Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Text with EEA relevance)

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Purpose and subject matter

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

2 This Regulation lays down rules for:

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

b the authorisation of biocidal products;

c the mutual recognition of authorisations within the Union;

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

e the placing on the market of treated articles.

Article 2

Scope

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

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

a Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[(1)];

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

c Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(2)], 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[(3)] and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision

of medicinal products for human and veterinary use and establishing a European Medicines Agency[4];

d Regulation (EC) No 1831/2003;

e Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[5] and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[6];

f Regulation (EC) No 1333/2008;

g Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods[7];

h Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed[8];

i Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market[9];

j Regulation (EC) No 1223/2009;

k Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys[10].

Notwithstanding the first subparagraph, when a biocidal product falls within the scope of one of the abovementioned instruments and is intended to be used for purposes not covered by those instruments, this Regulation shall also apply to that biocidal product insofar as those purposes are not addressed by those instruments.

3 Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall be without prejudice to the following instruments:

a Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[11];

b Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[12];

c Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work[13];

d Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption[14];

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[15];

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[16];

g Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy[17];

h Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work[18];

i Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants[19];

j Regulation (EC) No 1907/2006;

k Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising[(20)];

l Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals[(21)];

m Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures[(22)];

n Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides[(23)];

o Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer[(24)];

p Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes[(25)];

q Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions[(26)].

4 Article 69 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

5 This Regulation shall not apply to:

a food or feed used as repellents or attractants;

b biocidal products when used as processing aids.

6 Biocidal products which obtained final approval under the International Convention for the Control and Management of Ships' Ballast Water and Sediments shall be considered as authorised under Chapter VIII of this Regulation. Articles 47 and 68 shall apply accordingly.

7 Nothing in this Regulation shall prevent Member States from restricting or banning the use of biocidal products in the public supply of drinking water.

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

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

Article 3

Definitions

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

a 'biocidal product' means

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

— any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or

otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

A treated article that has a primary biocidal function shall be considered a biocidal product.

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

c ‘active substance’ means a substance or a micro-organism that has an action on or against harmful organisms;

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

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

f ‘substance of concern’ means any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect.

Such a substance would, unless there are other grounds for concern, normally be:

— a substance classified as dangerous or that meets the criteria to be classified as dangerous according to Directive 67/548/EEC, and that is present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, or

— a substance classified as hazardous or that meets the criteria for classification as hazardous according to Regulation (EC) No 1272/2008, and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation,

— a substance which meets the criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004, or which meets 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;

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

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

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

j ‘placing on the market’ means the first making available on the market of a biocidal product or of a treated article;

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

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

m ‘national authorisation’ means an administrative act by which the competent authority of a Member State authorises the making available on the market and the use of a biocidal product or a biocidal product family in its territory or in a part thereof;

n ‘Union authorisation’ means an administrative act by which the Commission authorises the making available on the market and the use of a biocidal product or a biocidal product family in the territory of the Union or in a part thereof;

o ‘authorisation’ means national authorisation, Union authorisation or authorisation in accordance with Article 26;

p ‘authorisation holder’ means the person established within the Union who is responsible for the placing on the market of a biocidal product in a particular Member State or in the Union and specified in the authorisation;

q ‘product-type’ means one of the product-types specified in Annex V;

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

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

t ‘letter of access’ means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by competent authorities, the Agency, or the Commission for the purposes of this Regulation;

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

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

w ‘technical equivalence’ means similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out, as established in Article 54;

x ‘Agency’ means the European Chemicals Agency established by Regulation (EC) No 1907/2006;

y ‘advertisement’ means a means of promoting the sale or use of biocidal products by printed, electronic or other media;

z ‘nanomaterial’ means a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm.

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials.

For the purposes of the definition of nanomaterial, 'particle', 'agglomerate' and 'aggregate' are defined as follows:

— 'particle' means a minute piece of matter with defined physical boundaries,

— 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components,

— 'aggregate' means a particle comprising strongly bound or fused particles;

aa 'administrative change' means an amendment of an existing authorisation of a purely administrative nature involving no change to the properties or efficacy of the biocidal product or biocidal product family;

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

ac 'major change' means an amendment of an existing authorisation which is neither an administrative change nor a minor change;

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

ae 'small and medium-sized enterprises' or 'SMEs' means small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises[(27)].

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

a 'substance';

b 'mixture';

c 'article';

d 'product and process-orientated research and development';

e 'scientific research and development'.

3 The Commission may, at the request of a Member State, decide, by means of implementing acts, whether a substance is a nanomaterial, having regard in particular to Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial[(28)], and whether a specific product or group of products is a biocidal product or a treated article or neither. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

4 The Commission shall be empowered to adopt delegated acts in accordance with Article 83 in order to adapt the definition of nanomaterial set out in point (z) of paragraph 1 of this Article in view of technical and scientific progress and taking into account the Recommendation 2011/696/EU.

CHAPTER II

APPROVAL OF ACTIVE SUBSTANCES

Article 4

Conditions for approval

1 An active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in point (b) of Article 19(1) taking into account the factors set out in Article 19(2) and (5). An active substance that falls under Article 5 may only be approved for an initial period not exceeding five years.

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

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

a the minimum degree of purity of the active substance;

b the nature and maximum content of certain impurities;

c the product-type;

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

e designation of categories of users;

f where relevant, characterisation of the chemical identity with regard to stereoisomers;

g other particular conditions based on the evaluation of the information related to that active substance;

h the date of approval and the expiry date of the approval of the active substance.

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

Article 5

Exclusion criteria

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

a active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B;

b active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;

c active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;

d active substances which, on the basis of the criteria specified pursuant to the first subparagraph of paragraph 3 or, pending the adoption of those criteria, on the basis of the second and third subparagraphs of paragraph 3, are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are 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 meet the criteria for being PBT or vPvB according to Annex XIII to Regulation (EC) No 1907/2006.

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

a the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment;

b it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or

c not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

When deciding whether an active substance may be approved in accordance with the first subparagraph, the availability of suitable and sufficient alternative substances or technologies shall be a key consideration.

The use of a biocidal product containing active substances approved in accordance with this paragraph shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment to those active substances is minimised. The use of the biocidal product with the active substances concerned shall be restricted to Member States in which at least one of the conditions set out in this paragraph is met.

3 No later than 13 December 2013, the Commission shall adopt delegated acts in accordance with Article 83 specifying scientific criteria for the determination of endocrine-disrupting properties.

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

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

Article 6

Data requirements for an application

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

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

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

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

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

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

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

c it is not technically possible to generate the data.

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

3 An applicant may propose to adapt the data as part of the dossiers required under points (a) and (b) of paragraph 1 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with a reference to the specific rules in Annex IV.

4 The Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying criteria for determining what constitutes adequate justification to adapt the data requirements under paragraph 1 of this Article on the grounds referred to in point (a) of paragraph 2 of this Article.

Article 7

Submission and validation of applications

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

2 The Agency shall inform the applicant of the fees payable under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of the acceptance of the application and its unique identification code.

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

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

The evaluating competent authority shall, as soon as possible after the Agency has accepted an application, inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

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

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

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Agency accordingly. In such cases, part of the fees paid in accordance with Article 80(1) and (2) shall be reimbursed.

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

6 An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 2 of this Article.

Article 8

Evaluation of applications

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

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

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

3 Where the evaluating competent authority considers that there are concerns for human health, animal health or the environment as a result of the cumulative effects from the use of biocidal products containing the same or different active substances, it shall document its concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 and include this as part of its conclusions.

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

Article 9

Approval of an active substance

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

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

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

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

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

Article 10

Active substances which are candidates for substitution

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

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

b it meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser;

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

d it meets two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006;

e there are reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures;

f it contains a significant proportion of non-active isomers or impurities.

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

3 Prior to submitting its opinion on the approval or renewal of the approval of an active substance to the Commission, the Agency shall make publicly available, without prejudice to Articles 66 and 67, information on potential candidates for substitution during a period of no more than 60 days, during which time interested third parties may submit relevant information, including information on available substitutes. The Agency shall take due account of the information received when finalising its opinion.

4 By way of derogation from Article 4(1) and Article 12(3), the approval of an active substance that is considered as a candidate for substitution and each renewal shall be for a period not exceeding seven years.

5 Active substances that are considered as candidates for substitution in accordance with paragraph 1 shall be identified as such in the relevant Regulation adopted in accordance with Article 9.

Article 11

Technical guidance notes

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

CHAPTER III

RENEWAL AND REVIEW OF APPROVAL OF AN ACTIVE SUBSTANCE

Article 12

Conditions for renewal

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

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

3 The renewal of an approval of an active substance shall be for 15 years for all product-types to which the approval applies, unless a shorter period is specified in the implementing regulation adopted in accordance with point (a) of Article 14(4) renewing such an approval.

Article 13

Submission and acceptance of applications

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

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

a without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial approval or, as appropriate, previous renewal; and

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

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

The Agency shall inform the applicant of the fees payable under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of the acceptance.

4 An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 3 of this Article.

Article 14

Evaluation of applications for renewal

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

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

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

The evaluating competent authority shall, as soon as possible after the Agency has accepted an application, notify the applicant of the fees payable under Article 80(2). The evaluating competent authority shall reject the application if the applicant fails to pay the fees within 30 days of the notification and shall inform the applicant accordingly.

