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 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);

[[F1]l providing support and assistance to Member States with regard to control and enforcement activities.**]**

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.

Textual Amendments

F1 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).

Article 77

Appeal

[[F2]1 Appeals against decisions of the Agency taken pursuant to Articles 7(2), 13(3), 43(2) and 45(3), Article 54(3), (4) and (5), and Articles 63(3) and 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.

Textual Amendments

F2 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 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.

[[F2]Revenues of the Agency as referred to in Article 96(1) of Regulation (EC) No 1907/2006 shall not be used for carrying out tasks under this Regulation, unless for a joint purpose or a temporary transfer to ensure the proper functioning of the Agency. Revenues of the Agency as referred to in paragraph 1 of this Article shall not be used for carrying out tasks under Regulation (EC) No 1907/2006, unless for a joint purpose or a temporary transfer to ensure the proper functioning of the Agency.**]**

Textual Amendments

F2 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 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.

Status:
Point in time view as at 31/01/2020.

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.