

Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (Text with EEA relevance)

COMMISSION REGULATION (EU) No 1141/2010

of 7 December 2010

laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market<sup>(1)</sup>, and in particular Article 6(5) thereof,

Whereas:

- (1) Directive 91/414/EEC provides that, on request, the inclusion of an active substance may be renewed.
- (2) The Commission has received letters from several producers requesting a renewal for active substances included in Annex I to Directive 91/414/EEC and for which the inclusion period is to expire in 2011 and 2012.
- (3) It is necessary to provide for a procedure for the submission and appraisal of applications for the renewal of the inclusion in Annex I to Directive 91/414/EEC of those active substances.
- (4) Periods should be set for the different steps of that procedure to ensure that they are carried out rapidly.
- (5) Producers wishing to secure the renewal of active substances covered by this Regulation should be required to apply to the relevant rapporteur Member State.
- (6) Where two or more applications for the same active substance have been submitted separately and fulfil the requirements, the rapporteur Member States should communicate the updated contact details of each applicant to the other applicants to facilitate the submission of joint dossiers and to avoid, whenever possible, duplication of studies involving vertebrate animals.
- (7) In order to ensure the efficiency of renewal procedures, rapporteur Member States should organise, prior to the submission of the dossiers, a meeting to discuss the state of the art of the active substance and consider whether and, if necessary, how the dossiers submitted for the first inclusion are to be updated.

---

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

- (8) The dossiers submitted for renewal should include new data relevant to the active substance and new risk assessments to reflect any changes in data requirements and any changes in scientific or technical knowledge since the active substance was first included in Annex I to Directive 91/414/EEC, as reflected in guidance documents published by the Commission and in relevant opinions from the Scientific Committee on Plants or the European Food Safety Authority (hereinafter ‘the Authority’). The range of uses submitted should reflect the representative uses. The applicant should demonstrate, on the basis of the data submitted, that for one or more preparations the requirements of Article 5 of Directive 91/414/EEC will be fulfilled.
- (9) The applicants should list separately vertebrate studies to be submitted with the dossier and the rapporteur Member States should make such lists available on request to promote early discussions on the sharing of vertebrates data to avoid duplication of vertebrate studies.
- (10) Technical or scientific information about an active substance, in particular with regard to potentially dangerous effects, submitted within the relevant period by third parties should be taken into consideration in the evaluations. The applicants should be given the opportunity to comment on such information.
- (11) The renewal assessment reports prepared by the rapporteur Member States may, where necessary, be the subject of a consultation of experts organised by the Authority on request of the Commission before they are submitted to the Standing Committee on the Food Chain and Animal Health.
- (12) The rules on data protection of Article 13 of Directive 91/414/EEC are intended to provide an incentive to applicants to assemble the detailed studies required under Annexes II and III to that Directive. However, data protection should not be extended artificially by the production of new studies which are not needed to decide on the renewal of an active substance. To this end, applicants should be required to identify explicitly which studies are new compared to the original dossier used for the first inclusion of the substance in Annex I to Directive 91/414/EC and to provide justification for their submission.
- (13) In view of the particular situation, where parts of the renewal procedure still take place while Directive 91/414/EEC applies while the decisions on the renewals will be taken under 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<sup>(2)</sup>, applicants are encouraged, as regards the format of the updating statement and the format and content of the dossier, to pay particular attention to the specific guidance documents published by the Commission.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

---

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

## Article 1

### Scope

This Regulation lays down the procedure for the renewal of the inclusion in Annex I to Directive 91/414/EEC of the active substances listed in Annex I to this Regulation.

## Article 2

### Definitions

For the purposes of this Regulation the following definitions shall apply:

- (a) ‘producer’ means the person who manufactures the active substance on his own or who contracts out the manufacturing to another party or a person designated by the manufacturer as his sole representative for the purpose of compliance with this Regulation;
- (b) ‘applicant’ means a producer who applies for the renewal of the inclusion of an active substance referred to in column A of Annex I;
- (c) ‘rapporteur Member State’ means the Member State which evaluates an active substance, as listed in column B of Annex I for the respective active substance;
- (d) ‘co-rapporteur Member State’ means a Member State which cooperates in the evaluation carried out by the rapporteur Member State, as listed in column C of Annex I for the respective active substance;
- (e) ‘inclusion’ means inclusion of an active substance in Annex I to Directive 91/414/EEC;
- (f) ‘renewal’ means renewal of the inclusion of an active substance in Annex I to Directive 91/414/EEC.

