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 1

Requirements and contents

Article 28

Authorisation for placing on the market and use

1 A plant protection product shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with this Regulation.

2 By way of derogation from paragraph 1, no authorisation shall be required in the following cases:

a use of products containing exclusively one or more basic substances;

b placing on the market and use of plant protection products for research or development purposes in accordance with Article 54;

c production, storage or movement of a plant protection product intended for use in another Member State, provided that the product is authorised in that Member State and that the Member State of production, storage or movement has put in place inspection requirements to ensure that the plant protection product is not used in its territory;

d production, storage or movement of a plant protection product intended for use in a third country provided that the Member State of production, storage or movement has put in place inspection requirements to ensure that the plant protection product is exported from its territory;

e placing on the market and use of plant protection products for which a parallel trade permit has been granted in accordance with Article 52.

Article 29

Requirements for the authorisation for placing on the market

1 Without prejudice to Article 50 a plant protection product shall only be authorised where following the uniform principles referred to in paragraph 6 it complies with the following requirements:

a its active substances, safeners and synergists have been approved;

b where its active substance, safener or synergist is produced by a different source, or by the same source with a change in the manufacturing process and/or manufacturing location:

(i) the specification, pursuant to Article 38, does not deviate significantly from the specification included in the Regulation approving that substance, safener or synergist; and

(ii) the active substance, safener or synergist has no more harmful effects within the meaning of Article 4(2) and (3) due to its impurities than if it had been produced in accordance with the manufacturing process specified in the dossier that supported the approval;

c its co-formulants are not included in Annex III;

d its technical formulation is such that user exposure or other risks are limited as much as possible without compromising the functioning of the product;

e in the light of current scientific and technical knowledge, it complies with the requirements provided for in Article 4(3);

f the nature and quantity of its active substances, safeners and synergists and, where appropriate, any toxicologically, ecotoxicologically or environmentally relevant impurities and co-formulants can be determined by appropriate methods;

g its residues, resulting from authorised uses, and which are of toxicological, ecotoxicological or environmental relevance, can be determined by appropriate methods in general use in all Member States, with appropriate limits of determination on relevant samples;

h its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;

i for plants or plant products to be used as feed or food, where appropriate, the maximum residue levels for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with Regulation (EC) No 396/2005.

2 The applicant shall demonstrate that the requirements provided for in points (a) to (h) of paragraph 1 are met.

3 Compliance with the requirements set out in point (b) and points (e) to (h) of paragraph 1 shall be established by official or officially recognised tests and analyses carried out under agricultural, plant health and environmental conditions relevant to the use of the plant protection product in question and representative of the conditions prevailing in the zone where the product is intended to be used.

4 With respect to point (f) of paragraph 1, harmonised methods may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

5 Article 81 shall apply.

6 Uniform principles for evaluation and authorisation of plant protection products shall contain the requirements set out in Annex VI to Directive 91/414/EEC and shall be laid down in Regulations adopted in accordance with the advisory procedure referred to in Article 79(2) without any substantial modifications. Subsequent amendments to these Regulations shall be adopted in accordance with Article 78(1)(c).

Following these principles, interaction between the active substance, safeners, synergists and co-formulants shall be taken into account in the evaluation of plant protection products.

Article 30

Provisional authorisations

1 By way of derogation from Article 29(1)(a), Member States may authorise for a provisional period not exceeding 3 years, the placing on the market of plant protection products containing an active substance not yet approved, provided that:

a the decision on approval could not be finalised within a period of 30 months from the date of admissibility of the application, extended by any additional period set in accordance with Article 9(2), Article 11(3) or Article 12(2) or (3); and

b pursuant to Article 9 the dossier on the active substance is admissible in relation to the proposed uses; and

c the Member State concludes that the active substance can satisfy the requirements of Article 4(2) and (3) and that the plant protection product may be expected to satisfy the requirements of Article 29(1)(b) to (h); and

d maximum residue levels have been established in accordance with Regulation (EC) No 396/2005.

2 In such cases the Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorisation, giving at least the information provided for in Article 57(1).

