COMMISSION IMPLEMENTING REGULATION (EU) No 810/2011
of 11 August 2011

approving the active substance kresoxim-methyl, in accordance with Regulation (EC) No 1107/2009
of the European Parliament and of the Council concerning the placing of plant protection products
on the market, and amending the Annex to Commission Implementing Regulation (EU) No
540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the
concerning the placing of plant protection products on the
market and repealing Council Directives 79/117/EEC and
91/414/EEC (1), and in particular Articles 13(2) and 78(2)
thereof,

Whereas:

(1) In accordance with Article 80(1)(b) of Regulation (EC) No
1107/2009, Council Directive 91/414/EEC (2) is to apply
to active substances listed in Annex I to Commission
Regulation (EC) No 737/2007 of 27 June 2007 on
laying down the procedure of the renewal of the
inclusion of a first group of active substances in Annex
list of those substances (3), with respect to the procedure
and the conditions for approval. Kresoxim-methyl is

(2) The approval of kresoxim-methyl, as set out in Part A of
the Annex to Commission Implementing Regulation (EU)
No 540/2011 of 25 May 2011 implementing Regulation
(EC) No 1107/2009 of the European Parliament and of
the Council as regards the list of approved active
substances (4), expires on 31 December 2011. A notifi-
cation was submitted in accordance with Article 4 of
Regulation (EC) No 737/2007 for the renewal of the
inclusion of kresoxim-methyl in Annex I to Directive
91/414/EEC within the time period provided for in that Article.

(3) That notification was found to be admissible by
on the admissibility of the notifications concerning the
91/414/EEC of the active substances azimsulfuron,
a zoxytrobin, fluroxypyr, imazalil, kresoxim-methyl,
prohexadione and spiroxamine, and establishing the list
of the notifiers concerned (5).

(4) Within the time period provided for in Article 6 of
Regulation (EC) No 737/2007, the notifier submitted
the data required in accordance with that Article
together with an explanation as regards the relevance
of each new study submitted.

(5) The rapporteur Member State prepared an assessment
report in consultation with the co-rapporteur Member
State and submitted it to the European Food Safety
Authority (hereinafter ‘the Authority’) and the
Commission. In addition to the assessment of the
active substance, that report includes a list of the
studies the rapporteur Member State relied on for its
assessment.

(6) The Authority communicated the assessment report to
the notifier and to the Member States for comments
and forwarded the comments received to the
Commission. The Authority also made the assessment
report available to the public.

(7) At the request of the Commission, the assessment report
was peer reviewed by the Member States and the
Authority. The Authority presented its conclusion on
the peer review of the risk assessment of kresoxim-
methyl (6) to the Commission. The assessment report
and the conclusion of the Authority were reviewed by
the Member States and the Commission within the
Standing Committee on the Food Chain and Animal
Health and finalised on 17 June 2011 in the format of
the Commission review report for kresoxim-methyl.

(8) It has appeared from the various examinations made that
plant protection products containing kresoxim-methyl
may be expected to continue to satisfy, in general, the
requirements laid down in Article 5(1)(a) and (b) of
Directive 91/414/EEC, in particular as regards the uses
which were examined and detailed in the Commission
review report. It is therefore appropriate to approve
kresoxim-methyl.

(9) In accordance with Article 13(2) of Regulation (EC) No
1107/2009 in conjunction with Article 6 thereof and in
the light of current scientific and technical knowledge, it
is, however, necessary to include certain conditions and
restrictions not provided for in the first inclusion in
Annex I to Directive 91/414/EEC.

(6) European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance kresoxim-methyl. EFSA Journal 2010;8(11):1891. [88 pp.]. doi:10.2903/j.efsajournal. 0
Without prejudice to the conclusion that kresoxim-methyl should be approved, it is, in particular, appropriate to require further confirmatory information.

A reasonable period should be allowed to elapse before approval in order to permit Member States and interested parties to prepare themselves to meet the new requirements resulting from the approval.

Without prejudice to the obligations provided for by Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of 6 months after approval to review authorisations of plant protection products containing kresoxim-methyl. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the update of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.