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

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

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

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

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Article 9(2) shall apply.

5 Where, for reasons beyond the control of the applicant, the approval of the active substance is likely to expire before a decision has been taken on its renewal, the Commission shall, by means of implementing acts, adopt a decision postponing the expiry date of approval for a period sufficient to enable it to examine the application. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

6 Where the Commission decides not to renew or decides to amend the approval of an active substance for one or more product-types, the Member States or, in the case of a Union authorisation, the Commission shall cancel or, where appropriate, amend the authorisations of biocidal products of the product-type(s) concerned containing that active substance. Articles 48 and 52 shall apply accordingly.

Article 15

Review of approval of an active substance

1 The Commission may review the approval of an active substance for one or more product-types at any time where there are significant indications that the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2) are no longer met. The Commission may also review the approval of an active substance for one or more product-types at the request of a Member State if there are indications that the use of the active substance in biocidal products or treated articles raises significant concerns about the safety of such biocidal products or treated articles. The Commission shall make publicly available the information that it is carrying out a review and shall provide an opportunity for applicant to submit comments. The Commission shall take due account of those comments in its review.

Where those indications are confirmed, the Commission shall adopt an implementing Regulation amending the conditions of approval of an active substance or cancelling its approval. That implementing Regulation shall be adopted in accordance with the examination procedure referred to in Article 82(3). Article 9(2) shall apply. The Commission shall inform the initial applicants for the approval accordingly.

On duly justified imperative grounds of urgency the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 82(4).

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

3 Where the Commission decides to cancel or amend the approval of an active substance for one or more product-types, the Member States or, in the case of a Union authorisation, the Commission shall cancel or, where appropriate, amend the authorisations of biocidal products of the product-type(s) concerned containing that active substance. Articles 48 and 52 shall apply accordingly.

Article 16

Implementing measures

The Commission may adopt, by means of implementing acts, detailed measures for the implementation of Articles 12 to 15, further specifying the procedures for the renewal

and review of the approval of an active substance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

CHAPTER IV

GENERAL PRINCIPLES CONCERNING THE AUTHORISATION OF BIOCIDAL PRODUCTS

Article 17

Making available on the market and use of biocidal products

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

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

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

Applications for Union authorisation shall be submitted to the Agency.

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

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

5 Biocidal products shall be used in compliance with the terms and conditions of the authorisation stipulated in accordance with Article 22(1) and the labelling and packaging requirements laid down in Article 69.

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

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

6 The authorisation holder shall notify each competent authority that has granted a national authorisation for a biocidal product family of each product within the biocidal product family at least 30 days before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission.

7 The Commission shall, by means of an implementing act, specify procedures for the authorisation of the same biocidal products by the same or different enterprises under the same terms and conditions. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Article 18

Measures geared to the sustainable use of biocidal products

By 18 July 2015 the Commission shall, on the basis of experience gained with the application of this Regulation, submit to the European Parliament and the Council a report on how this Regulation is contributing to the sustainable use of biocidal products, including on the need to introduce additional measures, in particular for professional users, to reduce the risks posed to human health, animal health and the environment by biocidal products. That report shall, inter alia, examine:

(a) the promotion of best practices as a means of reducing the use of biocidal products to a minimum;

(b) the most effective approaches for monitoring the use of biocidal products;

(c) the development and application of integrated pest management principles with respect to the use of biocidal products;

(d) the risks posed by the use of biocidal products in specific areas such as schools, workplaces, kindergartens, public spaces, geriatric care centres or in the vicinity of surface water or groundwater and whether additional measures are needed to address those risks;

(e) the role that improved performance of the equipment used for applying biocidal products could play in sustainable use.

On basis of that report, the Commission shall, if appropriate, submit a proposal for adoption in accordance with the ordinary legislative procedure.

Article 19

Conditions for granting an authorisation

1 A biocidal product other than those eligible for the simplified authorisation procedure in accordance with Article 25 shall be authorised provided the following conditions are met:

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

b it is established, according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI, that the biocidal product, when used as authorised and having regard to the factors referred to in paragraph 2 of this Article, fulfils the following criteria:

(i) the biocidal product is sufficiently effective;

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

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

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

— the fate and distribution of the biocidal product in the environment,

— contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,

— the impact of the biocidal product on non-target organisms,

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

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

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

e where appropriate, maximum residue limits for food and feed have been established with respect to active substances contained in a biocidal product in accordance with Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[29], Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food[30], Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin[31], Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin[32] or Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[33];

f where nanomaterials are used in that product, the risk to human health, animal health and the environment has been assessed separately.

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

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

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

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

d cumulative effects;

e synergistic effects.

3 A biocidal product shall only be authorised for uses for which relevant information has been submitted in accordance with Article 20.

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

a it meets the criteria according to Directive 1999/45/EC for classification as:

— toxic or very toxic,

— a category 1 or 2 carcinogen,

— a category 1 or 2 mutagen, or
— toxic for reproduction category 1 or 2;

b it meets the criteria according to Regulation (EC) No 1272/2008 for classification as:
— acute oral toxicity category 1 or 2 or 3,
— acute dermal toxicity category 1 or 2 or 3,
— acute inhalation toxicity (gases and dust/mist) category 1 or 2 or 3,
— acute inhalation toxicity (vapours) category 1 or 2,
— a category 1A or 1B carcinogen,
— a category 1A or 1B mutagen, or
— toxic for reproduction category 1A or 1B;

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

d it has endocrine-disrupting properties; or

e it has developmental neurotoxic or immunotoxic effects.

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

The use of a biocidal product authorised pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to this paragraph shall be restricted to Member States in which the condition of the first subparagraph is met.

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

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

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

8 Where, for active substances covered by Article 10(1)(a) of Regulation (EC) No 470/2009, no maximum residue limit has been established in accordance with Article 9 of that Regulation at the time of the approval of the active substance, or where a limit established in accordance with Article 9 of that Regulation needs to be amended, the maximum residue limit shall be established or amended in accordance with the procedure referred to in Article 10(1)(b) of that Regulation.

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

Article 20

Requirements for applications for authorisation

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

a for biocidal products other than biocidal products meeting the conditions laid down in Article 25:

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

(ii) a summary of the biocidal product characteristics including the information referred to in points (a), (b) and (e) to (q) of Article 22(2), as applicable;

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

b for biocidal products that the applicant considers meet the conditions laid down in Article 25:

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

(ii) efficacy data; and

(iii) any other relevant information in support of the conclusion that the biocidal product meets the conditions laid down in Article 25.

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

3 For applications for Union authorisations submitted under Article 43, the applicant shall submit the summary of the biocidal product characteristics referred to in point (ii) of paragraph (1)(a) of this Article in one of the official languages of the Union accepted by the evaluating competent authority at the time of application and in all official languages of the Union before the authorisation of the biocidal product.

Article 21

Waiving of data requirements

1 By way of derogation from Article 20, the applicant need not provide data required under that Article where any of the following applies:

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

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

c it is not technically possible to generate the data.

2 The applicant may propose to adapt the data requirements of Article 20 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with reference to the specific rules in Annex IV.

3 In order to ensure the harmonised application of paragraph 1(a) of this Article, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying criteria for defining when the exposure associated with the proposed uses would justify adapting the data requirements of Article 20.

Article 22

Content of authorisation

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

2 Without prejudice to Articles 66 and 67, the summary of the biocidal product characteristics for a single biocidal product or, in the case of a biocidal product family, the biocidal products within that biocidal product family, shall include the following information:

a trade name of the biocidal product;

b name and address of the authorisation holder;

c date of the authorisation and its date of expiry;

d authorisation number of the biocidal product, together with, in the case of a biocidal product family, the suffixes to apply to individual biocidal products within the biocidal product family;

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

f manufacturers of the biocidal product (names and addresses including location of manufacturing sites);

g manufacturers of the active substances (names and addresses including location of manufacturing sites);

h type of formulation of the biocidal product;

i hazard and precautionary statements;

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

k target harmful organisms;

l application doses and instructions for use;

m categories of users;

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

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

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

q where relevant, other information about the biocidal product.

Article 23

Comparative assessment of biocidal products

1 The receiving competent authority or, in the case of an evaluation of an application for a Union authorisation, the evaluating competent authority, shall perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1).

2 The results of the comparative assessment shall be forwarded, without delay, to the competent authorities of other Member States and the Agency and, in the case of evaluation of an application for a Union authorisation, also to the Commission.

3 The receiving competent authority or, in the case of a decision on an application for a Union authorisation, the Commission shall prohibit or restrict the making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment in accordance with Annex VI (‘comparative assessment’) demonstrates that both of the following criteria are met:

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

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

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

5 Where the comparative assessment involves a question which, by reason of its scale or consequences, would be better addressed at Union level, in particular where it is relevant to two or more competent authorities, the receiving competent authority may refer the question to the Commission for a decision. The Commission shall adopt that decision by means of implementing acts in accordance with the examination procedure referred to in Article 82(3).

The Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying the criteria for determining when comparative assessments involve questions better addressed at Union level and the procedures for such comparative assessments.

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

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

Article 24

Technical guidance notes

The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter and, in particular, Article 22(2) and Article 23(3).