3 The provisions laid down in paragraphs 1 and 2 shall apply until 14 June 2016. If necessary, that time limit may be extended in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Article 31

Contents of authorisations

1 The authorisation shall define plants or plant products and non-agricultural areas (for example railways, public areas, storage rooms) on which and the purposes for which the plant protection product may be used.

2 The authorisation shall set out the requirements relating to the placing on the market and use of the plant protection product. Those requirements shall as a minimum include the conditions of use necessary to comply with the conditions and requirements provided for in the Regulation approving the active substances, safeners and synergists.

The authorisation shall include a classification of the plant protection product for the purpose of Directive 1999/45/EC. Member States may provide that authorisation holders shall classify or update the label without undue delay following any change to the classification and labelling of the plant protection product in accordance with Directive 1999/45/EC. In such cases, they shall immediately inform the competent authority thereof.

3 The requirements referred to in paragraph 2 shall also include where applicable:

a the maximum dose per hectare in each application;

b the period between the last application and harvest;

c the maximum number of applications per year.

4 The requirements referred to in paragraph 2 may include the following:

a a restriction with respect to the distribution and use of the plant protection product in order to protect the health of the distributors, users, bystanders, residents, consumers or workers concerned or the environment, taking into consideration requirements imposed by other Community provisions; such restriction shall be indicated on the label;

b the obligation before the product is used to inform any neighbours who could be exposed to the spray drift and who have requested to be informed;

c indications for proper use according to the principles of Integrated Pest Management referred to in Article 14 of and Annex III to Directive 2009/128/EC;

d designation of categories of users, such as professional and non-professional;

e the approved label;

f the interval between applications;

g the period between the last application and consumption of the plant product where applicable;

h the re-entry interval;

i the packaging size and material.

Article 32

Duration

1 The period of authorisation shall be laid down in the authorisation.

Without prejudice to Article 44, the duration of an authorisation shall be set for a period not exceeding 1 year from the date of expiry of the approval of the active substances, safeners and synergists contained in the plant protection product and thereafter for as long as the active substances, safeners and synergists contained in the plant protection product are approved.

This period shall allow the examination as provided for in Article 43 to be carried out.

2 Authorisations may be granted for shorter periods to synchronise the re-evaluation of similar products for the purposes of a comparative assessment of products containing candidates for substitution as provided for in Article 50.

Subsection 2

Procedure

Article 33

Application for authorisation or amendment of an authorisation

1 An applicant who wishes to place a plant protection product on the market shall apply for an authorisation or amendment of an authorisation himself, or through a representative, to each Member State where the plant protection product is intended to be placed on the market.

2 The application shall include the following:

a a list of intended uses in each zone as indicated in Annex I and the Member States where the applicant has made or intends to make an application;

b a proposal as to which Member State the applicant expects to evaluate the application in the zone concerned. In the case of an application for use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment, only one Member State shall be proposed, which evaluates the application taking account of all zones. In this case the applicant shall send the summary or complete dossier as referred to in Article 8 to other Member States on request;

c where relevant, a copy of any authorisations already granted for that plant protection product in a Member State;

d where relevant, a copy of any conclusion of the Member State assessing equivalence as referred to in Article 38(2).

3 The application shall be accompanied by the following:

a for the plant protection product concerned, a complete and a summary dossier for each point of the data requirements of the plant protection product;

b for each active substance, safener and synergist contained in the plant protection product, a complete and a summary dossier for each point of the data requirements of the active substance, safener and synergist;

c 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;

d the reasons why the test and study reports submitted are necessary for first authorisation or for amendments to the conditions of the authorisation;

e where relevant a copy of the 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;

f where relevant for an amendment of an authorisation an assessment of all information submitted in accordance with point (h) of Article 8(1);

g a draft label.

4 When submitting the application, the applicant may pursuant to Article 63, request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

The applicant shall at the same time submit the complete list of studies submitted pursuant to Article 8(2) and a list of test and study reports for which any claims for data protection pursuant to Article 59 are requested.

Upon a request for access to information the Member State examining the application shall decide what information is to be kept confidential.

5 Where requested by the Member State the applicant shall submit his application in the national or official languages of that Member State or one of those languages.

