# 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 1*

### *Authorisation*

#### *Subsection 5*

#### *Special cases*

##### *Article 47*

##### Placing on the market of low-risk plant protection products

1 Where all the active substances contained in a plant protection product are low-risk active substances as referred to in Article 22, that product shall be authorised as a low-risk plant protection product provided no specific risk mitigation measures are needed following a risk assessment. This plant protection product shall also meet the following requirements:

a the low-risk active substances, safeners and synergists contained in it have been approved under Chapter II;

b it does not contain a substance of concern;

c it is sufficiently effective;

d it does not cause unnecessary pain and suffering to vertebrates to be controlled;

e it complies with points (b), (c) and (f) to (i) of Article 29(1).

These products are referred to as ‘low-risk plant protection products’.

2 An applicant for authorisation of a low-risk plant protection product shall demonstrate that the requirements set out in paragraph 1 are met and shall submit with the application a complete and a summary dossier for each point of the data requirements of the active substance and the plant protection product.

3 The Member State shall decide within 120 days whether to approve an application for authorisation of a low-risk plant protection product.

Where the Member State needs additional information, it shall set a time limit for the applicant to supply it. In that case, the period specified shall be extended by the additional time limit granted by the Member State.

The additional period shall be of a maximum of 6 months and shall cease at the moment when the additional information is received by the Member State. Where at the end of that period the applicant has not submitted the missing elements, the Member State shall inform the applicant that the application is inadmissible.

4 Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

*Article 48*

**Placing on the market and use of plant protection products containing a genetically modified organism**

1 A plant protection product which contains an organism falling within the scope of Directive 2001/18/EC shall be examined in respect of the genetic modification in accordance with that Directive, in addition to the assessment under this Chapter.

An authorisation under this Regulation shall not be granted for such a plant protection product unless written consent, as referred to in Article 19 of Directive 2001/18/EC, has been granted for it.

2 Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

*Article 49*

**Placing on the market of treated seeds**

1 Member States shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use in at least one Member State.

2 Where there are substantial concerns that treated seeds as referred to in paragraph 1 are likely to constitute a serious risk to human or animal health or to the environment and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, measures to restrict or prohibit the use and/or sale of such treated seeds shall be taken immediately in accordance with the regulatory procedure referred to in Article 79(3). Before taking such measures the Commission shall examine the evidence and may request an opinion from the Authority. The Commission may set a time limit within which such an opinion shall be provided.

3 Articles 70 and 71 shall apply.

4 Without prejudice to other Community legislation concerning the labelling of seeds, the label and documents accompanying the treated seeds shall include the name of the plant protection product with which the seeds were treated, the name(s) of the active substance(s) in that product, standard phrases for safety precautions as provided for in Directive 1999/45/EC and risk mitigation measures set out in the authorisation for that product where appropriate.

*Article 50*

**Comparative assessment of plant protection products containing candidates for substitution**

1 A comparative assessment shall be performed by Member States when evaluating an application for authorisation for a plant protection product containing an active substance approved as a candidate for substitution. Member States shall not authorise or shall restrict the use of a plant protection product containing a candidate for substitution for use on a particular

crop where the comparative assessment weighing up the risks and benefits, as set out in Annex IV, demonstrates that:

a for the uses specified in the application an authorised plant protection product, or a non-chemical control or prevention method, already exists which is significantly safer for human or animal health or the environment;

b the substitution by plant protection products or non-chemical control or prevention methods referred to in point (a) does not present significant economic or practical disadvantages;

c the chemical diversity of the active substances, where relevant, or methods and practices of crop management and pest prevention are adequate to minimise the occurrence of resistance in the target organism; and

d the consequences on minor use authorisations are taken into account.

2 By way of derogation from Article 36(2) Member States may in exceptional cases also apply the provisions of paragraph 1 of this Article when evaluating an application for authorisation of a plant protection product not containing a candidate for substitution or a low-risk active substance, if a non-chemical control or prevention method exists for the same use and it is in general use in that Member State.

3 By way of derogation from paragraph 1, a plant protection product containing a candidate for substitution shall be authorised without comparative assessment in cases where it is necessary to acquire experience first through using that product in practice.

Such authorisations shall be granted once for a period not exceeding five years.

4 For plant protection products containing a candidate for substitution Member States shall perform the comparative assessment provided for in paragraph 1 regularly and at the latest at renewal or amendment of the authorisation.

Based on the results of that comparative assessment, Member States shall maintain, withdraw or amend the authorisation.

5 Where a Member State decides to withdraw or amend an authorisation pursuant to paragraph 4, that withdrawal or amendment shall take effect 3 years after the decision of the Member State or at the end of the approval period of the candidate for substitution where that period ends earlier.

6 Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

*Article 51*

**Extension of authorisations for minor uses**

1 The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations or professional users may ask for the authorisation of a plant protection product already authorised in the Member State concerned to be extended to minor uses not yet covered by that authorisation.