CHAPTER V

SIMPLIFIED AUTHORISATION PROCEDURE

Article 25

Eligibility for the simplified authorisation procedure

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

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

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

(c) the biocidal product does not contain any nanomaterials;

(d) the biocidal product is sufficiently effective; and

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

Article 26

Applicable procedure

1 Applicants seeking the authorisation of a biocidal product meeting the conditions of Article 25 shall submit an application to the Agency, informing it of the name of the competent authority of the Member State that it proposes should evaluate the application and providing written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

2 The evaluating competent authority shall inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

Upon receipt of the fees payable under Article 80(2), the evaluating competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

3 Within 90 days of accepting an application, the evaluating competent authority shall authorise the biocidal product if satisfied that the product meets the conditions laid down in Article 25.

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

The evaluating competent authority shall, within 90 days of receipt of the additional information, authorise the biocidal product if satisfied, on the basis of the additional information submitted, that the product meets the conditions laid down in Article 25.

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, where fees have been paid, part of the fees paid in accordance with Article 80(2) shall be reimbursed.

Article 27

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

1 A biocidal product authorised in accordance with Article 26 may be made available on the market in all Member States without the need for mutual recognition. However, the authorisation holder shall notify each Member State no later than 30 days before placing the biocidal product on the market within the territory of that Member State and shall use the official language or languages of that Member State in the product's labelling, unless that Member State provides otherwise.

2 Where a Member State other than that of the evaluating competent authority considers that a biocidal product authorised in accordance with Article 26 has not been notified or labelled in accordance with paragraph 1 of this Article or does not meet the requirements of Article 25, it may refer that matter to the coordination group established in accordance with Article 35(1). Article 35(3) and Article 36 shall apply *mutatis mutandis*.

Where a Member State has valid reasons to consider that a biocidal product authorised in accordance with Article 26 does not meet the criteria laid down in Article 25 and a decision pursuant to Articles 35 and 36 has not yet been taken, that Member State may provisionally restrict or prohibit making available on the market or use of that product on its territory.

Article 28

Amendment of Annex I

1 The Commission shall be empowered to adopt delegated acts in accordance with Article 83 amending Annex I, after receiving the opinion of the Agency, in order to include active substances provided that there is evidence that they do not give rise to concern according to paragraph 2 of this Article.

2 Active substances give rise to concern where:

a they meet the criteria for classification according to Regulation (EC) No 1272/2008 as:
- explosive/highly flammable,
- organic peroxide,
- acutely toxic of category 1, 2 or 3,
- corrosive of category 1A, 1B or 1C,

— respiratory sensitiser,
— skin sensitiser,
— germ cell mutagen of category 1 or 2;
— carcinogen of category 1 or 2,
— human reproductive toxicant of category 1 or 2 or with effects on or via lactation,
— specific target organ toxicant by single or repeated exposure, or
— toxic to aquatic life of acute category 1;

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

c they have neurotoxic or immunotoxic properties.

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

3 The Commission shall also be empowered to adopt delegated acts in accordance with Article 83 amending Annex I, after receiving the opinion of the Agency, in order to restrict or to remove the entry for an active substance if there is evidence that biocidal products containing that substance do not, in certain circumstances, satisfy the conditions set out in paragraph 1 of this Article or in Article 25. Where imperative grounds of urgency so require, the procedure provided for in Article 84 shall apply to delegated acts adopted pursuant to this paragraph.

4 The Commission shall apply paragraph 1 or 3 at its own initiative or at the request of an economic operator or a Member State providing the necessary evidence as referred to in those paragraphs.

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

5 The Commission may adopt implementing acts further specifying the procedures to be followed with respect to an amendment of Annex I. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

CHAPTER VI

NATIONAL AUTHORISATIONS OF BIOCIDAL PRODUCTS

Article 29

Submission and validation of applications

1 Applicants wishing to apply for a national authorisation in accordance with Article 17 shall submit an application to the receiving competent authority. The receiving competent authority shall inform the applicant of the fees payable under Article 80(2), and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly. Upon receipt of the fees payable under Article 80(2), the receiving competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

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

a the relevant information referred to in Article 20 has been submitted; and

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

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

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

The receiving competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirements laid down in paragraph 2.

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

4 Where the Register for Biocidal Products referred to in Article 71 shows that a competent authority other than the receiving competent authority is examining an application relating to the same biocidal product or has already authorised the same biocidal product, the receiving competent authority shall decline to evaluate the application. In that event, the receiving competent authority shall inform the applicant of the possibility of seeking mutual recognition in accordance with Article 33 or 34.

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

Article 30

Evaluation of applications

1 The receiving competent authority shall, within 365 days of the validation of an application in accordance with Article 29, decide whether to grant an authorisation in accordance with Article 19. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable.

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

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

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

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

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

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

Article 31

Renewal of a national authorisation

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

2 The receiving competent authority shall renew the national authorisation, provided that the conditions set out in Article 19 are still satisfied. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable.

3 When applying for renewal, the applicant shall submit:

a without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial authorisation or, as appropriate, previous renewal; and

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

4 The receiving competent authority shall inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

Upon receipt of the fees payable under Article 80(2), the receiving competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

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

6 Where the receiving competent authority decides that a full evaluation of the application is necessary, it shall decide on the renewal of the authorisation after carrying out an evaluation of the application in accordance with paragraphs 1, 2 and 3 of Article 30.

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

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

CHAPTER VII

MUTUAL RECOGNITION PROCEDURES

Article 32

Authorisation through mutual recognition

1 Applications for mutual recognition of a national authorisation shall be made in accordance with the procedures set out in Article 33 (mutual recognition in sequence) or Article 34 (mutual recognition in parallel).

2 Without prejudice to Article 37, all Member States receiving applications for mutual recognition of a national authorisation for a biocidal product shall, in accordance with and subject to the procedures set out in this Chapter, authorise the biocidal product under the same terms and conditions.

Article 33

Mutual recognition in sequence

1 Applicants wishing to seek the mutual recognition in sequence, in one or more Member States ('the Member States concerned'), of the national authorisation of a biocidal product already granted in another Member State in accordance with Article 17 ('the reference Member State') shall submit an application to each of the competent authorities of the Member States concerned containing, in each case, a translation of the national authorisation granted by the reference Member State into such official languages of the Member State concerned as it may require.

The competent authorities of the Member States concerned shall inform the applicant of the fees payable under Article 80 and shall reject the application if the applicant fails to pay the fees within 30 days. They shall inform the applicant and the other competent authorities accordingly. Upon receipt of the fees payable under Article 80, the competent authorities of the Member States concerned shall accept the application and inform the applicant indicating the date of acceptance.

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

Within 90 days of validating the application, and subject to Articles 35, 36 and 37, the Member States concerned shall agree on the summary of biocidal product characteristics referred to in Article 22(2) and shall record their agreement in the Register for Biocidal Products.

3 Within 30 days of reaching agreement, each of the Member States concerned shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics.

4 Without prejudice to Articles 35, 36, and 37, if no agreement is reached within the 90-day period referred to in the second subparagraph of paragraph 2, each Member State that agrees to the summary of biocidal product characteristics referred to in paragraph 2, may authorise the product accordingly.

Article 34

Mutual recognition in parallel

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

a the information referred to in Article 20;

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

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

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

a the names of the reference Member State and of the Member States concerned;

b the summary of biocidal product characteristics referred to in Article 20(1)(a)(ii) in such official languages of the Member States concerned as they may require.

3 The competent authorities of the reference Member State and of the Member States concerned shall inform the applicant of the fees payable in accordance with Article 80 and shall reject the application if the applicant fails to pay the fees within 30 days. They shall inform the applicant and the other competent authorities accordingly. Upon receipt of the fees payable under Article 80, the competent authorities of the reference Member State and of the Member States concerned shall accept the application and inform the applicant indicating the date of acceptance.

4 The reference Member State shall validate the application in accordance with Article 29(2) and (3) and inform the applicant and the Member States concerned accordingly.

Within 365 days of validating an application, the reference Member State shall evaluate the application and draft an assessment report in accordance with Article 30(3) and shall send its assessment report and the summary of biocidal product characteristics to the Member States concerned and to the applicant.

5 Within 90 days of receipt of the documents referred to in paragraph 4, and subject to Articles 35, 36 and 37, the Member States concerned shall agree on the summary of biocidal product characteristics, and shall record their agreement in the Register for Biocidal Products. The reference Member State shall enter the agreed summary of biocidal product characteristics and the final assessment report in the Register for Biocidal Products, together with any agreed terms or conditions imposed on the making available on the market or use of the biocidal product.

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

7 Without prejudice to Articles 35, 36, and 37, if no agreement is reached within the 90-day period referred to in paragraph 5, each Member State that agrees to the summary of biocidal product characteristics referred to in paragraph 5 may authorise the product accordingly.

Article 35

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 37, relating to whether a biocidal product for which an application for mutual recognition has been made in accordance with Article 33 or 34 meets the conditions for granting an authorisation laid down in Article 19.

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

The coordination group shall establish its rules of procedure.

2 If any of the Member States concerned considers that a biocidal product assessed by the reference Member State does not meet the conditions laid down in Article 19, it shall send a detailed explanation of the points of disagreement and the reasons for its position to the reference Member State, the other Member States concerned, the applicant, and, where applicable, to the authorisation holder. The points of disagreement shall be referred without delay to the coordination group.