6 On request, the applicant shall provide the Member State with samples of the plant protection product and analytical standards of its ingredients.

Article 34

Exemption from the submission of studies

1 Applicants shall be exempted from supplying the test and study reports referred to in Article 33(3) where the Member State to which an application is made has the test and study reports concerned and the applicants demonstrate that they have been granted access in accordance with Article 59, 61 or 62 or that any data protection period has expired.

2 However, applicants to whom paragraph 1 applies shall provide the following information:

a all necessary data for the identification of the plant protection product including its complete composition as well as a declaration that no unacceptable co-formulants are used;

b the information needed to identify the active substance, safener or synergist, where they have been approved, and to establish whether the conditions for approval are met and comply with point (b) of Article 29(1), where appropriate;

c on the request of the concerned Member State, the data needed to demonstrate that the plant protection product has comparable effects to the plant protection product for which they show access to the protected data.

Article 35

Member State examining the application

The application shall be examined by the Member State proposed by the applicant, unless another Member State in the same zone agrees to examine it. The Member State which will examine the application shall inform the applicant.

At the request of the Member State examining the application, the other Member States in the same zone to which an application has been submitted shall cooperate to ensure a fair division of the workload.

The other Member States within the zone to which an application has been submitted shall refrain from proceeding with the file pending assessment by the Member State examining the application.

Where an application has been made in more than one zone, Member States evaluating the application shall agree on the evaluation of data which are not related to the environmental and agricultural conditions.

Article 36

Examination for authorisation

1 The Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application. It shall give all Member States in the same zone the opportunity to submit comments to be considered in the assessment.

It shall apply the uniform principles for evaluation and authorisation of plant protection products, referred to in Article 29(6), to establish, as far as possible, whether the plant protection product meets the requirements provided for in Article 29 in the same zone, where used in accordance with Article 55, and under realistic conditions of use.

The Member State examining the application shall make available its assessment to the other Member States within the same zone. The format of the assessment report shall be established in accordance with the advisory procedure referred to in Article 79(2).

2 The Member States concerned shall grant or refuse authorisations accordingly on the basis of the conclusions of the assessment of the Member State examining the application as provided for in Articles 31 and 32.

3 By way of derogation from paragraph 2 and subject to Community law, appropriate conditions may be imposed with respect to the requirements referred to in Article 31(3) and (4) and other risk mitigation measures deriving from specific conditions of use.

Where the concerns of a Member State relating to human or animal health or the environment cannot be controlled by the establishment of the national risk mitigation measures referred to in the first subparagraph, a Member State may refuse authorisation of the plant protection product in its territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment.

That Member State shall immediately inform the applicant and the Commission of its decision and provide a technical or scientific justification therefor.

Member States shall provide for the possibility of challenging a decision refusing the authorisation of such products before national courts or other instances of appeal.

Article 37

Period for examination

1 The Member State examining the application shall decide within 12 months of receiving it whether the requirements for authorisation are met.

Where the Member State needs additional information, it shall set a period for the applicant to supply it. In that case, the 12-month period shall be extended by the additional period granted by the Member State. That additional period shall be 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.

2 The time limits provided for in paragraph 1 shall be suspended during the application of the procedure set out in Article 38.

3 For an application for authorisation of a plant protection product containing an active substance not yet approved, the Member State examining the application shall start the evaluation as soon as it has received the draft assessment report referred to in Article 12(1). In case the application concerns the same plant protection product and the same uses as contained in the dossier referred to in Article 8, the Member State shall decide on the application at the latest within six months of the active substance being approved.

4 The other Member States concerned shall at the latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the Member State examining the application decide on the application as referred to in Article 36(2) and (3).

Article 38

Assessment of equivalence under point (b) of Article 29(1)

1 Where it is necessary to establish for an active substance, safener or synergist whether a different source or, for the same source a change of the manufacturing process and/or manufacturing location complies with point (b) of Article 29(1), this shall be assessed by the Member State which acted as rapporteur for the active substance, safener or synergist as referred

to in Article 7(1) unless the Member State examining the application as referred to in Article 35 agrees to assess the equivalence. The applicant shall submit all necessary data to the Member State assessing equivalence.

