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.

[F1 Article 86

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

Active substances for which the Commission has adopted directives including them in Annex I to Directive 98/8/EC shall be deemed to have been approved under this Regulation on the date of inclusion and shall be included in the list referred to in Article 9(2). Approval shall be subject to the conditions set out in those Commission directives.**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

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

[[F2]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 31 December 2024. 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.

[[F1]2 By way of derogation from Articles 17(1), 19(1) and 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 available on the market or using a given biocidal product for up to three years after the date of approval of the last of the active substances to be approved in that biocidal product. The Member State concerned may, in accordance with its national rules, authorise the making available on the market or use in its territory only of a biocidal product containing only:

a existing active substances which:

(i) have been evaluated under Commission Regulation (EC) No 1451/2007[(1)], but which have not yet been approved for that product-type; or

(ii) are being evaluated, under Regulation (EC) No 1451/2007, but which have not yet been approved for that product-type;

or

b a combination of active substances referred to in point (a) and active substances approved in accordance with this Regulation.

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, and may continue to apply its current system or practice of using biocidal products for up to 18 months after that decision.**]**

[F1 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 three 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 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 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 use of existing stocks of the biocidal product may continue for up to 365 days after the date of approval of the active substance(s).**]**

[F1 4 Where a Member State's competent authority, or where relevant, the Commission, decides to reject an application submitted in accordance with paragraph 3 for authorisation of a biocidal product already made available on the market, or decides not to grant an authorisation or to impose conditions for the authorisation making it necessary to change such a product, the following shall apply:

a a biocidal product which has not been authorised or, where relevant, which does not comply with the conditions of the authorisation, shall no longer be made available on the market with effect from 180 days after the date of the decision of the authority; and

b use of existing stocks of the biocidal product may continue for up to 365 days after the date of the decision of the authority.**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

F2 Substituted by Commission Delegated Regulation (EU) No 736/2013 of 17 May 2013 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the duration of the work programme for examination of existing biocidal active substances (Text with EEA relevance).

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.

[[F3]Biocidal products authorised in accordance with Article 3 or 4 of Directive 98/8/EC shall be considered as authorised in accordance with Article 17 of this Regulation.**]**

Textual Amendments

F3 Inserted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

[[F1]*Article 93*

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

By way of derogation from Article 17(1), a Member State may continue to apply its current system or practice of making available on the market and using a biocidal product not covered by the scope of Directive 98/8/EC, but falling within the scope of this Regulation, and consisting of, containing or generating only active substances that were available on the market, or used in biocidal products, on 1 September 2013. The derogation shall apply until one of the following dates:

(a) where applications for approval of all those active substances, which the biocidal product consists of, contains or generates, are submitted for the relevant product-type by 1 September 2016, the deadlines provided for in the second subparagraph of Article 89(2), in Article 89(3) and in Article 89(4); or

(b) where an application is not submitted in accordance with point (a) for one of the active substances, until 1 September 2017.**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

I[F1] Article 94

Transitional measures concerning treated articles

1 By way of derogation from Article 58(2), a treated article treated with or intentionally incorporating one or more biocidal products containing only active substances that are under examination for the relevant product-type in the work programme referred to in Article 89(1) on 1 September 2016 or for which an application for approval for the relevant product-type is submitted by that date, or containing only a combination of such substances and active substances included in the list drawn up in accordance with Article 9(2) for the relevant product-type and use or included in Annex I, may be placed on the market until one of the following dates:

a in the case of a decision adopted after 1 September 2016 to reject the application for approval of, or not to approve, one of the active substances for the relevant use, the date falling 180 days after such a decision;

b in other cases, the date of approval for the relevant product-type and use of the last active substance to be approved and contained in the biocidal product.

2 By way of further derogation from Article 58(2), a treated article treated with or intentionally incorporating one or more biocidal products containing any active substances other than those referred to in paragraph 1 of this Article or those included in the list drawn up in accordance with Article 9(2) for the relevant product-type and use or included in Annex I, may be placed on the market until 1 March 2017.

Textual Amendments

F1 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

Article 95

Transitional measures concerning access to the active substance dossier

1 As of 1 September 2013, the Agency shall make publicly available and shall regularly update a list of all active substances, and all substances generating an active substance, for which a dossier complying with Annex II to this Regulation or with Annex IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive (‘the complete substance dossier’) has been submitted and accepted or validated by a Member State in a procedure provided for by this Regulation or that Directive (‘the relevant substances’). For each relevant substance, the list shall also include all persons having made such a submission or a submission to the Agency in accordance with the second subparagraph of this paragraph, and indicate their role as specified in that subparagraph, and the product-type(s) for which they have made a submission, as well as the date of inclusion of the substance in the list.

A person established within the Union who manufactures or imports a relevant substance, on its own or in biocidal products (‘the substance supplier’) or who manufactures or makes available on the market a biocidal product consisting of, containing or generating that relevant substance (‘the product supplier’), may at any time

submit to the Agency either a complete substance dossier for that relevant substance, a letter of access to a complete substance dossier, or a reference to a complete substance dossier for which all data protection periods have expired. Following the renewal of the approval of an active substance, any substance supplier or product supplier may submit to the Agency a letter of access to all the data which was considered by the evaluating competent authority as relevant for the purpose of the renewal, and for which the protection period has not yet expired ('the relevant data').

The Agency shall inform the submitting supplier of the fees payable under Article 80(1). It shall reject the application if the submitting supplier fails to pay those fees within 30 days and shall inform the submitting supplier accordingly.

Upon receipt of the fees payable under Article 80(1), the Agency shall verify whether the submission complies with the second subparagraph of this paragraph and shall inform the submitting supplier accordingly.

2 As of 1 September 2015, a biocidal product consisting of, containing or generating a relevant substance, included in the list referred to in paragraph 1, shall not be made available on the market unless either the substance supplier or the product supplier is included in the list referred to in paragraph 1 for the product-type(s) to which the product belongs.

3 For the purposes of making a submission in accordance with the second subparagraph of paragraph 1 of this article, Article 63(3) of this Regulation shall apply to all toxicological, ecotoxicological and environmental fate and behaviour studies relating to substances listed in Annex II to Regulation (EC) No 1451/2007, including any such studies not involving tests on vertebrates.

4 A substance supplier or a product supplier included in the list referred to in paragraph 1 to whom a letter of access has been issued for the purpose of this Article or a right to refer to a study has been granted in accordance with paragraph 3 shall be entitled to allow applicants for the authorisation of a biocidal product to make reference to that letter of access or that study for the purposes of Article 20(1).

5 By way of derogation from Article 60, all data protection periods for active substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but for which a decision on inclusion in Annex I to Directive 98/8/EC was not taken before 1 September 2013, shall end on 31 December 2025.

6 Paragraphs 1 to 5 shall not apply to substances listed in Annex I in categories 1 to 5 and category 7 or to biocidal products containing only such substances.

7 The Agency shall regularly update the list referred to in paragraph 1 of this Article. Following the renewal of the approval of an active substance, the Agency shall remove from the list any substance supplier or product supplier who has not, within 12 months of the renewal, submitted all the relevant data or a letter of access to all the relevant data, either in accordance with the second subparagraph of paragraph 1 of this Article or in an application in accordance with Article 13.**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

Article 96

Repeal

[[F1]Without prejudice to Articles 86, 89 to 93 and 95 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.

Textual Amendments

F1 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

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) **[**[F1]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 of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).**]**

Textual Amendments

F1 Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

Status:
Point in time view as at 31/12/2020.

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.