

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 ^{F1}... and the plant protection product as referred to in Article 8(2) when they are submitted to a [^{F2}competent authority] 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 [^{F3}any competent authority] for the benefit of other applicants for authorisation of plant protection products, safeners or synergists ^{F4}... , 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 [^{F5}the first authorisation by a competent authority in Great Britain in relation to which the report is submitted], 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 [^{F6}described in the fourth subparagraph]. 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*.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1107/2009 of the European Parliament and of the Council, Article 59. (See end of Document for details)

- 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 ^{F7}... and the plant protection product at the time of submitting the dossier and has provided to the [^{F8}competent authority] 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.

Textual Amendments

- F1** Word in Art. 59(1) omitted (31.12.2020) by virtue of [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **7(2)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F2** Words in Art. 59(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **7(2)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in Art. 59(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **7(2)(a)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F4** Words in Art. 59(1) omitted (31.12.2020) by virtue of [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **7(2)(a)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Art. 59(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **7(2)(a)(iii)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(7)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F6** Words in Art. 59(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **7(2)(a)(iv)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Art. 59(3) omitted (31.12.2020) by virtue of [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **7(2)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Art. 59(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **7(2)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EC) No 1107/2009 of the European Parliament and of the Council, Article 59.