## Article 3

### Coordinating authority of the Member State

Each Member State shall appoint an authority, hereinafter ‘the coordinating authority’, which coordinates and ensures contacts with applicants, other Member States, the Commission and the European Food Safety Authority, hereinafter ‘the Authority’, in accordance with this Regulation. Each Member State shall communicate the name and the contact details of its coordinating authority and any modifications to the Commission.

The Commission shall publish a list including the names and the contact details of the coordinating authorities of the Member States. It shall keep that list updated according to the modifications communicated to it.

---

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

## Article 4

### Submission of application

1 A producer wishing to renew the inclusion in Annex I to Directive 91/414/EEC of an active substance referred to in column A of Annex I to this Regulation, or any variants thereof, shall, for each active substance separately, submit an application to the rapporteur Member State and to the co-rapporteur Member State by 28 March 2011 at the latest.

2 When submitting an application, the applicant may, pursuant to Article 14 of Directive 91/414/EEC, request certain parts of the information to be kept confidential. It shall present such parts of the application separately, setting out the reasons for requesting confidentiality.

At the same time, the applicant shall submit any data protection claims pursuant to Article 13 of Directive 91/414/EEC.

3 The applicant shall send a copy of the application, without the updating statement referred to in Article 5(2), to the Commission and to the Authority.

4 Where several producers wish to renew the inclusion of the same active substance in Annex I to Directive 91/414/EEC, a joint application may be submitted by a joint representative.

5 Where applicable, a fee, as referred to in Article 19, shall be paid upon submission of an application.

## Article 5

### Format and content of application

1 An application shall be submitted in the format set out in Annex II.

2 The application shall state which sections of the dossiers submitted for the first inclusion of the active substance require updating with new information.

Hereinafter, that part of the application is referred to as ‘the updating statement’.

3 The updating statement shall list the new information the applicant intends to submit and demonstrate that such information is necessary, because of data requirements or criteria which were not applicable at the time of the first inclusion of the active substance or because of changes in the representative uses or because the application is for an amended renewal.

The updating statement shall separately list new studies the applicant intends to submit on vertebrate animals.

4 Upon request from any interested party, the rapporteur Member State shall make available the information listed by the applicant as referred to in paragraph 3.

## Article 6

### Checking of application

1 Within 1 month of receipt of the application, the rapporteur Member State shall check whether the application fulfils the requirements of Articles 4 and 5.

---

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

2 Where the rapporteur Member State considers that the application fulfils the requirements of Articles 4 and 5, it shall, within the period of 1 month provided for in paragraph 1, inform the applicant, the Commission and the Authority of the date of receipt and that the application fulfils the requirements.

3 Where the rapporteur Member State considers that the application does not fulfil the requirements of Articles 4 and 5, it shall, within the period of 1 month provided for in paragraph 1, inform the applicant of the date of receipt and explain which requirements have not been fulfilled. It shall at the same time set the applicant a period of 14 days to render the application compliant. That period shall extend the period of 1 month provided for in paragraph 1. Where, at the end of the period set for rendering the application compliant, the rapporteur Member States considers that the application fulfils the requirements of Articles 4 and 5, paragraph 2 shall apply.

Where, at the end of the period set for rendering the application compliant, the rapporteur Member States considers that the application still does not fulfil the requirements of Articles 4 and 5, it shall, stating its reasons, immediately so inform the applicant, the Commission and the Authority.

Upon receiving the communication from the rapporteur Member State, the Commission shall, taking into account the view of the rapporteur Member State, decide whether the application fulfils the requirements of Articles 4 and 5 and inform the rapporteur Member State, the other Member States and the Authority of its decision. The rapporteur Member State shall immediately inform the applicant of that decision.

4 Where for an active substance no application fulfils the requirements of Articles 4 and 5, in accordance with Directive 91/414/EEC, the active substance shall be removed from Annex I to that Directive. Its non-inclusion and the withdrawal of the authorisations of plant-protection products containing that active substance shall be provided for.

