

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 3*

***Renewal and review***

*Article 14*

**Renewal of approval**

1 On application the approval of an active substance shall be renewed where it is established that the approval criteria provided for in Article 4 are satisfied.

Article 4 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

Such renewal of the approval may include conditions and restrictions, as referred to in Article 6.

2 The renewal of the approval shall be for a period not exceeding 15 years. The renewal of approval of active substances covered by Article 4(7) shall be for a period not exceeding five years.

*Article 15*

**Application for renewal**

1 The application provided for in Article 14 shall be submitted by a producer of the active substance to a Member State, with a copy to the other Member States, the Commission and the Authority, no later than three years before the expiry of the approval.

2 When applying for renewal, the applicant shall identify new data he intends to submit and demonstrate that they are necessary, because of data requirements or criteria which were not applicable at the time of the last approval of the active substance or because his request is for an amended approval. The applicant shall at the same time submit a timetable of any new and ongoing studies.

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The applicant shall identify, giving reasons, the parts of the information submitted that he requests to be kept confidential in accordance with Article 63 and at the same time any data protection claims pursuant to Article 59.

#### *Article 16*

##### **Access to the information for renewal**

The Authority shall, without delay, make available to the public the information provided by the applicant under Article 15, excluding any information in respect of which confidential treatment has been requested and justified pursuant to Article 63, unless there is an overriding public interest in its disclosure.

#### *Article 17*

##### **Extension of approval period for the duration of the procedure**

Where for reasons beyond the control of the applicant it appears that the approval is likely to expire before a decision has been taken on renewal, a decision shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), postponing the expiry of the approval period for that applicant for a period sufficient to examine the application.

A Regulation postponing the expiry for a period sufficient to examine the application shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(5) where an applicant could not give the three years' notice required under Article 15(1) because the active substance was included in Annex I to Directive 91/414/EEC for a duration which expired before 14 June 2014.

The length of that period shall be established on the basis of the following:

- (a) the time needed to provide the information requested;
- (b) the time needed to complete the procedure;
- (c) where appropriate, the need to ensure the establishment of a coherent work programme, as provided for in Article 18.

#### *Article 18*

##### **Work programme**

The Commission may establish a work programme grouping together similar active substances setting priorities on the basis of safety concerns for human and animal health or the environment and taking into account, as far as possible, the need for an effective control and resistance management of target pest. The programme may require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a period provided for in the programme.

The programme shall include the following:

- (a) the procedures concerning the submission and assessment of applications for renewal of approvals;

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- (b) the necessary data to be submitted, including measures to minimise animal testing, in particular the use of non-animal test methods and intelligent testing strategies;
- (c) the periods for submission of such data;
- (d) rules on the submission of new information;
- (e) period for assessment and decision making;
- (f) the allocation of evaluation of active substances to Member States, taking into account a balance in the responsibilities and work to be done among Member States acting as rapporteurs.

#### *Article 19*

### **Implementing measures**

A Regulation, adopted in accordance with the regulatory procedure referred to in Article 79(3), shall set out the provisions necessary for the implementation of the renewal procedure, including, where relevant, the implementation of a work programme, as provided for in Article 18.

#### *Article 20*

### **Renewal Regulation**

1 A Regulation shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), providing that:

- a the approval of an active substance is renewed, subject to conditions and restrictions where appropriate; or
- b the approval of an active substance is not renewed.

2 Where the reasons for not renewing the approval do not concern the protection of health or the environment, the Regulation referred to in paragraph 1 shall provide for a grace period not exceeding six months for the sale and distribution, and in addition a maximum of one year for the disposal, storage, and use of existing stocks of the plant protection products concerned. The grace period for the sale and distribution shall take into account the normal period of use of the plant protection product but the total grace period shall not exceed 18 months.

In the case of a withdrawal of the approval or if the approval is not renewed because of the immediate concerns for human health or animal health or the environment, the plant protection products concerned shall be withdrawn from the market immediately.

3 Article 13(4) shall apply.

#### *Article 21*

### **Review of approval**

1 The Commission may review the approval of an active substance at any time. It shall take into account the request of a Member State to review, in the light of new scientific and technical knowledge and monitoring data, the approval of an active substance, including where,

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after the review of the authorisations pursuant to Article 44(1), there are indications that the achievement of the objectives established in accordance with Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC is compromised.

Where, in the light of new scientific and technical knowledge it considers that there are indications that the substance no longer satisfies the approval criteria provided for in Article 4, or further information required in accordance with Article 6(f) has not been provided, it shall inform the Member States, the Authority and the producer of the active substance, setting a period for the producer to submit its comments.

2 The Commission may ask the Member States and the Authority for an opinion, or for scientific or technical assistance. The Member States may provide their comments to the Commission within three months from the date of the request. The Authority shall provide its opinion or the results of its work to the Commission within three months of the date of the request.

3 Where the Commission concludes that the approval criteria provided for in Article 4 are no longer satisfied, or the further information required in accordance with Article 6(f) has not been provided, a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3).

Article 13(4) and Article 20(2) shall apply.

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