3 Within the coordination group, all Member States referred to in paragraph 2 of this Article shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known. Where they reach agreement within 60 days of the referral of the points of disagreement referred to in paragraph 2 of this Article, the reference Member State shall record the agreement in the Register for Biocidal Products. The procedure shall then be considered to be closed and the reference Member State and each of the Member States concerned shall authorise the biocidal product in accordance with Article 33(4) or Article 34(6) as appropriate.

Article 36

Referral of unresolved objections to the Commission

1 If the Member States referred to in Article 35(2) fail to reach agreement within the 60-day period laid down in Article 35(3), the reference Member State shall immediately inform the Commission, and provide it with a detailed statement of the matters on which Member States have been unable to reach agreement and the reasons for their disagreement. A copy of that statement shall be forwarded to the Member States concerned, the applicant and, where applicable, the authorisation holder.

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

3 The Commission shall adopt, by means of implementing acts, a decision on the matter referred to it. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

4 The decision referred to in paragraph 3 shall be addressed to all Member States and reported for information to the applicant and, where applicable, the authorisation holder. The Member States concerned and the reference Member State shall, within 30 days of notification

of the decision, either grant, refuse to grant or cancel the authorisation, or vary its terms and conditions as necessary to comply with the decision.

Article 37

Derogations from mutual recognition

1 By way of derogation from Article 32(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, particularly of vulnerable groups, or of animals or plants;

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

e the target organisms not being present in harmful quantities.

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

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

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

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

b shall adopt a decision on the derogation in accordance with the examination procedure referred to in Article 82(3).

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

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

3 If the Commission has not adopted a decision pursuant to paragraph 2 within 90 days of being informed in accordance with the second subparagraph of paragraph 2, the Member State concerned may implement the derogation proposed pursuant to paragraph 1.

While the procedure under this Article is ongoing, the Member States' obligation to authorise a biocidal product within two years of the date of approval, referred to in the first subparagraph of Article 89(3), shall be temporarily suspended.

4 By way of derogation from Article 32(2), a Member State may refuse to grant authorisations for product-types 15, 17 and 20 on grounds of animal welfare. Member States shall without delay inform other Member States and the Commission of any decision taken in this respect and its justification.

Article 38

Opinion of the Agency

1 If so requested by the Commission pursuant to Article 36(2) or Article 37(2), the Agency shall issue an opinion within 120 days from the date on which the matter in question was referred to it.

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

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

Article 39

Application for mutual recognition by official or scientific bodies

1 Where no application for a national authorisation has been submitted in a Member State for a biocidal product that is already authorised in another Member State, official or scientific bodies involved in pest control activities or the protection of public health may apply, under the mutual recognition procedure provided for in Article 33 and with the consent of the authorisation holder in that other Member State, for a national authorisation for the same biocidal product, with the same use and the same conditions for use as in that Member State.

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

The application shall be accompanied by the fees payable under Article 80.

2 Where the competent authority of the Member State concerned considers that the biocidal product fulfils the conditions referred to in Article 19 and the conditions under this Article are met, the competent authority shall authorise the making available on the market and use of the biocidal product. In that case, the body that made the application shall have the same rights and obligations as other authorisation holders.

Article 40

Supplementary rules and technical guidance notes

The Commission shall be empowered to adopt delegated acts in accordance with Article 83 laying down supplementary rules for the renewal of authorisations subject to mutual recognition.

The Commission shall also draw up technical guidance notes to facilitate the implementation of this Chapter and, in particular, Articles 37 and 39.

CHAPTER VIII

UNION AUTHORISATIONS OF BIOCIDAL PRODUCTS

SECTION 1

Granting of Union authorisations

Article 41

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 42(1), the applicant may apply for Union authorisation as an alternative to applying for a national authorisation and mutual recognition.

Article 42

Biocidal products for which Union authorisation may be granted

1 Applicants may apply for Union authorisation for biocidal products which have similar conditions of use across the Union with the exception of biocidal products that contain active substances that fall under Article 5 and those of product-types 14, 15, 17, 20 and 21. The Union authorisation may be granted:

a from 1 September 2013, to biocidal products containing one or more new active substances and biocidal products of product-types 1, 3, 4, 5, 18 and 19;

b from 1 January 2017, to biocidal products of product-types 2, 6 and 13; and

c from 1 January 2020, to biocidal products of all remaining product-types.

2 The Commission shall by 1 September 2013 draw up guidance documents on the definition of ‘similar conditions of use across the Union’.

3 The Commission shall submit a report to the European Parliament and the Council on the application of this Article by 31 December 2017. That report shall contain an assessment of the exclusion of product-types 14, 15, 17, 20 and 21 from the Union authorisation.

The report shall, if appropriate, be accompanied by relevant proposals for adoption in accordance with the ordinary legislative procedure.

Article 43

Submission and validation of applications

1 Applicants wishing to apply for Union authorisation in accordance with Article 42(1) shall submit an application to the Agency, including a confirmation that the biocidal product would have similar conditions of use across the Union, informing the Agency of the name of the competent authority of the Member State that they propose should evaluate the application and

providing written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

2 The Agency shall inform the applicant of the fees payable under Article 80(1), and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of acceptance.

3 Within 30 days of the Agency accepting an application, the evaluating competent authority shall validate the application if the relevant information referred to in Article 20 has been submitted.

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

The evaluating competent authority shall, as soon as possible after the Agency has accepted an application, inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

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

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

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, part of the fees paid in accordance with Article 80(1) and (2) shall be reimbursed.

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

6 An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 2 of this Article.

Article 44

Evaluation of applications

1 The evaluating competent authority shall, within 365 days of the validation of an application, evaluate it in accordance with Article 19, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 21(2), and send an assessment report and the conclusions of its evaluation to the Agency.

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall provide the applicant with the opportunity to provide written comments on the

conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

2 Where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly. The 365-day period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received. However, the suspension shall not exceed 180 days in total other than in exceptional cases and where justified by the nature of the information requested.

3 Within 180 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product.

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

a a statement on whether the conditions laid down in Article 19(1) are fulfilled, and a draft summary of biocidal product characteristics, as referred to in Article 22(2);

b where relevant, details of any terms or conditions which should be imposed on the making available on the market or use of the biocidal product;

c the final assessment report on the biocidal product.

4 Within 30 days of submitting its opinion to the Commission, the Agency shall transmit to the Commission, in all the official languages of the Union, the draft summary of the biocidal product characteristics, as referred to in Article 22(2), where applicable.

5 On receipt of the opinion of the Agency, the Commission shall adopt either an implementing regulation granting the Union authorisation to the biocidal product or an implementing decision stating that the Union authorisation of the biocidal product has not been granted. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

The Commission shall, at the request of a Member State, decide to adjust certain conditions of a Union authorisation specifically for the territory of that Member State or decide that a Union authorisation shall not apply in the territory of that Member State, provided that such a request can be justified on one or more of the grounds referred to in Article 37(1).

SECTION 2

Renewal of Union authorisations

Article 45

Submission and acceptance of applications

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

The application shall be accompanied by the fees payable under Article 80(1).

2 When applying for renewal, the applicant shall submit:

a without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial authorisation or, as appropriate, previous renewal; and

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

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

The Agency shall inform the applicant of the fees payable to it under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable to it under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of acceptance.

4 An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 3 of this Article.

Article 46

Evaluation of applications for renewal

1 On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for Union authorisation or, as appropriate, the previous renewal, the evaluating competent authority shall, within 30 days of the Agency accepting the application in accordance with Article 45(3), decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary.

2 Where the evaluating competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1 and 2 of Article 44.

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

The evaluating competent authority shall, as soon as possible after the Agency has accepted the application, inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

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

4 On receipt of the opinion of the Agency, the Commission shall adopt either an implementing Regulation to renew the Union authorisation or an implementing decision to refuse to renew the Union authorisation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

The Commission shall renew a Union authorisation, provided that the conditions set out in Article 19 are still satisfied.

5 Where, for reasons beyond the control of the holder of the Union authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Commission shall grant the renewal of the Union authorisation for the period necessary to complete the evaluation by means of implementing acts. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

CHAPTER IX

CANCELLATION, REVIEW AND AMENDMENT OF AUTHORISATIONS

Article 47

Obligation for notification of unexpected or adverse effects

1 On becoming aware of information concerning the authorised biocidal product, or the active substance(s) it contains, that may affect the authorisation, the holder of an authorisation shall without delay notify the competent authority that granted the national authorisation and the Agency or, in the case of a Union authorisation, the Commission and the Agency. In particular, the following shall be notified:

a new data or information on the adverse effects of the active substance or biocidal product for humans, in particular vulnerable groups, animals or the environment;

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

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

2 The competent authority that granted the national authorisation or, in the case of a Union authorisation, the Agency, shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 48.

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

Competent authorities of Member States that have issued a national authorisation 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 48.

