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 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[(1)], 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.

(**1**) 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.