Commission may adopt delegated acts in accordance with Article 72a to carry out the work programme and to specify the related rights and obligations of the competent authorities and the participants in the programme. [...]

Depending upon the progress of the work programme, the Commission may adopt delegated acts in accordance with Article 72a to extend the duration of the work programme for a determined period. [...]

In order to facilitate a smooth transition from Directive 98/8/EC to this Regulation, during the work programme the Commission shall decide by means of a delegated act adopted in accordance with Article 72a that an active substance shall be included in Annex I to 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 market⁴⁰ 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.

⁴⁰ OJ L 325, 11.12.2007, p. 3.

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 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 ... * 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.

* OJ: insert the date referred to in the first subparagraph of Article 85.

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 Union or in at least one Member State and which were available on the market on ... * may, until the date of a decision granting authorisation to these biocidal products, continue to be placed on the market if the application for authorisation is submitted at the latest by 1 January 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 ... * shall be submitted at the latest 1 January 2017.

Food contact materials which were available on the market on ... * for which an application was submitted in accordance with paragraph 1 may continue to be placed on the market until the date of the decision granting the authorisation or refusing to grant the authorisation. In 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 ... * 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.

* OJ: insert the date referred to in the first subparagraph of Article 85.

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

[Annexes omitted.]

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