2 After giving the applicant the opportunity to submit comments, which the applicant shall also communicate to the rapporteur Member State or the Member State examining the application as the case may be, the Member State assessing equivalence shall prepare a report on equivalence within 60 days from receiving the application and shall communicate the report to the Commission, the other Member States and the applicant.

3 In the case of a positive conclusion on equivalence and where no objection to this conclusion has been raised, point (b) of Article 29(1) shall be considered to be complied with. However, where a Member State examining the application does not agree with the conclusion of the rapporteur Member State or vice versa, it shall inform the applicant, the other Member States and the Commission stating its reasons.

The Member States concerned shall try to reach agreement on whether point (b) of Article 29(1) is complied with. They shall provide the applicant with an opportunity to submit comments.

4 Where the Member States concerned do not reach agreement within 45 days, the Member State assessing equivalence shall submit the matter to the Commission. A decision on whether the conditions referred to in point (b) of Article 29(1) are complied with shall be adopted in accordance with the regulatory procedure referred to in Article 79(3). The 45-day period begins on the date on which the Member State examining the application for authorisation informed the rapporteur Member State or vice versa that it does not agree with the conclusion of the latter, in accordance with paragraph 3.

Before such a decision is adopted, the Commission may ask the Authority for an opinion, or for scientific or technical assistance which shall be provided within 3 months of the request.

5 Detailed rules and procedures for the implementation of paragraphs 1 to 4 may be established in accordance with the regulatory procedure referred to in Article 79(3), after consultation of the Authority.

Article 39

Reporting and exchange of information on applications for authorisation

1 Member States shall compile a file on each application. Each file shall contain the following:

a a copy of the application;

b a report containing information on the evaluation of and decision on the plant protection product; the format of the report shall be established in accordance with the advisory procedure referred to in Article 79(2);

c a record of the administrative decisions taken by the Member State concerning the application and of the documentation provided for in Article 33(3) and Article 34 together with a summary of the latter;

d the approved label, where applicable.

2 On request, Member States shall, without delay, make available to the other Member States, the Commission and the Authority a file containing the documentation provided for in points (a) to (d) of paragraph 1.

3 On request, applicants shall provide a copy of the documentation to be submitted with an application pursuant to Article 33(3) and Article 34 to Member States, the Commission and the Authority.

4 Detailed rules for the implementation of paragraphs 2 and 3 may be established in accordance with the regulatory procedure referred to in Article 79(3).

Subsection 3

Mutual recognition of authorisations

Article 40

Mutual recognition

1 The holder of an authorisation granted in accordance with Article 29 may apply for an authorisation for the same plant protection product, the same use and under the comparable agricultural practices in another Member State under the mutual recognition procedure, provided for in this subsection, in the following cases:

a the authorisation was granted by a Member State (reference Member State) which belongs to the same zone;

b the authorisation was granted by a Member State (reference Member State) which belongs to a different zone provided that the authorisation for which the application was made is not used for the purpose of mutual recognition in another Member State within the same zone;

c the authorisation was granted by a Member State for use in greenhouses, or as post-harvest treatment, or for treatment of empty rooms or containers used for storing plant or plant products, or for seed treatment, regardless of the zone to which the reference Member State belongs.

2 Where a plant protection product is not authorised in a Member State because no application for an authorisation has been submitted in that Member State, official or scientific bodies involved in agricultural activities or professional agricultural organisations may apply, with the consent of the authorisation holder, for an authorisation for the same plant protection product, the same use and under the same agricultural practices in that Member State under the mutual recognition procedure referred to in paragraph 1. In that case the applicant must demonstrate that the use of such a plant protection product is of general interest for the Member State of introduction.

Where the authorisation holder refuses its consent, the competent authority of the Member State concerned may accept the application, on grounds of public interest.

Article 41

Authorisation

1 The Member State to which an application under Article 40 is submitted shall, having examined the application and the accompanying documents referred to in Article 42(1), as appropriate with regard to the circumstances in its territory, authorise the plant protection product concerned under the same conditions as the Member State examining the application, except where Article 36(3) applies.