5 Where two or more applications for the same active substance have been submitted separately and each is considered to fulfil the requirements of Articles 4 and 5, the rapporteur Member State shall communicate the contact details of each applicant to the other applicants.

6 The Commission shall publish, for each active substance, the names and the addresses of the applicants whose applications are considered to fulfil the requirements of Articles 4 and 5.

#### *Article 7*

##### **Pre-submission contacts**

Where an application fulfils the requirements of Articles 4 and 5, the applicant may request a meeting with the rapporteur Member State and the co-rapporteur Member State to discuss the updating statement. If requested, such pre-submission contacts shall take place prior to the submission of supplementary dossiers, as provided for in Article 9.

#### *Article 8*

##### **Access to the application**

Upon request from any interested party, the rapporteur Member State shall make available the application, excluding any information for which confidential treatment has been requested and is justified pursuant to Article 14 of Directive 91/414/EEC.

---

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

## Article 9

### Submission of supplementary dossiers

1 Where the rapporteur Member State has informed the applicant in accordance with Article 6(2) that its application fulfils the requirements of Articles 4 and 5, the applicant shall submit to the rapporteur Member State and the co-rapporteur Member State a supplementary summary dossier and a supplementary complete dossier, hereinafter ‘the supplementary dossiers’. The supplementary dossiers shall be added to the dossiers submitted for the first inclusion, with their subsequent updates, hereinafter ‘the original dossiers’.

2 The contents of the supplementary dossiers shall comply with Article 10.

3 The supplementary dossiers shall be submitted by the date set out for the respective active substance in column D of Annex I.

4 At the request of the Authority or a Member State, the applicant shall make available the original dossiers where it has access to them.

5 Where there is more than one applicant requesting renewal of the same active substance, those applicants shall take all reasonable steps to submit their dossiers jointly. Where dossiers are not submitted jointly by all applicants concerned, the reasons shall be set out in the dossiers. For each study involving vertebrate animals, the applicants concerned shall detail the attempts made to avoid duplication of testing and justify, if applicable, the need for conducting a duplicate study.

## Article 10

### Contents of supplementary dossiers

- 1 The supplementary summary dossier shall include the following:
- a a copy of the application, where the applicant is joined by another applicant the name and address of that applicant and of the joint representative, provided for in Article 4(4), where the applicant is replaced by another applicant the name and address of that applicant;
  - b information with respect to one or more representative uses on a widely grown crop of at least one plant protection product containing the active substance, demonstrating that the inclusion requirements provided for in Article 5(1) and (2) of Directive 91/414/EEC are fulfilled; where the information submitted does not concern a widely grown crop, a justification shall be submitted;
  - c data and risk assessments which were not part of the original dossiers and which are necessary to reflect changes:
    - (i) in requirements under Annexes II and III to Directive 91/414/EEC;
    - (ii) in scientific and technical knowledge since the first inclusion of the active substance concerned; or
    - (iii) to representative uses;
  - d for each point of the requirements for the active substance, as set out in Annex II to Directive 91/414/EEC, for which new data are necessary within the meaning of point (c), the summaries and results of tests and studies, the name of their owner and of the

---

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

- person or institute having carried these out and the reason why each test or study is necessary either in the light of current scientific and technical knowledge or with a view to an amended renewal;
- e for each point of the requirements for the plant protection product, as set out in Annex III to Directive 91/414/EEC, for which new data are necessary within the meaning of point (c), the summaries and results of tests and studies, the name of their owner and of the person or institute having carried out the tests and studies, for one or more plant protection products which are representative of the supported uses, and the reason why each test or study is necessary either in the light of current scientific and technical knowledge or with a view to an amended renewal of the active substance;
  - f for each test or study involving vertebrate animals, a description of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;
  - g where relevant, a copy of an application for maximum residue levels as referred to in Article 7 of Regulation (EC) No 396/2005 of the European Parliament and of the Council<sup>(3)</sup>;
  - h an assessment of all information submitted;
  - i a checklist demonstrating that the supplementary dossiers referred to in paragraph 3 are complete, indicating which data are new.
- 2 The uses referred to in point (b) of paragraph 1 shall, where appropriate, include the uses evaluated for the first inclusion. At least one plant protection product referred to in that point (b) shall contain no other active substance, where such a product exists for a representative use.
- 3 The complete supplementary dossiers shall contain the full text of each test and study report referred to in points (d) and (e) of paragraph 1.

