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 and repealing Council Directives 79/117/EEC and 91/414/EEC

CHAPTER V

DATA PROTECTION AND DATA SHARING

Article 59

Data protection

1 Test and study reports shall benefit from data protection under the conditions laid down in this Article.

The protection shall apply to test and study reports concerning the active substance, safener or synergist, adjuvants and the plant protection product as referred to in Article 8(2) when they are submitted to a Member State by an applicant for authorisation under this Regulation, (the first applicant), provided that those test and study reports were:

a necessary for the authorisation or an amendment of an authorisation in order to allow the use on another crop; and

b certified as compliant with the principles of good laboratory practice or of good experimental practice.

Where a report is protected, it may not be used by the Member State which received it for the benefit of other applicants for authorisation of plant protection products, safeners or synergists and adjuvants, except as provided in paragraph 2 of this Article, in Article 62 or in Article 80.

The period of data protection is 10 years starting at the date of first authorisation in that Member State, except as provided in paragraph 2 of this Article or in Article 62. That period is extended to 13 years for plant protection products covered by Article 47.

Those periods shall be extended by 3 months for each extension of authorisation for minor uses as defined in Article 51(1), except where the extension of authorisation is based on extrapolation, if the applications for such authorisations are made by the authorisation holder at the latest 5 years after the date of the first authorisation in that Member State. The total period of data protection may in no case exceed 13 years. For plant protection products covered by Article 47 the total period of data protection may in no case exceed 15 years.

The same data protection rules as for the first authorisation shall also apply to test and study reports submitted by third parties for the purpose of extension of authorisation for minor uses as referred to in Article 51(1).

A study shall also be protected if it was necessary for the renewal or review of an authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply *mutatis mutandis*.

2 Paragraph 1 shall not apply:

a to test and study reports for which the applicant has submitted a letter of access; or

b where any period of data protection granted for the test and study reports concerned in relation to another plant protection product has expired.

3 Data protection under paragraph 1 shall only be granted where the first applicant has claimed data protection for test and study reports concerning the active substance, safener or synergist, adjuvant and the plant protection product at the time of submitting the dossier and has provided to the Member State concerned for each test or study report the information referred to in point (f) of Article 8(1) and in point (d) of Article 33(3) as well as confirmation that a period of data protection has never been granted for the test or study report or that any period granted has not expired.

Article 60

List of test and study reports

1 For each active substance, safener and synergist and adjuvant, rapporteur Member States shall prepare a list of the test and study reports necessary for first approval, amendment of approval conditions or renewal of the approval and make it available to the Member States and the Commission.

2 For each plant protection product which they authorise, Member States shall keep and make available to any interested party upon request:

a a list of the test and study reports concerning the active substance, safener or synergist, adjuvant and the plant protection product necessary for first authorisation, amendment of the authorisation conditions or renewal of the authorisation; and

b a list of test and study reports for which the applicant claimed data protection under Article 59 and any reasons submitted in accordance with that Article.

3 The lists provided for in paragraphs 1 and 2 shall include information on whether those test and study reports were certified as compliant with the principles of good laboratory practice or of good experimental practice.

Article 61

General rules on avoidance of duplicative testing

1 In order to avoid duplicative testing, any persons intending to seek an authorisation for a plant protection product shall, before carrying out tests or studies, consult the information referred to in Article 57 to ascertain if and to whom an authorisation has already been granted for a plant protection product containing the same active substance, safener or synergist or for an adjuvant. The competent authority shall on request from the prospective applicant provide him with the list of test and study reports prepared in accordance with Article 60 for that product.

The prospective applicant shall submit all data regarding the identity and impurities of the active substance he proposes to use. The enquiry shall be supported by evidence that the prospective applicant intends to apply for an authorisation.

2 The competent authority of the Member State, where satisfied that the prospective applicant intends to apply for an authorisation, or the renewal or review thereof, shall provide him with the name and address of the holder or holders of previous relevant authorisations and shall at the same time inform the holders of the authorisations of the name and address of the applicant.

3 The prospective applicant for the authorisation, or the renewal or review thereof, and the holder or holders of relevant authorisations shall take all reasonable steps to reach agreement on the sharing of any test and study reports protected under Article 59, in a fair, transparent and non-discriminatory way.

Article 62

Sharing of tests and studies involving vertebrate animals

1 Testing on vertebrate animals for the purposes of this Regulation shall be undertaken only where no other methods are available. Duplication of tests and studies on vertebrates undertaken for the purposes of this Regulation shall be avoided in accordance with paragraphs 2 to 6.

2 Member States shall not accept duplication of tests and studies on vertebrate animals or those initiated where conventional methods described in Annex II to Directive 1999/45/EC could reasonably have been used, in support of applications for authorisations. Any person intending to perform tests and studies involving vertebrate animals shall take the necessary measures to verify that those tests and studies have not already been performed or initiated.

3 The prospective applicant and the holder or holders of the relevant authorisations shall make every effort to ensure that they share tests and studies involving vertebrate animals. The costs of sharing the test and study reports shall be determined in a fair, transparent and non-discriminatory way. The prospective applicant is only required to share in the costs of information he is required to submit to meet the authorisation requirements.

4 Where the prospective applicant and the holder or holders of the relevant authorisations of plant protection products containing the same active substance, safener or synergist, or of adjuvants cannot reach agreement on the sharing of test and study reports involving vertebrate animals, the prospective applicant shall inform the competent authority of the Member State referred to in Article 61(1).

The failure to reach agreement, as provided in paragraph 3, shall not prevent the competent authority of that Member State from using the test and study reports involving vertebrate animals for the purpose of the application of the prospective applicant.

5 By 14 December 2016, the Commission shall report on the effects of the provisions in this Regulation concerning data protection of tests and studies involving vertebrate animals. The Commission shall submit this report to the European Parliament and the Council accompanied, if necessary, by an appropriate legislative proposal.

6 The holder or holders of the relevant authorisation shall have a claim on the prospective applicant for a fair share of the costs incurred by him. The competent authority of the Member State may direct the parties involved to resolve the matter by formal and binding arbitration administered under national law. Otherwise the parties may resolve the matter through litigation in the courts of the Member States. Awards from arbitration or litigation shall have regard to the principles determined in paragraph 3 and shall be enforceable in the courts of the Member States.