Article 48

Cancellation or amendment of an authorisation

1 Without prejudice to Article 23, the competent authority of a Member State or, in the case of a Union authorisation, the Commission shall at any time cancel or amend an authorisation it has granted where it considers that:

a the conditions referred to in Article 19 or, where relevant, in Article 25 are not satisfied;

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

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

2 Where the competent authority or, in the case of a Union authorisation, the Commission, intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give it the opportunity to submit comments or additional information within a specified time limit. The evaluating competent authority or, in the case of a Union authorisation, the Commission, shall take due account of those comments when finalising its decision.

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

Competent authorities that have issued authorisations under the mutual recognition procedure for biocidal products for which the authorisation has been cancelled or amended shall, within 120 days of the notification, cancel or amend the authorisations and shall notify the Commission accordingly.

In the case of disagreement between competent authorities of certain Member States concerning national authorisations subject to mutual recognition the procedures laid down in Articles 35 and 36 shall apply *mutatis mutandis*.

Article 49

Cancellation of an authorisation at the request of the authorisation holder

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

Article 50

Amendment of an authorisation at the request of the authorisation holder

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

2 An authorisation holder seeking to change any of the information submitted in relation to the initial application for authorisation of the product shall apply to the competent authorities of relevant Member States having authorised the biocidal product concerned, or in the case of a Union authorisation, the Agency. Those competent authorities shall decide, or, in the case of a Union authorisation, the Agency shall examine and the Commission decide whether the conditions of Article 19 or, where relevant, Article 25 are still met and whether the terms and conditions of the authorisation need to be amended.

The application shall be accompanied by the fees payable under Article 80(1) and (2).

3 An amendment to an existing authorisation shall fall under one of the following categories of changes:

a administrative change;

b minor change; or

c major change.

Article 51

Detailed rules

In order to ensure a harmonised approach to the cancellation and amendment of authorisations, the Commission shall lay down detailed rules for the application of Articles 47 to 50 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

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

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

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

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

Article 52

Period of grace

Notwithstanding Article 89, where the competent authority or, in the case of a biocidal product authorised at Union level, the Commission, cancels or amends an authorisation or decides not to renew it, it shall grant a period of grace for the disposal, making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

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

CHAPTER X

PARALLEL TRADE

Article 53

Parallel trade

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

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

The application shall be accompanied by the information referred to in paragraph 4 and all other information necessary to demonstrate that the biocidal product is identical to the reference product as defined in paragraph 3.

2 Where the competent authority of the Member State of introduction determines that a biocidal product is identical to the reference product, it shall grant a parallel trade permit within 60 days of receipt of the fees payable under Article 80(2). The competent authority of the Member State of introduction may request from the competent authority of the Member State of origin additional information necessary to determine whether the product is identical to the reference product. The competent authority of the Member State of origin shall provide the requested information within 30 days of receiving the request.

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

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

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

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

d they are either the same or equivalent in packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human health, animal health or the environment.

4 An application for a parallel trade permit shall include the following information and items:

a name and authorisation number of the biocidal product in the Member State of origin;

b name and address of the competent authority of the Member State of origin;

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

d original label and instructions for use with which the biocidal product is distributed in the Member State of origin if it is considered as necessary for the examination by the competent authority of the Member State of introduction;

e name and address of the applicant;

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

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

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

i name and authorisation number of the reference product in the Member State of introduction.

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

5 The parallel trade permit shall prescribe the same conditions for making available on the market and use as the authorisation of the reference product.

6 The parallel trade permit shall be valid for the duration of authorisation of the reference product in the Member State of introduction.

If the authorisation holder of the reference product applies for cancellation of authorisation in accordance with Article 49 and the requirements of Article 19 are still fulfilled, the validity of the parallel trade permit shall expire on the date on which the authorisation of the reference product would normally have expired.

7 Without prejudice to specific provisions in this Article, Articles 47 to 50 and Chapter XV shall apply *mutatis mutandis* to biocidal products made available on the market under a parallel trade permit.

8 The competent authority of the Member State of introduction may withdraw a parallel trade permit if the authorisation of the introduced biocidal product is withdrawn in the Member State of origin because of safety or efficacy reasons.

CHAPTER XI

TECHNICAL EQUIVALENCE

Article 54

Assessment of technical equivalence

1 Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence ('the applicant') shall submit an application to the Agency and pay the applicable fees in accordance with Article 80(1).

2 The applicant shall submit all data that the Agency requires to assess technical equivalence.

3 The Agency shall inform the applicant of the fees payable under Article 80(1), and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

4 After giving the applicant the opportunity to submit comments, the Agency shall take a decision within 90 days of receipt of the application referred to in paragraph 1 and shall communicate it to Member States and to the applicant.

5 Where, in the opinion of the Agency, additional information is necessary to carry out the assessment of technical equivalence, the Agency shall ask the applicant to submit such information within a time limit specified by the Agency. The Agency shall reject the application if the applicant fails to submit the additional information within the specified time limit. The 90-day period referred to in paragraph 4 shall be suspended from the date of issue of the request until the information is received. The suspension shall not exceed 180 days except where justified by the nature of the data requested or in exceptional circumstances.

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

7 An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraphs 3, 4 and 5 of this Article.

8 The Agency shall draw up technical guidance notes to facilitate the implementation of this Article.

CHAPTER XII

DEROGATIONS

Article 55

Derogation from the requirements

1 By way of derogation from Articles 17 and 19, a competent authority may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use under the supervision of the competent authority, if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means.

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

On receipt of a reasoned request from the competent authority, the Commission shall, without delay and by means of implementing acts, decide whether, and under what conditions, the action taken by that competent authority may be extended, for a period not exceeding 550 days. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

2 By way of derogation from point (a) of Article 19(1) and until an active substance is approved, competent authorities and the Commission may authorise, for a period not exceeding three years, a biocidal product containing a new active substance.

Such a provisional authorisation may be issued only if, after dossiers have been evaluated in accordance with Article 8, the evaluating competent authority has submitted a recommendation for approval of the new active substance and the competent authorities which received the application for the provisional authorisation or, in the case of a provisional Union authorisation, the Agency, consider that the biocidal product is expected to comply with points (b), (c) and (d) of Article 19(1) taking into account the factors set out in Article 19(2).

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

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

3 By way of derogation from point (a) of Article 19(1), the Commission may, by means of implementing acts, allow a Member State to authorise a biocidal product containing a non-approved active substance if it is satisfied that that active substance is essential for the protection of cultural heritage and that no appropriate alternatives are available. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2). A Member State wishing to obtain such a derogation shall apply to the Commission, providing due justification.

Article 56

Research and development

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

Persons carrying out an experiment or test shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. They shall make this information available to the competent authority on request.

2 Any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the competent authority of the Member State where the experiment or test will occur. The notification shall include the identity of the biocidal product or active substance, labelling data and quantities supplied, and all available data on possible effects on human or animal health or impact on the environment. The person concerned shall make available any other information requested by the competent authorities.

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

3 If the experiments or tests could have harmful effects, whether immediate or delayed, on the health of humans, particularly of vulnerable groups, or animals, or any unacceptable adverse effect on humans, animals or the environment, the relevant competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The competent authority shall, without delay, inform the Commission and other competent authorities of its decision.

4 The Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying detailed rules supplementing this Article.

Article 57

Exemption from registration under Regulation (EC) No 1907/2006

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 authorised for placing on the market in accordance with Article 27, 55 or 56 shall be

regarded as being registered and the registration as completed for manufacture or import for use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5, Title II of Regulation (EC) No 1907/2006.

CHAPTER XIII

TREATED ARTICLES

Article 58

Placing on the market of treated articles

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

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

3 The person responsible for the placing on the market of such a treated article shall ensure that the label provides the information listed in the second subparagraph, where:

— in the case of a treated article containing a biocidal product, a claim is made by the manufacturer of that treated article regarding the biocidal properties of the article, or

— in relation to the active substance(s) concerned, having particular regard to the possibility of contact with humans or the release into the environment, the conditions associated with the approval of the active substance(s) so require.

The label referred to in the first subparagraph shall provide the following information:

a a statement that the treated article incorporates biocidal products;

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

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

d the name of all nanomaterials contained in the biocidal products, followed by the word ‘nano’ in brackets;

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

This paragraph shall not apply where at least equivalent labelling requirements already exist under sector-specific legislation for biocidal products in treated articles to meet information requirements concerning those active substances.

4 Notwithstanding the labelling requirements set out in paragraph 3, the person responsible for the placing on the market of a treated article shall label it with any relevant instructions for use, including any precautions to be taken, if this is necessary to protect humans, animals and the environment.

5 Notwithstanding the labelling requirements set out in paragraph 3, the supplier of a treated article shall, where a consumer so requests, provide that consumer, within 45 days, free of charge, with information on the biocidal treatment of the treated article.

6 The labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty in the official language or languages of the Member State of introduction, unless that Member State provides otherwise. In the case of treated articles that are not produced as part of a series but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the customer with the relevant information.

7 The Commission may adopt implementing acts for the application of paragraph 2 of this Article, including appropriate notification procedures, possibly involving the Agency, and further specifying the labelling requirements under paragraphs 3, 4 and 6 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

8 Where there are significant indications that an active substance contained in a biocidal product with which a treated article is treated or which it incorporates does not meet the conditions laid down in Article 4(1), Article 5(2) or Article 25, the Commission shall review the approval of that active substance or its inclusion in Annex I in accordance with Article 15(1) or Article 28(2).