## *Article 11*

### **Checking of supplementary dossiers**

- 1 Within 1 month of receipt of the supplementary dossiers, the rapporteur Member State shall check whether the supplementary dossiers have been submitted by the date set in column D of Annex I for the respective active substance and whether they contain all the elements provided for in Article 10(1) and 10(3), using the checklist referred to in Article 10(1)(i).
- 2 Where the supplementary dossiers have been submitted by the applicable date and contain all the elements provided for in Article 10(1) and 10(3), the rapporteur Member State shall, within the period provided for in paragraph 1, inform the applicant, the Commission and the Authority of the date of receipt and that the dossiers are considered to be complete.
- The rapporteur Member State shall then start assessing the active substance.
- 3 Where the supplementary dossiers have not been submitted by the applicable date or do not contain all the elements provided for in Article 10(1) and 10(3), the rapporteur Member State shall, within the period provided for in paragraph 1, inform the applicant of the date of receipt and explain which elements are missing. It shall at the same time set the applicant a period of 14 days to render the dossier compliant. That period shall extend the period of 1 month provided for in paragraph 1.

Where, at the end of the period set for rendering the supplementary dossiers compliant, the dossiers contain all the elements provided for in Article 10(1) and 10(3), paragraph 2 shall apply.

---

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

Where, at the end of the period set for rendering the supplementary dossiers compliant, the dossiers still do not contain all the elements provided for in Article 10(1) and 10(3), the rapporteur Member State shall immediately inform the applicant, the Commission and the Authority that the application is rejected, explaining the reasons for its decision.

4 Where for an active substance no supplementary dossiers that fulfil the requirements of Article 10(1) and 10(3) have been submitted by the applicable date, in accordance with Directive 91/414/EEC, the active substance shall be removed from Annex I to that Directive. Its non-inclusion and the withdrawal of the authorisations of plant-protection products containing that active substance shall be provided for.

### *Article 12*

#### **Withdrawal and replacement of the applicant**

1 An applicant may withdraw its application by informing the rapporteur Member State. In that case the applicant shall at the same time inform the co-rapporteur Member State, the Commission, the Authority and any other applicants having submitted an application for the same active substance of the withdrawal.

2 An applicant may be replaced by another producer in respect of all of its rights and obligations under this Regulation by informing the rapporteur Member State, through a joint declaration by the applicant and the other producer. In that case the applicant and the other producer shall at the same time inform the co-rapporteur Member State, the Commission, the Authority and any other applicants having submitted an application for the same active substance of the replacement.

3 Where an applicant withdraws its application and where no other application has been submitted for the same active substance fulfilling the requirements of Articles 4, 5, 9 and 10, the active substance shall be removed from Annex I to Directive 91/414/EEC. Its non-inclusion and the withdrawal of the authorisations of plant-protection products containing that active substance shall be provided for.

4 Paragraph 3 shall not apply where several applicants have jointly submitted their dossiers and not all of these applicants have withdrawn their application. In such a case the procedure for the renewal of the inclusion of the active substance shall continue on the basis of the submitted dossiers.

### *Article 13*

#### **Submission of information by third parties**

Any person or Member State wishing to submit information which might contribute to the assessment, in particular with regard to the potentially dangerous effects of the active substance or its residues on human and animal health and on the environment, shall do so to the rapporteur Member State by the date set out for the respective active substance in column D of Annex I.

The rapporteur Member State shall, without delay, communicate any information received to the co-rapporteur Member State, the Authority, and the applicant. The applicant may send its comments on the submitted information to the rapporteur Member State and the other parties concerned at the latest by 2 months after receipt.



---

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

---

## Article 14

### Assessment by the rapporteur Member State and the co-rapporteur Member State

1 Within 11 months of informing the applicant that the supplementary dossiers are considered to be complete in accordance with Article 11(2), the rapporteur Member State shall, after consulting the co-rapporteur Member State, prepare and submit to the Commission, with a copy to the Authority, a report assessing whether the active substance can be expected to continue to meet the requirements for inclusion, as provided for in Article 5(1) and (2) of Directive 91/414/EEC, hereinafter ‘the renewal assessment report’.