2 Member States shall extend the authorisation provided that:

a the intended use is minor in nature;

b the conditions referred to in points (b), (d) and (e) of Article 4(3) and Article 29(1)(i) are satisfied;

c the extension is in the public interest; and

d the documentation and information to support the extension of use has been submitted by the persons or bodies referred to in paragraph 1, especially data on the magnitude of residues and where necessary on the risk assessment to the operator, worker and bystander.

3 Member States may take measures to facilitate or encourage the submission of applications to extend the authorisation of already authorised plant protection products to minor uses.

4 The extension may take the form of an amendment to the existing authorisation or may be a separate authorisation, in accordance with the administrative procedures of the Member State concerned.

5 When Member States grant an extension of authorisation for a minor use, they shall inform if necessary the authorisation holder and request him to change the labelling accordingly.

Where the authorisation holder declines, the Member States shall ensure that users are fully and specifically informed as to instructions for use, by means of an official publication or an official website.

The official publication or where applicable the label shall include a reference to the liability of the person using the plant protection product with respect to failures concerning the efficacy or to phytotoxicity of the product for which the minor use was granted. The minor use extension shall be separately identified in the label.

6 Extensions on the basis of this Article shall be separately identified and separate reference shall be made to liability restrictions.

7 The applicants referred to in paragraph 1 may also apply for authorisation of a plant protection product for minor uses in accordance with Article 40(1) provided that a plant protection product concerned is authorised in that Member State. Member States shall authorise such uses in accordance with the provisions of Article 41 provided that those uses are also considered minor in the Member States of application.

8 Member States shall establish and regularly update a list of minor uses.

9 By 14 December 2011, the Commission shall present a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal.

10 Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

*Article 52*

**Parallel trade**

1 A plant protection product that is authorised in one Member State (Member State of origin) may, subject to granting a parallel trade permit, be introduced, placed on the market or used in another Member State (Member State of introduction), if this Member State determines that the plant protection product is identical in composition to a plant protection product already authorised in its territory (reference product). The application shall be submitted to the competent authority of the Member State of introduction.

2 From receiving a complete application, a parallel trade permit shall be granted in a simplified procedure within 45 working days if the plant protection product to be introduced is

identical in terms of paragraph 3. Member States shall on request provide each other with the information necessary to assess whether the products are identical within 10 working days of receiving the request. The procedure for granting a parallel trade permit is interrupted from the day the request for information is sent to the competent authority of the Member State of origin until the complete information required is delivered to the competent authority of the Member State of introduction.

3 Plant protection products shall be considered as identical to the reference products if:

- a they have been manufactured by the same company or by an associated undertaking or under licence in accordance with the same manufacturing process;
- b they are identical in specification and content to the active substances, safeners and synergists, and in the type of formulation; and
- c they are either the same or equivalent in the co-formulants present and the packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.

4 The application for a parallel trade permit shall include the following information:

- a the name and registration number of the plant protection product in the Member State of origin;
- b the Member State of origin;
- c the name and address of the authorisation holder in the Member State of origin;
- d the original label and instructions for use with which the plant protection product to be introduced is distributed in the Member State of origin if it is considered as necessary for the examination by the competent authority of the Member State of introduction. This competent authority may require a translation of the relevant parts of the original instructions for use;
- e the name and address of the applicant;
- f the name to be given to the plant protection product to be distributed in the Member State of introduction;
- g a draft label for the product intended to be placed on the market;
- h a sample of the product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;
- i the name and registration number of the reference product.

The information requirements may be amended or completed and further details and specific requirements shall be established in cases of application for a plant protection product for which a parallel trade permit has already been granted and in cases of an application for a plant protection product for a personal use in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

5 A plant protection product for which a parallel trade permit has been issued shall be placed on the market and used only in accordance with the provisions of the authorisation of the reference product. To facilitate monitoring and controls the Commission shall set out specific control requirements for the product to be introduced in a Regulation referred to in Article 68.

6 The parallel trade permit shall be valid for the duration of authorisation of the reference product. If the authorisation holder of the reference product applies for a withdrawal of authorisation in accordance with Article 45(1) and the requirements of Article 29 are still fulfilled, the validity of the parallel trade permit shall expire by the date on which the authorisation of the reference product would normally have expired.

7 Without prejudice to specific provisions of this Article, Articles 44, 45, 46, and 55 and Article 56(4) and Chapters VI to X shall apply to parallel traded plant protection products correspondingly.

8 Without prejudice to Article 44, a parallel trade permit may be withdrawn if the authorisation of the introduced plant protection product is withdrawn in the Member State of origin because of safety or efficacy reasons.

9 Where the product is not identical, in terms of paragraph 3, to the reference product, the Member State of introduction may only grant the authorisation required for placing on the market and use in accordance with Article 29.

10 The provisions of this Article shall not apply to plant protection products which are authorised in the Member State of origin in accordance with Article 53 or 54.

11 Without prejudice to Article 63, Member State authorities shall make publicly available information about parallel trade permits.