CHAPTER XIV

DATA PROTECTION AND DATA-SHARING

Article 59

Protection of data held by competent authorities or the Agency

1 Without prejudice to Articles 62 and 63, data submitted for the purposes of Directive 98/8/EC or of this Regulation shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except where:

a the subsequent applicant submits a letter of access; or

b the relevant time limit for data protection has expired.

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

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

4 The advisory scientific committees set up under Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment[34] shall also have access to the data referred to in paragraph 1 of this Article.

Article 60

Data protection periods

1 Data submitted for the purposes of Directive 98/8/EC or of this Regulation shall benefit from data protection under the conditions laid down in this Article. The protection period for the data shall start when they are submitted for the first time.

Data protected under this Article or for which the protection period under this Article has expired shall not be protected again.

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

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

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

3 The protection period for data submitted with a view to the authorisation of a biocidal product containing only existing active substances shall end 10 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 30(4), Article 34(6) or Article 44(4).

The protection period for data submitted with a view to the authorisation of a biocidal product containing a new active substance shall end 15 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 30(4), Article 34(6) or Article 44(4).

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

Article 61

Letter of access

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

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

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

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

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

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

Article 62

Data sharing

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

2 Any person intending to perform tests or studies ('the prospective applicant')

a shall, in the case of data involving tests on vertebrates; and

b may, in the case of data not involving tests on vertebrates,

submit a written request to the Agency to determine whether such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application under this Regulation or Directive 98/8/EC. The Agency shall verify whether such tests or studies have already been submitted.

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

The data submitter shall, where relevant, facilitate contacts between the prospective applicant and the data owner.

Where the data acquired under those tests or studies are still protected under Article 60, the prospective applicant:

a shall, in the case of data involving tests on vertebrates; and

b may, in the case of data not involving tests on vertebrates,

request from the data owner all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications under this Regulation.

Article 63

Compensation for data sharing

1 Where a request has been made in accordance with Article 62(2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.

2 Where such agreement is reached, the data owner shall make all the scientific and technical data related to the tests and studies concerned available to the prospective applicant or shall give the prospective applicant permission to refer to the data owner's tests or studies when submitting applications under this Regulation.

3 Where no agreement is reached with respect to data involving tests or studies on vertebrates, the prospective applicant shall inform the Agency and the data owner thereof, at

the earliest one month after the prospective applicant receives the name and address of the data submitter from the Agency.

Within 60 days of being informed, the Agency shall give the prospective applicant permission to refer to the requested tests or studies on vertebrates, provided that the prospective applicant demonstrates that every effort has been made to reach an agreement and that the prospective applicant has paid the data owner a share of the costs incurred. Where the prospective applicant and data owner cannot agree, national courts shall decide on the proportionate share of the cost that the prospective applicant is to pay to the data owner.

The data owner shall not refuse to accept any payment offered pursuant to the second subparagraph. Any acceptance is without prejudice, however, to his right to have the proportionate share of the cost determined by a national court, in accordance with the second subparagraph.

4 Compensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner, having regard to the guidance established by the Agency[35]. The prospective applicant shall be required to share only in the costs of information that it is required to submit for the purposes of this Regulation.

5 An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 3 of this Article.

Article 64

Use of data for subsequent applications

1 Where the relevant data protection period according to Article 60 has expired in relation to an active substance, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the active substance is technically equivalent to the active substance for which the data protection period has expired, including the degree of purity and the nature of any relevant impurities.

Where the relevant data protection period according to Article 60 has expired in relation to a biocidal product, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the biocidal product is the same as the one already authorised, or the differences between them are not significant in relation to the risk assessment and the active substance(s) in the biocidal product are technically equivalent to those in the biocidal product already authorised, including the degree of purity and the nature of any impurities.

An appeal may be brought, in accordance with Article 77, against decisions of the Agency under the first and second subparagraphs of this paragraph.

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

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

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

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

CHAPTER XV

INFORMATION AND COMMUNICATION

SECTION 1

Monitoring and reporting

Article 65

Compliance with requirements

1 Member States shall make the necessary arrangements for the monitoring of biocidal products and treated articles which have been placed on the market to establish whether they comply with the requirements of this Regulation. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products[(36)] shall apply accordingly.

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

In order to facilitate such enforcement, manufacturers of biocidal products placed on the Union market shall maintain, in relation to the manufacturing process, appropriate documentation in paper or electronic format relevant for the quality and safety of the biocidal product to be placed on the market and shall store production batch samples. The documentation shall include as a minimum:

a safety data sheets and specifications of active substances and other ingredients used for manufacturing the biocidal product;

b records of the various manufacturing operations performed;

c results of internal quality controls;

d identification of production batches.

Where necessary in order to ensure uniform application of this paragraph, the Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 82(3).

Measures taken pursuant to this paragraph shall avoid causing disproportionate administrative burden to economic operators and Member States.

3 Every five years, from 1 September 2015, Member States shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The report shall include in particular:

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

b information on any poisonings and, where available, occupational diseases involving biocidal products, especially regarding vulnerable groups, and any specific measures taken to mitigate the risk of future cases;

c any available information on adverse environmental effects experienced through using biocidal products;

d information on the use of nanomaterials in biocidal products and the potential risks thereof.

Reports shall be submitted by 30 June of the relevant year and shall cover the period until 31 December of the year preceding their submission.

The reports shall be published on the relevant website of the Commission.

4 On the basis of the reports received in accordance with paragraph 3, and within 12 months from the date referred to in the second subparagraph of that paragraph, the Commission shall draw up a composite report on the implementation of this Regulation, in particular Article 58. The Commission shall submit the report to the European Parliament and to the Council.

Article 66

Confidentiality

1 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents[37] and the rules of the Management Board of the Agency, adopted in accordance with Article 118(3) of Regulation (EC) No 1907/2006, shall apply to documents held by the Agency for the purposes of this Regulation.

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

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

a details of the full composition of a biocidal product;

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

c links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;

d names and addresses of persons involved in testing on vertebrates.

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

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

a the name and address of the authorisation holder;

b the name and address of the biocidal product manufacturer;

c the name and address of the active substance manufacturer;

d the content of the active substance or substances in the biocidal product and the name of the biocidal product;

e physical and chemical data concerning the biocidal product;

f any methods for rendering the active substance or biocidal product harmless;

g a summary of the results of the tests required pursuant to Article 20 to establish the product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;

h recommended methods and precautions to reduce dangers from handling, transport and use as well as from fire or other hazards;

i safety data sheets;

j methods of analysis referred to in Article 19(1)(c);

k methods of disposal of the product and of its packaging;

l procedures to be followed and measures to be taken in the case of spillage or leakage;

m first aid and medical advice to be given in the case of injury to persons.

4 Any person submitting information related to an active substance or a biocidal product to the Agency or a competent authority for the purposes of this Regulation can request that the information in Article 67(3) shall not be made available, including a justification as to why the disclosure of the information could be harmful for their commercial interests or those of any other party concerned.

Article 67

Electronic public access

1 From the date on which an active substance is approved, the following up-to-date information held by the Agency or the Commission on active substances shall be made publicly and easily available free of charge:

a where available, the ISO name and the name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature;

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

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

d physicochemical endpoints and data on pathways and environmental fate and behaviour;

e the result of each toxicological and ecotoxicological study;

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

g the guidance on safe use provided in accordance with Annexes II and III;

h analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 4.2 of Title 2 of Annex II.

2 From the date on which a biocidal product is authorised, the Agency shall make publicly and easily available free of charge the following up-to-date information:

a the terms and conditions of the authorisation;

b the summary of the biocidal product characteristics; and

c analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 5.2 of Title 2 of Annex III.

3 From the date on which an active substance is approved, the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority or the Agency as to why such publication is potentially harmful for

its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to-date information on active substances:

a if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives of active substances which are known to be hazardous;

b the study summaries or robust study summaries of studies submitted to support the approval of the active substance;

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 the assessment report.

4 From the date on which a biocidal product is authorised, the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to date information:

a study summaries, or robust study summaries, of studies submitted to support the biocidal product authorisation; and

b the assessment report.

Article 68

Record-keeping and reporting

1 Authorisation holders shall keep records of the biocidal products they place on the market for at least 10 years after placing on the market, or 10 years after the date on which the authorisation was cancelled or expired, whichever is the earlier. They shall make available the relevant information contained in these records to the competent authority on request.

2 To ensure the uniform application of paragraph 1 of this Article, the Commission shall adopt implementing acts to specify the form and content of the information in records. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

SECTION 2

Information about biocidal products

Article 69

Classification, packaging and labelling of biocidal products

1 Authorisation holders shall ensure that biocidal products are classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 22(2), and with Directive 1999/45/EC and, where applicable, Regulation (EC) No 1272/2008.

In addition, products which may be mistaken for food, including drink, or feed shall be packaged to minimise the likelihood of such a mistake being made. If they are available

to the general public, they shall contain components to discourage their consumption and, in particular, shall not be attractive to children.

