

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 III

PLANT PROTECTION PRODUCTS

SECTION 2

Use and information

Article 56

Information on potentially harmful or unacceptable effects

1 The holder of an authorisation for a plant protection product shall immediately notify [^{F1}each competent authority] that granted an authorisation of any new information concerning that plant protection product, the active substance, its metabolites, a safener, synergist or co-formulant contained in the plant protection product, which suggests that the plant protection product no longer complies with the criteria set out in Articles 29 and 4 respectively.

In particular, potentially harmful effects of that plant protection product, or of residues of an active substance, its metabolites, a safener, synergist or co-formulant contained in it, on human or animal health or on groundwater, or their potentially unacceptable effects on plants or plant products or the environment shall be notified.

To this end the authorisation holder shall record and report all suspected adverse reactions in humans, in animals and the environment related to the use of the plant protection product.

The obligation to notify shall include relevant information on decisions or assessments by international organisations or by public bodies which authorise plant protection products or active substances in [^{F2}other] countries.

2 The notification shall include an assessment of whether and how the new information would result in the plant protection product or the active substance, its metabolites, a safener, or synergist or co-formulant no longer complying with the requirements set out in Article 29 and Article 4 or Article 27, respectively.

3 Without prejudice to the right of [^{F3}competent authorities] to adopt interim protective measures, [^{F4}where paragraph 3A applies, the competent authority] which first granted an authorisation ^{F5}... shall evaluate the information received and inform the other [^{F6}competent authorities which granted authorisation for the plant protection product], where it decides to withdraw or amend the authorisation under Article 44.

That [^{F7}competent authority] shall inform the other [^{F8}competent authorities] where it considers that the conditions of the approval of the active substance, safener or synergist contained in the plant protection product are no longer fulfilled or whether in the case

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of a co-formulant it has been considered unacceptable and propose that the approval be withdrawn or the conditions amended.

[^{F9}3A This paragraph applies where—

- a each competent authority which granted authorisation agrees which competent authority is to evaluate the information;
- b each active substance, safener or synergist in the plant protection product to which the information relates has the same conditions of approval in relation to the constituent territory of each competent authority concerned;
- c any data requirements specified in regulations made under Article 8(4)(a) and (b), any uniform principles for evaluation and authorisation of plant protection products prescribed by regulations made under Article 29(6)(a) and any guidance issued under Article 77 relating to those requirements or principles are the same in relation to the constituent territory of each competent authority concerned.]

4 The holder of an authorisation for a plant protection product shall report annually to the competent authorities ^{F10}... which authorised his plant protection product if he has any information available relating to the lack of expected efficacy, the development of resistance and to any unexpected effect on plants, plant products or the environment.

Textual Amendments

- F1** Words in Art. 56(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F2** Word in Art. 56(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in Art. 56(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(b)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F4** Words in Art. 56(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(b)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Art. 56(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), **5(34)(b)(i)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 56(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(b)(i)(dd)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Art. 56(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(b)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Art. 56(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(b)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F9** Art. 56(3A) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F10** Words in Art. 56(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(34)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

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