2 By way of derogation from paragraph 1, the Member State may authorise the plant protection product where:

a an authorisation under point (b) of Article 40(1) was applied for;

b it contains a candidate of substitution;

c Article 30 has been applied; or

d it contains a substance approved in accordance with Article 4(7).

Article 42

Procedure

1 The application shall be accompanied by the following:

a a copy of the authorisation granted by the reference Member State as well as a translation of the authorisation into an official language of the Member State receiving the application;

b a formal statement that the plant protection product is identical to that authorised by the reference Member State;

c a complete or summary dossier as required in Article 33(3) when requested by the Member State;

d an assessment report of the reference Member State containing information on the evaluation and decision on the plant protection product.

2 The Member State to which an application under Article 40 is submitted shall decide on the application within 120 days.

3 Where requested by the Member State, the applicant shall submit the application in the national or official languages of that Member State or one of those languages.

Subsection 4

Renewal, withdrawal and amendment

Article 43

Renewal of authorisation

1 An authorisation shall be renewed upon application by the authorisation holder, provided that the requirements referred to in Article 29 are still met.

2 Within 3 months from the renewal of the approval of an active substance, safener or synergist contained in the plant protection product, the applicant shall submit the following information:

a a copy of the authorisation of the plant protection product;

b any new information required as a result of amendments in data requirements or criteria;

c evidence that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval;

d any information required to demonstrate that the plant protection product meets the requirements set out in the Regulation on the renewal of the approval of the active substance, safener or synergist contained therein;

e a report on the monitoring information, where the authorisation was subject to monitoring.

3 Member States shall check compliance of all plant protection products containing the active substance, safener or synergist concerned with any conditions and restrictions provided for in the Regulation renewing the approval under Article 20.

The Member State referred to in Article 35 within each zone shall coordinate the compliance check and assessment of the information submitted for all Member States within that zone.

4 Guidelines on the organisation of compliance checks may be established in accordance with the advisory procedure referred to in Article 79(2).

5 Member States shall decide on the renewal of the authorisation of a plant protection product at the latest 12 months after the renewal of the approval of the active substance, safener or synergist contained therein.

6 Where, for reasons beyond the control of the holder of the authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Member State in question shall extend the authorisation for the period necessary to complete the examination and adopt a decision on the renewal.

Article 44

Withdrawal or amendment of an authorisation

1 Member States may review an authorisation at any time where there are indications that a requirement referred to in Article 29 is no longer satisfied.

A Member State shall review an authorisation where it concludes that the objectives of Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may not be achieved.

2 Where a Member State intends to withdraw or amend an authorisation, it shall inform the authorisation holder and give him the possibility to submit comments or further information.

3 The Member State shall withdraw or amend the authorisation, as appropriate, where:

a the requirements referred to in Article 29 are not or are no longer satisfied;

b false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted;

c a condition included in the authorisation has not been met;

d on the basis of developments in scientific and technical knowledge, the manner of use and amounts used can be modified; or

e the authorisation holder fails to comply with the obligations resulting from this Regulation.

4 Where a Member State withdraws or amends an authorisation in accordance with paragraph 3, it shall immediately inform the holder of the authorisation, the other Member States, the Commission and the Authority. The other Member States belonging to the same zone shall withdraw or amend the authorisation accordingly taking into account national conditions and risk mitigation measures except for cases where the second, third or fourth subparagraphs of Article 36(3) have been applied. Article 46 shall apply where appropriate.

Article 45

Withdrawal or amendment of an authorisation at the request of the authorisation holder

1 An authorisation may be withdrawn or amended at the request of the holder of the authorisation, who shall state the reasons for his request.

2 Amendments may only be granted where it is established that the requirements referred to in Article 29 continue to be met.

3 Article 46 shall apply where appropriate.

Article 46

Grace period

Where a Member State withdraws or amends an authorisation or does not renew it, it may grant a grace period for the disposal, storage, placing on the market and use of existing stocks.

Where the reasons for withdrawal, amendment or non-renewal of the authorisation are not related to the protection of human and animal health or the environment, the grace period shall be limited and shall not exceed 6 months for the sale and the distribution and an additional maximum of 1 year for the disposal, storage, and use of existing stocks of the plant protection products concerned.