The renewal assessment report shall also include the following:

- a a recommendation with regard to the renewal of the inclusion;
- b where relevant, a suggestion for maximum residue levels to be set;
- c a conclusion on which of the new studies included in the supplementary dossiers are relevant for the assessment;
- d a recommendation as to the parts of the report on which a consultation of experts is to be organised in accordance with Article 16(2);
- e the points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur Member State, where relevant.

2 For the assessment, the rapporteur Member State shall take into account the supplementary dossiers, any information submitted by a third party, comments on such information received from the applicant and, where appropriate, the original dossiers.

3 Where the rapporteur Member State needs additional information, it shall set a period for the applicant to supply that information. That period shall not lead to an extension of the period of 11 months provided for in paragraph 1.

4 The rapporteur Member State may consult the Authority and request additional technical or scientific information from other Member States. Such consultations and requests shall not lead to an extension of the period of 11 months provided for in paragraph 1.

5 Information submitted by the applicant without having been requested, or after expiry of the period set for its submission in accordance with the first subparagraph of paragraph 3, shall not be taken into account, unless submitted in accordance with Article 7 of Directive 91/414/EEC.

6 When submitting the renewal assessment report to the Commission, the rapporteur Member State shall request the applicant to submit the supplementary summary dossier, updated to include the additional information requested by the rapporteur Member State in accordance with paragraph 3 or submitted in accordance with Article 7 of Directive 91/414/EEC, to the Authority, the other Member States and, on request, to the Commission.

[<sup>F1</sup>In addition, the rapporteur Member State shall request the applicant to submit the supplementary complete dossier to the Authority, to the other Member States and, on request, to the Commission.]

---

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

#### Textual Amendments

- F1** Inserted by [Commission Implementing Regulation \(EU\) No 380/2013 of 25 April 2013 amending Regulation \(EU\) No 1141/2010 as regards the submission of the supplementary complete dossier to the Authority, the other Member States and the Commission.](#)

#### Article 15

##### **Comments upon the renewal assessment report and access to that report and to the supplementary summary dossiers**

- 1 After receiving the renewal assessment report, the Authority shall immediately communicate it for comments to the applicant and to the Member States. Such comments shall be communicated to the Authority within 2 months, which shall collate and forward those comments, including its own, to the Commission.
- 2 Upon request from any interested party, the Authority shall make the renewal assessment report available, excluding any information for which confidential treatment has been requested and is justified pursuant to Article 14 of Directive 91/414/EEC.
- 3 The Authority shall make the supplementary summary dossier available to the public, with the exception of parts of it for which confidential treatment has been requested and is justified pursuant to Article 14 of Directive 91/414/EEC.

#### Article 16

##### **Evaluation of the renewal assessment report**

- 1 The Commission shall, without delay, examine the renewal assessment report and the comments received in accordance with Article 15(1).
- 2 The Commission may consult the Authority asking it for a conclusion on the entire risk assessment or on specific points thereof. Such consultation may include a request to organise a consultation of experts. The Authority shall use the guidance documents available at the time of the entry into force of this Regulation.

The Authority shall deliver its conclusion at the latest 6 months after receipt of the request.

Where paragraph 3 applies, that period shall be extended by the periods referred to in the first and the second subparagraph of that paragraph.

- 3 Where the Authority considers that additional information or data from the applicant is necessary to comply with a request made by the Commission pursuant to paragraph 2, it shall in consultation with the rapporteur Member State, set a period of maximum 1 month for the applicant to supply it. It shall at the same time inform the Commission and the Member States. The applicant shall communicate the requested information to the Authority, the rapporteur Member State and the co-rapporteur Member State.

The rapporteur Member State shall, within 2 months of receipt, evaluate the information received and send its evaluation to the Authority.

---

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

4 Information submitted by the applicant without having been requested, or after expiry of the period set for its submission in accordance with the first subparagraph of paragraph 3, shall not be taken into account, unless submitted in accordance with Article 7 of Directive 91/414/EEC.