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

a the identity of every active substance and its concentration in metric units;

b the nanomaterials contained in the product, if any, and any specific related risks, and, following each reference to nanomaterials, the word 'nano' in brackets;

c the authorisation number allocated to the biocidal product by the competent authority or the Commission;

d the name and address of the authorisation holder;

e the type of formulation;

f the uses for which the biocidal product is authorised;

g directions for use, frequency of application and dose rate, expressed in metric units, in a manner which is meaningful and comprehensible to the user, for each use provided for under the terms of the authorisation;

h particulars of likely direct or indirect adverse side effects and any directions for first aid;

i if accompanied by a leaflet, the sentence 'Read attached instructions before use' and, where applicable, warnings for vulnerable groups;

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

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

l where applicable, the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use and transport;

m where applicable, the categories of users to which the biocidal product is restricted;

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

o for biocidal products containing micro-organisms, labelling requirements in accordance with Directive 2000/54/EC.

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

3 Member States may require:

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

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

Article 70

Safety data sheets

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

Article 71

Register for Biocidal Products

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

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

3 Applicants shall use the Register for Biocidal Products to submit applications and data for all procedures covered by this Regulation.

4 Upon submission of applications and data by applicants, the Agency shall check that these have been submitted in the correct format and notify the relevant competent authority accordingly without delay.

Where the Agency decides that the application has not been submitted in the correct format, it shall reject the application and inform the applicant accordingly.

5 Once the relevant competent authority has validated or accepted an application, it shall be made available via the Register for Biocidal Products to all other competent authorities and to the Agency.

6 The competent authorities and the Commission shall use the Register for Biocidal Products to record and communicate the decisions they have taken in relation to the authorisations of biocidal products and shall update the information in the Register for Biocidal Products at the time such decisions are taken. The competent authorities shall, in particular, update the information in the Register for Biocidal Products relating to biocidal products which have been authorised within their territory or for which a national authorisation has been refused, amended, renewed or cancelled, or for which a parallel trade permit has been granted, refused or cancelled. The Commission shall, in particular, 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.

The information to be introduced into the Register for Biocidal Products shall include, as appropriate:

a the terms and conditions of the authorisation;

b the summary of the biocidal product characteristics referred to in Article 22(2);

c the assessment report of the biocidal product.

The information referred to in this paragraph shall also be made available to the applicant through the Register for Biocidal Products.

7 In the event that the Register for Biocidal Products is not fully operational by 1 September 2013 or ceases to be operational after that date, all obligations in relation to submissions and communication placed upon Member States, competent authorities, the Commission and applicants by this Regulation shall continue to apply. With a view to ensuring the uniform application of this paragraph, particularly with regard to the format in which information may be submitted and exchanged, the Commission shall adopt the necessary measures in accordance with the examination procedure referred to in Article 82(3). Those measures shall be limited in time to the period strictly necessary for the Register for Biocidal Products to become fully operational.

8 The Commission may adopt implementing acts laying down detailed rules on the types of information to be entered in the Register for Biocidal Products. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

9 The Commission shall be empowered to adopt delegated acts in accordance with Article 83 laying down supplementary rules for the use of the Register.

Article 72

Advertising

1 Any advertisement for biocidal products shall, in addition to complying with Regulation (EC) No 1272/2008, include the sentences ‘Use biocides safely. Always read the label and product information before use.’. The sentences shall be clearly distinguishable and legible in relation to the whole advertisement.

2 Advertisers may replace the word ‘biocides’ in the prescribed sentences with a clear reference to the product-type being advertised.

3 Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention ‘low-risk biocidal product’, ‘non-toxic’, ‘harmless’, ‘natural’, ‘environmentally friendly’, ‘animal friendly’ or any similar indication.

Article 73

Poison control

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

CHAPTER XVI

THE AGENCY

Article 74

Role of the Agency

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

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

Article 75

Biocidal Products Committee

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

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

a applications for approval and renewal of approval of active substances;

b review of approval of active substances;

c applications for inclusion in Annex I of active substances meeting the conditions laid down in Article 28 and review of the inclusion of such active substances in Annex I;

d identification of active substances which are candidates for substitution;

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

f scientific and technical matters concerning mutual recognition in accordance with Article 38;

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

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

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

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

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

Article 76

Secretariat of the Agency

1 The Secretariat of the Agency referred to in point (g) of Article 76(1) of Regulation (EC) No 1907/2006 shall undertake the following tasks:

a establishing and maintaining the Register for Biocidal Products;

b performing the tasks relating to the acceptance of the applications covered by this Regulation;

c establishing technical equivalence;

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

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

f preparing explanatory information on this Regulation;

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

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

i notification of decisions taken by the Agency;

j specification of formats and software packages for the submission of information to the Agency;

k providing support and assistance to Member States in order to avoid the parallel assessment of applications relating to the same or similar biocidal products referred to in Article 29(4);

2 The Secretariat shall make the information identified in Article 67 publicly available, free of charge, over the internet, except where a request made under Article 66(4) is considered justified. The Agency shall make other information available on request in accordance with Article 66.

Article 77

Appeal

1 Appeals against decisions of the Agency taken pursuant to Article 7(2), Article 13(3), Article 26(2), Article 43(2), Article 45(3), Article 54(3), (4) and (5), Article 63(3) and Article 64(1) shall lie with the Board of Appeal set up in accordance with Regulation (EC) No 1907/2006.

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

Fees may be payable, in accordance with Article 80(1) of this Regulation, by the person bringing an appeal.

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

Article 78

The budget of the Agency

1 For the purposes of this Regulation, the revenues of the Agency shall consist of:

a a subsidy from the Union, entered in the general budget of the European Union (Commission Section);

b the fees paid to the Agency in accordance with this Regulation;

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

d any voluntary contributions from Member States.

2 Revenue and expenditure for activities related to this Regulation and to Regulation (EC) No 1907/2006 shall be dealt with separately in the Agency's budget and shall have separate budgetary and accounting reporting.

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

Article 79

Formats and software for submission of information to the Agency

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

The technical dossier referred to in Article 6(1) and Article 20 shall be submitted using the IUCLID software package.

CHAPTER XVII

FINAL PROVISIONS

Article 80

Fees and charges

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

a the fees payable to the Agency, including an annual fee for products granted a Union authorisation in accordance with Chapter VIII and a fee for applications for mutual recognition in accordance with Chapter VII;

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

c conditions of payment.

That implementing Regulation shall be adopted in accordance with the examination procedure referred to in Article 82(3). It shall apply only with respect to fees paid to the Agency.

The Agency may collect charges for other services it provides.

The fees payable to the Agency shall be set at such a level as to ensure that the revenue derived from the fees, when combined with other sources of the Agency's revenue pursuant to this Regulation, is sufficient to cover the cost of the services delivered. The fees payable shall be published by the Agency.

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

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

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

Member States may collect charges for other services they provide.

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

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

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

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

c the specific needs of SMEs shall be taken into account, as appropriate, including the possibility of splitting payments into several instalments and phases;

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

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

f the deadlines for the payment of fees shall be fixed taking due account of the deadlines of the procedures provided for in this Regulation.

Article 81

Competent authorities

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

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

2 Competent authorities shall provide advice to applicants, in particular to SMEs, and to any other interested parties on their respective responsibilities and obligations under this Regulation. That shall include the provision of advice about the possibility of adapting the data requirements of Articles 6 and 20, the grounds on which such an adaptation can be made, and on how to prepare a proposal. It shall be in addition to the advice and assistance that the Secretariat of the Agency shall provide in accordance with Article 76(1)(d).

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

3 Member States shall inform the Commission of the names and addresses of the designated competent authorities and, where they exist, helpdesks by 1 September 2013. Member States shall, without undue delay, inform the Commission of any changes to the names and addresses of the competent authorities or helpdesks.

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

Article 82

Committee procedure

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

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

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

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

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

Article 83

Exercise of the delegation

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

2 The power to adopt delegated acts referred to in Article 3(4), Article 5(3), Article 6(4), Article 21(3), Article 23(5), Article 28(1) and (3), Article 40, Article 56(4), Article 71(9), Article 85 and Article 89(1) shall be conferred on the Commission for a period of five years from 17 July 2012. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3 The delegation of power referred to in Article 3(4), Article 5(3), Article 6(4), Article 21(3), Article 23(5), Article 28(1) and (3), Article 40, Article 56(4), Article 71(9), Article 85 and Article 89(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5 A delegated act adopted pursuant to Article 3(4), Article 5(3), Article 6(4), Article 21(3), Article 23(5), Article 28(1) and (3), Article 40, Article 56(4), Article 71(9), Article 85 and Article 89(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 84

Urgency procedure

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

2 Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 83(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

Article 85

Adaptation to scientific and technical progress

In order to allow the provisions of this Regulation to be adapted to scientific and technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the adaptation of Annexes II, III and IV to such scientific and technical progress.

Article 86

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

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

Article 87

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 September 2013 and shall notify the Commission without delay of any subsequent amendment affecting them.

Article 88

Safeguard clause

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

The Commission shall, by means of implementing acts, either permit the provisional measure for a time period defined in the decision or require the Member State to revoke the provisional measure. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Article 89

Transitional measures

1 The Commission shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC with the aim of achieving it by 14 May 2014. To that end, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the carrying out of the work programme and specification of the related rights and obligations of the competent authorities and the participants in the programme.

Depending upon the progress of the work programme, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the extension of the duration of the work programme for a determined period.