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.

Subsection 6

Derogations

Article 53

Emergency situations in plant protection

1 By way of derogation from Article 28, in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means.

The Member State concerned shall immediately inform the other Member States and the Commission of the measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety.

2 The Commission may ask the Authority for an opinion, or for scientific or technical assistance.

The Authority shall provide its opinion or the results of its work to the Commission within 1 month of the date of the request.

3 If necessary, a decision shall be taken, in accordance with the regulatory procedure referred to in Article 79(3), as to when and under what conditions the Member State:

a may or may not extend the duration of the measure or repeat it; or

b shall withdraw or amend its measure.

4 Paragraphs 1 to 3 shall not apply to plant protection products containing or composed of genetically modified organisms unless such release has been accepted in accordance with Directive 2001/18/EC.

Article 54

Research and development

1 By way of derogation from Article 28, experiments or tests for research or development purposes involving the release into the environment of an unauthorised plant protection product or involving unauthorised use of a plant protection product may be carried out if the Member State in whose territory the experiment or test is to be carried out has assessed the available data and granted a permit for trial purposes. The permit may limit the quantities to be used and the areas to be treated and may impose further conditions to prevent any harmful effects on human or animal health or any unacceptable adverse effect on the environment, such as the need to prevent entry into the food chain of feed and food containing residues unless a relevant provision has already been established under Regulation (EC) No 396/2005.

The Member State may authorise a programme of experiments or tests in advance or require a permit for each experiment or test.

2 An application shall be submitted to the Member State in whose territory the experiment or test is to be conducted, together with a dossier containing all the available data to permit an assessment of possible effects on human or animal health or the possible impact on the environment.

3 A permit for trial purposes shall not be granted for experiments or tests involving the release into the environment of a genetically modified organism unless such release has been accepted under Directive 2001/18/EC.

4 Paragraph 2 shall not apply if the Member State has granted the person concerned the right to undertake certain experiments and tests and has determined the conditions under which the experiments and tests have to be undertaken.

5 Detailed rules for the implementation of this Article, in particular the maximum quantities of plant protection products that may be released during experiments or tests and the minimum data to be submitted in accordance with paragraph 2, may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

SECTION 2

Use and information

Article 55

Use of plant protection products

Plant protection products shall be used properly.

Proper use shall include the application of the principles of good plant protection practice and compliance with the conditions established in accordance with Article 31 and specified on the labelling. It shall also comply with the provisions of Directive 2009/128/EC and, in particular, with general principles of integrated pest management, as referred to in Article 14 of and Annex III to that Directive, which shall apply at the latest by 1 January 2014.

Article 56

Information on potentially harmful or unacceptable effects

1 The holder of an authorisation for a plant protection product shall immediately notify the Member States 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 third 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 Member States to adopt interim protective measures, the Member State which first granted an authorisation within each zone shall evaluate the information received and inform the other Member States, belonging to the same zone, where it decides to withdraw or amend the authorisation under Article 44.

That Member State shall inform the other Member States and the Commission 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

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

4 The holder of an authorisation for a plant protection product shall report annually to the competent authorities of the Member States 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.

Article 57

Obligation to keep information available

1 Member States shall keep information electronically available to the public on plant protection products authorised or withdrawn in accordance with this Regulation, containing at least:

a the name or business name of the holder of the authorisation and the authorisation number;
b the trade name of the product;
c the type of preparation;
d the name and amount of each active substance, safener or synergist which it contains;
e the classification, risk and safety phrases in accordance to Directive 1999/45/EC and to the Regulation referred to in Article 65;
f the use or uses for which it is authorised;
g the reasons for withdrawal of an authorisation if they are related to safety concerns;
h the list of minor uses referred to in Article 51(8).

2 The information referred to in paragraph 1 shall be readily accessible and updated at least once every 3 months.

3 In accordance with the regulatory procedure referred to in Article 79(3), an authorisation information system may be set up to facilitate the application of paragraphs 1 and 2 of this Article.

Status:
Point in time view as at 21/10/2009.

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, CHAPTER III.