#### *Article 17*

##### **Review report and presentation of draft acts**

1 The Commission shall draft a review report, hereinafter ‘the review report’, taking into account the renewal assessment report by the rapporteur Member State, the comments referred to in Article 15(1) and, where applicable, the conclusion of the Authority.

The applicant shall be given the possibility to submit comments on the draft review report within a period set by the Commission.

The Commission shall present to the Committee referred to in Article 19(1) of Directive 91/414/EEC the draft review report within 6 months of receipt of the comments referred to in Article 15(1) or, where the Commission has consulted it in accordance with Article 16(2), of receipt of the conclusion of the Authority.

2 On the basis of the review report and taking into account any comments submitted by the applicant within the period set by the Commission pursuant to the second subparagraph of paragraph 1, the Commission shall submit to the Committee:

- a a draft act renewing the inclusion of the active substance concerned in Annex I to Directive 91/414/EEC, setting out, where appropriate, the conditions and restrictions, including the period for such inclusion; or
- b a draft act removing the active substance from Annex I to Directive 91/414/EEC and providing for its non-inclusion and the withdrawal of the authorisations of plant-protection products containing that active substance.

3 The draft acts referred to in paragraph 2 shall be adopted in accordance with the procedure referred to in Article 19(2) of Directive 91/414/EEC.

#### *Article 18*

##### **Access to review report**

The Commission shall make the review report available to the public, with the exception of parts of it for which confidential treatment has been requested and is justified pursuant to Article 14 of Directive 91/414/EEC.

#### *Article 19*

##### **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

---

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

- 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 20*

#### **Other charges, levies or fees**

Article 19 is without prejudice to Member States' rights to maintain or introduce, in accordance with the Treaty, charges, levies or fees with regard to the authorisation, placing on the market, use and control of active substances and plant protection products other than the fee provided for in Article 19.

#### *Article 21*

#### **Entry into force**

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

## ANNEX I

### LIST OF ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 1 AND THEIR RAPPORTEUR MEMBER STATES (RMS), CO-RAPPORTEUR MEMBER STATES (CO-RMS) AND OF THE FINAL DATES FOR SUBMISSION OF DOSSIERS

<b>Column A</b>		<b>Column B</b>	<b>Column C</b>	<b>Column D</b>
<b>Substance</b>		<b>New RMS</b>	<b>Co-RMS</b>	<b>Deadline for submission of dossier</b>
2,4-D	2012	EL	PL	29 February 2012
Amitrole	2011	FR	HU	29 February 2012
Esfenvalerate	2011	UK	PT	29 February 2012
Flumioxazine	2012	CZ	FR	29 February 2012
Lambda-Cyhalothrin	2011	SE	ES	29 February 2012
Acibenzolar-s-methyl	2011	FR	ES	29 February 2012
Bentazone	2011	NL	DE	29 February 2012
Cyclanilide	2011	AT	EL	29 February 2012
Fenhexamid	2011	UK	IT	29 February 2012
Ferric phosphate	2011	DE	PL	29 February 2012
Pymetrozine	2011	DE	BE	29 February 2012
Flupyr-sulfuron-methyl	2011	FR	DK	31 May 2012
Diquat	2011	UK	SE	31 May 2012
Glyphosate	2012	DE	SK	31 May 2012
Iprovalicarb	2012	IE	IT	31 May 2012
Paecilomyces fumosoroseus	2011	BE	NL	31 May 2012
Thiabendazole	2011	ES	NL	31 May 2012
Pyridate	2011	AT	LV	31 May 2012
Sulfosulfuron	2012	SE	IE	31 May 2012

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Pyraflufen-ethyl	2011	NL	LT	31 May 2012
Prosulfuron	2012	FR	SK	31 May 2012
Thifensulfuron-methyl	2012	UK	AT	31 August 2012
Cinidon-ethyl	2012	HU	UK	31 August 2012
Cyhalofop butyl	2012	IT	AT	31 August 2012
Florasulam	2012	PL	BE	31 August 2012
Metalaxyl-M	2012	BE	EL	31 August 2012
Picolinafen	2012	DE	LV	31 August 2012
Isoproturon	2012	DE	CZ	31 August 2012
Metsulfuron methyl	2011	SI	SE	31 August 2012
Triasulfuron	2011	FR	DK	31 August 2012
Famoxadone	2012	UK	FI	31 August 2012

## ANNEX II

### Format for application, as provided for in Article 5(1)

The application shall be in writing, signed by the applicant, and sent by registered mail to the rapporteur Member State listed in column B of Annex I and to the co-rapporteur Member State listed in column C of Annex I.

