

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 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.