In order to facilitate a smooth transition from Directive 98/8/EC to this Regulation, during the work programme the Commission shall adopt either implementing regulations providing that an active substance is approved, and under which conditions, or, in cases where the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, implementing decisions stating that an active substance is not approved. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3). Regulations approving an active substance shall specify the date of approval. Article 9(2) shall apply.

2 By way of derogation from Article 17(1), Article 19(1) and Article 20(1) of this Regulation, and without prejudice to paragraphs 1 and 3 of this Article, a Member State may continue to apply its current system or practice of making a given biocidal product available on the market until two years after the date of approval of the last of the active substances to be approved in that biocidal product. It may, according to its national rules, authorise the making available on the market in its territory only of a biocidal product containing existing active substances which have been or are being evaluated under Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC[38], but which have not yet been approved for that product-type.

By way of derogation from the first subparagraph, in the case of a decision not to approve an active substance, a Member State may continue to apply its current system or practice of making biocidal products available on the market for up to 12 months after the date of the decision not to approve an active substance in accordance with the third subparagraph of paragraph 1.

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

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

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

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

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

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

Article 90

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

1 The Agency shall be responsible for coordinating the process of evaluation of dossiers submitted after 1 September 2012 and shall facilitate the evaluation by providing organisational and technical support to the Member States and the Commission.

2 Applications submitted for the purposes of Directive 98/8/EC for which the Member States' evaluation in accordance with Article 11(2) of Directive 98/8/EC has not been completed by 1 September 2013 shall be evaluated by the competent authorities in accordance with the provisions of this Regulation and, where relevant, Regulation (EC) No 1451/2007.

That evaluation shall be carried out on the basis of the information provided in the dossier submitted under Directive 98/8/EC.

Where the evaluation identifies concerns arising from the application of provisions of this Regulation which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information.

Every effort shall be made to avoid additional testing on vertebrates and to avoid causing delays to the review programme laid down in Regulation (EC) No 1451/2007 as a result of these transitional arrangements.

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 September 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 91

Transitional measures concerning applications for biocidal product authorisations submitted under Directive 98/8/EC

Applications for biocidal product authorisations submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by 1 September 2013 shall be evaluated by the competent authorities in accordance with that Directive.

Notwithstanding the first paragraph, the following shall apply:

— where the risk assessment of the active substance indicates that one or more of the criteria listed under Article 5(1) is met, the biocidal product shall be authorised in accordance with Article 19,

— where the risk assessment of the active substance indicates that one or more of the criteria listed under Article 10 is met, the biocidal product shall be authorised in accordance with Article 23.

Where the evaluation identifies concerns arising from the application of provisions of this Regulation which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information.

Article 92

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

1 Biocidal products for which an authorisation or registration in accordance with Article 3, 4, 15 or 17 of Directive 98/8/EC was granted before 1 September 2013 can continue to be made available on the market and used subject, where applicable, to any conditions of authorisation or registration stipulated under that Directive until the expiry date of the authorisation or registration or its cancellation.

2 Notwithstanding paragraph 1, this Regulation shall apply to biocidal products referred to in that paragraph from 1 September 2013.

Article 93

Transitional measures concerning biocidal products not covered by the scope of Directive 98/8/EC

1 Without prejudice to Article 89, applications for authorisation of biocidal products not covered by the scope of Directive 98/8/EC and falling within the scope of this Regulation and which were available on the market on 1 September 2013 shall be submitted at the latest by 1 September 2017.

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

By way of derogation from Article 17(1), biocidal products referred to in paragraph 1 of this Article for which an application was not submitted in accordance with paragraph 1 of this Article may continue to be made available on the market or used until 180 days after 1 September 2017.

Disposal and use of existing stocks of biocidal products which are not authorised for the relevant use by the competent authority or the Commission may continue until 365 days after the date of the decision referred to in the first subparagraph or 12 months after the date referred to in the second subparagraph, whichever is the later.

Article 94

Transitional measures concerning treated articles

1 By way of derogation from Article 58 and without prejudice to Article 89, treated articles that were available on the market on 1 September 2013 may, until the date of a decision concerning the approval for the relevant product-type of the active substance(s) contained in the biocidal products with which the treated articles were treated or which they incorporate, continue to be placed on the market if the application for the approval of the active substance(s) for the relevant product-type is submitted at the latest by 1 September 2016.

2 In the case of a decision not to approve an active substance for the relevant product-type, treated articles which were treated with, or which incorporate, biocidal product(s) containing that active substance shall no longer be placed on the market 180 days after such a decision or as of 1 September 2016, whichever is the later, unless an application for the approval has been submitted in accordance with paragraph 1.

Article 95

Transitional measures concerning access to the active substance dossier

1 As of 1 September 2013, any person wishing to place active substance(s) on the Union market on its own or in biocidal products (the 'relevant person') shall, for every active substance that they manufacture or import for use in biocidal products, submit to the Agency:

a a dossier complying with the requirements of Annex II or, where appropriate, with Annex IIA to Directive 98/8/EC; or

b a letter of access to a dossier as referred to under point (a); or

c a reference to a dossier as referred to under point (a) and for which all data protection periods have expired.

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

For the purposes of this paragraph and for existing active substances listed in Annex II to Regulation (EC) No 1451/2007, Article 63(3) of this Regulation shall apply

to all toxicological and ecotoxicological studies including any toxicological and ecotoxicological studies not involving tests on vertebrates.

The relevant person to whom a letter of access to a dossier on the active substance has been issued shall be entitled to allow applicants for the authorisation of a biocidal product containing that active substance to make reference to that letter of access for the purposes of Article 20(1).

By way of derogation from Article 60 of this Regulation, all data protection periods for substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but not yet approved under this Regulation shall end on 31 December 2025.

2 The Agency shall make publicly available the list of persons that have made a submission in accordance with paragraph 1 or for whom it has taken a decision in accordance with Article 63(3). The list shall also contain the names of persons who are participants in the work programme established under the first subparagraph of Article 89(1) or have taken over the role of the participant.

3 Without prejudice to Article 93, as of 1 September 2015, a biocidal product shall not be made available on the market if the manufacturer or importer of the active substance(s) contained in the product, or where relevant, the importer of the biocidal product, is not included in the list referred to in paragraph 2.

Without prejudice to Articles 52 and 89, disposal and use of existing stocks of biocidal products containing an active substance, for which no relevant person is included in the list referred to in paragraph 2, may continue until 1 September 2016.

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

Article 96

Repeal

Without prejudice to Articles 86, 89, 90, 91 and 92 of this Regulation, Directive 98/8/EC is hereby repealed with effect from 1 September 2013.

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

Article 97

Entry into force

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

It shall apply from 1 September 2013.

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

Done at Strasbourg, 22 May 2012.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

N. WAMMEN

(**1**) OJ L 92, 7.4.1990, p. 42.
(**2**) OJ L 311, 28.11.2001, p. 1.
(**3**) OJ L 311, 28.11.2001, p. 67.
(**4**) OJ L 136, 30.4.2004, p. 1.
(**5**) OJ L 139, 30.4.2004, p. 1.
(**6**) OJ L 139, 30.4.2004, p. 55.
(**7**) OJ L 354, 31.12.2008, p. 34.
(**8**) OJ L 229, 1.9.2009, p. 1.
(**9**) OJ L 309, 24.11.2009, p. 1.
(**10**) OJ L 170, 30.6.2009, p. 1.
(**11**) OJ 196, 16.8.1967, p. 1.
(**12**) OJ L 183, 29.6.1989, p. 1.
(**13**) OJ L 131, 5.5.1998, p. 11.
(**14**) OJ L 330, 5.12.1998, p. 32.
(**15**) OJ L 200, 30.7.1999, p. 1.
(**16**) OJ L 262, 17.10.2000, p. 21.
(**17**) OJ L 327, 22.12.2000, p. 1.
(**18**) OJ L 158, 30.4.2004, p. 50.
(**19**) OJ L 158, 30.4.2004, p. 7.
(**20**) OJ L 376, 27.12.2006, p. 21.
(**21**) OJ L 204, 31.7.2008, p. 1.
(**22**) OJ L 353, 31.12.2008, p. 1.
(**23**) OJ L 309, 24.11.2009, p. 71.
(**24**) OJ L 286, 31.10.2009, p. 1.
(**25**) OJ L 276, 20.10.2010, p. 33.
(**26**) OJ L 334, 17.12.2010, p. 17.
(**27**) OJ L 124, 20.5.2003, p. 36.
(**28**) OJ L 275, 20.10.2011, p. 38.
(**29**) OJ L 37, 13.2.1993, p. 1.
(**30**) OJ L 338, 13.11.2004, p. 4.
(**31**) OJ L 70, 16.3.2005, p. 1.
(**32**) OJ L 152, 16.6.2009, p. 11.
(**33**) OJ L 140, 30.5.2002, p. 10.
(**34**) OJ L 66, 4.3.2004, p. 45.
(**35**) Guidance on data sharing established in accordance with Regulation (EC) No 1907/2006.
(**36**) OJ L 218, 13.8.2008, p. 30.
(**37**) OJ L 145, 31.5.2001, p. 43.
(**38**) OJ L 325, 11.12.2007, p. 3.

Status:
Point in time view as at 22/05/2012.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EU) No 528/2012 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.