The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (1) has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.

In accordance with Article 13(4) of Regulation (EC) No 1107/2009 the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

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:

Article 1

Approval of active substance

The active substance kresoxim-methyl, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing kresoxim-methyl as an active substance by 30 June 2012.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in Part B of the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing kresoxim-methyl as either the only active substance or as one of several active substances all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 31 December 2011 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account Part B of the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

(a) in the case of a product containing kresoxim-methyl as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2015 at the latest; or

(b) in the case of a product containing kresoxim-methyl as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 2015 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or substances, whichever is the latest.
Article 3

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 4

Entry into force and application

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

It shall apply from 1 January 2012.

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

Done at Brussels, 11 August 2011.

For the Commission

The President

José Manuel BARROSO
## ANNEX I

Conditions of approval as active substance under Regulation (EC) No 1107/2009:

<table>
<thead>
<tr>
<th>Common Name, Identification Numbers</th>
<th>IUPAC Name</th>
<th>Purity (1)</th>
<th>Date of approval</th>
<th>Expiration of approval</th>
<th>Specific provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kresoxim-methyl, CAS No 143 390-89-0, CIPAC No 568</td>
<td>methyl (E)-methoxyimino [(a-(o-tolyloxy)-o-tolyl)acetate]</td>
<td>≥ 910 g/kg, Methanol: max. 5 g/kg, Methyl chloride: max. 1 g/kg, Toluene: max. 1 g/kg</td>
<td>1 January 2012</td>
<td>31 December 2021</td>
<td>PART A: Only uses as fungicide may be authorised. PART B: For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on kresoxim-methyl and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011, shall be taken into account. Member States shall pay particular attention to the protection of groundwater under vulnerable conditions; the conditions of authorisation shall include, where appropriate, risk mitigation measures. The applicant shall submit confirmatory information as regards: Groundwater exposure risk assessment, and in particular: — on the lysimeter study to support the statement that the two unidentified peaks observed do not correspond to metabolites individually exceeding the trigger value of 0.1 μg/L, — on the recovery of metabolite BF 490-5 in order to confirm its absence in the lysimeter leachate at levels exceeding 0.1 μg/L, — on a groundwater exposure risk assessment for the late application in apples, pears and grapes. The applicant shall submit to the Member States, the Commission and the Authority such information by 31 December 2013.</td>
</tr>
</tbody>
</table>

(1) Further details on identity and specification of active substance are provided in the review report.
The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, the entry relating to kresoxim-methyl is deleted;

(2) in Part B, the following entry is added:

<table>
<thead>
<tr>
<th>No</th>
<th>Common Name, Identification Numbers</th>
<th>IUPAC Name</th>
<th>Purity (*)</th>
<th>Date of approval</th>
<th>Expiration of approval</th>
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| 8  | Kresoxim-methyl CAS No 143 390-89-0 CIPAC No 568 | methyl (E)-methoxyimino [a-(o-tolyloxy)-o-tolyl]acetate | ≥ 910 g/kg Methanol: max. 5 g/kg Methyl chloride: max. 1 g/kg Toluene: max. 1 g/kg | 1 January 2012 | 31 December 2021 | PART A

Only uses as fungicide may be authorised.

PART B

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on kresoxim-methyl and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011, shall be taken into account.

Member States shall pay particular attention to the protection of groundwater under vulnerable conditions; the conditions of authorisation shall include, where appropriate, risk mitigation measures.

The applicant shall submit confirmatory information as regards:

Groundwater exposure risk assessment, and in particular:

— on the lysimeter study to support the statement that the two unidentified peaks observed do not correspond to metabolites individually exceeding the trigger value of 0.1 μg/L,

— on the recovery of metabolite BF 490-5 in order to confirm its absence in the lysimeter leachate at levels exceeding 0.1 μg/L,

— on a groundwater exposure risk assessment for the late application in apples, pears and grapes.

The applicant shall submit to the Member States, the Commission and the Authority such information by 31 December 2013.'

(*) Further details on identity and specification of active substance are provided in the review report.