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 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[(1)] 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.

[[F1]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 26(3), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 44(5).

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 26(3), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 44(5).**]**

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.

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 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[(2)]. 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.

(**1**) OJ L 66, 4.3.2004, p. 45.

(**2**) Guidance on data sharing established in accordance with Regulation (EC) No 1907/2006.

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.