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 II

ACTIVE SUBSTANCES, SAFENERS, SYNERGISTS AND CO-FORMULANTS

SECTION 1

Active substances

Subsection 2

Approval procedure

Article 8

Dossiers

1 The summary dossier shall include the following:

a information with respect to one or more representative uses on a **[**F1crop grown in the United Kingdom**]** of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 are met; where the information submitted does not F2... concern a crop F3... , justification for this approach;

b for each point of the data requirements for the active substance **[**F4which apply in each of the constituent territories to which the application relates**]**, the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried out the tests and studies;

c for each point of the data requirements for the plant protection product **[**F5which apply in each of the constituent territories to which the application relates**]**, the summaries and results of tests and studies, the name of their owner and of the person or institute that carried out the tests and studies, relevant to the assessment of the criteria provided for in Article 4(2) and (3) for one or more plant protection products which are representative of the uses referred to in point (a), taking into account the fact that data gaps in the dossier, as provided for in paragraph 2 of this Article, resulting from the proposed limited range of representative uses of the active substance, may lead to restrictions in the approval;

d for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

e a checklist demonstrating that the dossier provided for in paragraph 2 of this Article is complete in view of the uses applied for;

f the reasons why the test and study reports submitted are necessary for first approval of the active substance or for amendments to the conditions of the approval;

g where relevant, a copy of an application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;

h an assessment of all information submitted.

2 The complete dossier shall contain the full text of the individual test and study reports concerning all the information referred to in points (b) and (c) of paragraph 1. It shall not contain any reports of tests or studies involving the deliberate administration of the active substance or the plant protection product to humans.

F6 3 . . . . . .

[F7 4 The appropriate authority may by regulations prescribe the data requirements for—

a one or more active substances, safeners and synergists for the purposes of paragraph 1(b);

b plant protection products for the purposes of paragraph 1(c).**]**

5 Scientific peer-reviewed open literature, as **[**F8 described in guidance issued under Article 77**]**, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier.

Textual Amendments

F1 Words in Art. 8(1)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in Art. 8(1)(a) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in Art. 8(1)(a) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(i)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F4 Words in Art. 8(1)(b) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in Art. 8(1)(c) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F6 Art. 8(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), **4(6)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F7 Art. 8(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F8 Words in Art. 8(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(d)** (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 8.