

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 X

ADMINISTRATIVE AND FINANCIAL PROVISIONS

Article 72

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take the measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.

The Member States shall notify those rules and any subsequent amendment to the Commission without delay.

Article 73

Civil and criminal liability

The granting of authorisation and any other measures in conformity with this Regulation shall be without prejudice to general civil and criminal liability in the Member States of the producer and, where applicable, of the person responsible for placing the plant protection product on the market or using it.

Article 74

Fees and charges

1 Member States may recover the costs associated with any work they carry out within the scope of this Regulation, by means of fees or charges.

2 Member States shall ensure that the fees or charges referred to in paragraph 1:

- a are established in a transparent manner; and
- b correspond to the actual total cost of the work involved except if it is in public interest to lower the fees or charges.

The fees or charges may include a scale of fixed charges based on average costs for the work referred to in paragraph 1.

Article 75

Competent authority

1 Each Member State shall designate a competent authority or authorities to carry out the obligations of the Member States laid down in this Regulation.

2 Each Member State shall designate a coordinating national authority to coordinate and ensure all the necessary contacts with applicants, other Member States, the Commission and the Authority.

3 Member States shall ensure that competent authorities have a sufficient number of suitably qualified and experienced staff so that the obligations laid down in this Regulation shall be carried out efficiently and effectively.

4 Each Member State shall give the details concerning its national competent authority or authorities to the Commission, the Authority and the coordinating national authorities of the other Member States and inform them of any modifications thereof.

5 The Commission shall publish and keep updated on its website a list of the authorities referred to in paragraphs 1 and 2.

Article 76

Expenditure by the Commission

1 The Commission may incur expenditure for activities contributing to the aims of this Regulation including the organisation of the following:

- a development of a harmonised system, including an appropriate database, for gathering and storing all information concerning active substances, safeners, synergists, co-formulants, plant protection products and adjuvants and for making such information available to the Member States, producers and other interested parties;
- b performance of studies needed to prepare and develop further legislation on the placing on the market and use of plant protection products and adjuvants;
- c performance of studies needed to harmonise procedures, decision-making criteria and data requirements;
- d coordination, if necessary by electronic means, of cooperation between Member States, the Commission and the Authority and measures to facilitate work sharing;
- e development and maintenance of a coordinated electronic submission and evaluation system aimed at promoting electronic document exchange and work sharing between the applicants, the Member States, the Commission and the Authority;
- f development of guidance to facilitate the day-to-day application of this Regulation;
- g travel and subsistence expenses that Member States' experts incur as a result of the Commission appointing them to assist its experts in the framework of control activities laid down under Article 68;
- h training of control staff;
- i financing of other measures needed to ensure application of the Regulation adopted under Article 68.

2 The appropriations required under paragraph 1 shall be subject to authorisation by the budgetary authority each financial year.

Article 77

Guidance documents

The Commission may, in accordance with the advisory procedure referred to in Article 79(2), adopt or amend technical and other guidance documents such as explanatory notes or guidance documents on the content of the application concerning micro-organisms, pheromones and biological products, for the implementation of this Regulation. The Commission may ask the Authority to prepare or to contribute to such guidance documents.

Article 78

Amendments and implementing measures

1 The following measures designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4):

- a amendments to the Annexes, taking into account current scientific and technical knowledge;
- b amendments to the Regulations on data requirements for active substances and for plant protection products, as referred to in points (b) and (c) of Article 8(1), taking into account current scientific and technical knowledge;
- c amendments to the Regulation on uniform principles for evaluation and authorisation of plant protection products, as referred to in Article 29(6), taking into account current scientific and technical knowledge;
- d a Regulation postponing the expiry of the approval period referred to in the second subparagraph of Article 17;
- e a Regulation on data requirements for safeners and synergists referred to in Article 25(3);
- f a Regulation establishing a work programme for safeners and synergists referred to in Article 26;
- g adoption of the harmonised methods referred to in Article 29(4);
- h inclusion of co-formulants in Annex III, as referred to in Article 27(2);
- i extension of the date of application of this Regulation to provisional authorisations, as referred to in Article 30(3);
- j information requirements for parallel trade, as referred to in Article 52(4);
- k rules for the application of Article 54, in particular the maximum quantities of plant protection products to be released;
- l detailed rules for adjuvants, as referred to in Article 58(2);
- m a Regulation containing the requirements of the labelling of plant protection products, as referred to in Article 65(1);
- n a Regulation on controls, as referred to in the third subparagraph of Article 68.

2 Any further measures necessary for the implementation of this Regulation may be adopted in accordance with the regulatory procedure referred to in Article 79(3).

3 In accordance with the advisory procedure referred to in Article 79(2), a Regulation shall be adopted containing the list of active substances included in Annex I to Directive 91/414/EEC. Those substances shall be deemed to have been approved under this Regulation.

Article 79

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, as established by Article 58 of Regulation (EC) No 178/2002.

2 Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.

4 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5 Where reference is made to this paragraph, Article 5a(1) to (4) and (5)(b) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time limits laid down in Article 5a(3)(c) and (4)(b) and (e) of Decision 1999/468/EC shall be set at two months, one month and two months respectively.