A copy of the application without the updating statement shall be sent to the European Commission, DG Health and Consumers, unit E3, 1049 Brussels, Belgium and to the Authority, European Food Safety Authority, Largo N. Palli 5/A, 43121 Parma, Italy.

The application shall be submitted in accordance with the following model.

#### MODEL

1. *Information concerning the applicant*
  - 1.1. Name and address of the applicant including the name of the natural person responsible for the application and further engagements resulting from this Regulation:
    - 1.2.1.
      - (a) Telephone No:
      - (b) Fax No:
      - (c) E-mail address:
    - 1.2.2.
      - (a) Contact:
      - (b) Alternative:
2. *Information to facilitate identification*

---

**Changes to legislation:** *There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

---

- 2.1. Common name (proposed or ISO-accepted) specifying, where relevant, any variants thereof such as salts, esters or amines produced by the manufacturer.
- 2.2. Chemical name (IUPAC and CAS nomenclature).
- 2.3. CAS, CIPAC and EEC numbers (if available).
- 2.4. Empirical and structural formula, molecular mass.
- 2.5. Specification of purity of the active substance in g/kg which should be whenever possible identical or already accepted as equivalent to the one included in Annex I to Directive 91/414/EEC.
- 2.6. Classification and labelling of the active substance in accordance with the provisions of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures<sup>(4)</sup> (health and environment effects).

An updating statement, as provided for in Article 5(2), shall be attached as an Annex to the application.

The applicant confirms that the above information submitted on ... (date) is correct.

Signature (of the person competent to act for the applicant referred to under 1.1)

---

**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

- (1) [OJ L 230, 19.8.1991, p. 1.](#)
- (2) [OJ L 309, 24.11.2009, p. 1.](#)
- (3) [OJ L 70, 16.3.2005, p. 1.](#)
- (4) [OJ L 353, 31.12.2008, p. 1.](#)



**Changes to legislation:**

There are outstanding changes not yet made to Commission Regulation (EU) No 1141/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

[View outstanding changes](#)

**Changes and effects yet to be applied to :**

- Annex 1 omitted by [S.I. 2019/556 reg. 15\(7\)](#)
- Annex 1 Text replacement by [EUR 2019/336 Regulation](#)
- Annex 2 omitted by [S.I. 2019/556 reg. 15\(7\)](#)
- Art. 1 substituted by [S.I. 2019/556 reg. 15\(2\)](#)
- Art. 3-21 omitted by [S.I. 2019/556 reg. 15\(5\)](#)

**Changes and effects yet to be applied to the whole legislation item and associated provisions**

- Signature words omitted by [S.I. 2019/556 reg. 15\(6\)](#)
- Art. 1(2)(a) words substituted in earlier amending provision [S.I. 2019/556, reg. 15\(2\)](#) by [S.I. 2020/1376 reg. 3\(12\)\(a\)](#)
- Art. 1(3) words substituted in earlier amending provision [S.I. 2019/556, reg. 15\(2\)](#) by [S.I. 2020/1376 reg. 3\(12\)\(a\)](#)
- Art. 1(4)(a) words substituted in earlier amending provision [S.I. 2019/556, reg. 15\(2\)](#) by [S.I. 2020/1376 reg. 3\(12\)\(a\)](#)
- Art. 2(b) substituted by [S.I. 2019/556 reg. 15\(3\)\(a\)](#)
- Art. 2(c)-(f) omitted by [S.I. 2019/556 reg. 15\(3\)\(b\)](#)
- Art. 2(g)-(i) inserted by [S.I. 2019/556 reg. 15\(3\)\(c\)](#) (This S.I. is amended by [S.I. 2019/559, reg. 7](#))
- Art. 2A inserted by [S.I. 2019/556 reg. 15\(4\)](#)
- Art. 2A(6) words substituted in earlier amending provision [S.I. 2019/556, reg. 15\(4\)](#) by [S.I. 2020/1376 reg. 3\(12\)\(b\)](#)