COMMISSION IMPLEMENTING REGULATION (EU) No 1278/2011

of 8 December 2011

approving the active substance bitertanol, 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 and Commission Decision 2008/934/EC

(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 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 [1], and in particular Article 13(2) and Article 78(2) thereof,

Whereas:

(1) In accordance with Article 80(1)(c) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC [2] is to apply to active substances for which completeness has been established in accordance with Article 16 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I [3], with respect to the procedure and the conditions for approval. Bitertanol is an active substance for which completeness has been established in accordance with that Regulation.

(2) Commission Regulations (EC) No 451/2000 [4] and (EC) No 1490/2002 [5] lay down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list included bitertanol.

(3) In accordance with Article 3(2) of Commission Regulation (EC) No 1095/2007 of 20 September 2007 amending Regulation (EC) No 1490/2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and Regulation (EC) No 2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC [6] the notifier withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within two months from entry into force of that Regulation. Consequently, Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances [7] was adopted on the non-inclusion of bitertanol.

(4) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Regulation (EC) No 33/2008.

(5) The application was submitted to the United Kingdom, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/934/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(6) The United Kingdom evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 29 November 2009. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on bitertanol to the Commission on 6 October 2010 [8]. The draft assessment report, the additional 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 11 October 2011 in the format of the Commission review report for bitertanol.

[1] OJ L 309, 24.11.2009, p. 1.
[2] OJ L 230, 19.8.1991, p. 1.
[3] OJ L 15, 18.1.2008, p. 5.
[4] OJ L 55, 29.2.2000, p. 25.
[5] OJ L 224, 21.8.2002, p. 23.
[6] OJ L 246, 21.9.2007, p. 19.
[7] OJ L 333, 11.12.2008, p. 11.
[8] European Food Safety Authority, 'Conclusion on the peer review of the pesticide risk assessment of the active substance bitertanol'. *EFSA Journal* 2010; 8(10):1850. [63 pp.]. doi:10.2903/j.efsa.2010.1850. Available online: www.efsa.europa.eu

(7) It has appeared from the various examinations made that plant protection products containing bitertanol may be expected 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 bitertanol in accordance with Regulation (EC) No 1107/2009.

(8) 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.

(9) Without prejudice to the conclusion that bitertanol should be approved, it is, in particular, appropriate to require further confirmatory information.

(10) Concerns were expressed as regards the hazard profile of the active substance due to the proposed classification for this active substance as 'reproductive toxicant category 1B' in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council [1]. Data and information related to the hazard profile of the active substance will need to be reassessed. Account should also be taken on the progressive understanding of the need to ensure a high level of protection of human health and the sustainable environment. Therefore it is considered appropriate to limit the approval period to three and half years. This period is considered the shortest period possible to allow the applicant to submit an application for renewal under the provisions of Regulation (EC) No 1107/2009.

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

(12) Without prejudice to the obligations defined by Regulation (EC) No 1107/2009 as a consequence of the 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 six months after approval to review authorisations of plant protection products containing bitertanol. Member States should, as appropriate, vary, replace or withdraw existing authorisations. By way of derogation from the above 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. Given the hazardous properties of bitertanol, the period for Member States to verify whether the plant protection products, which contain bitertanol as the only active substance or in combination with other approved active substances, comply with the provisions of Article 29(6) of Regulation (EC) No 1107/2009 should not exceed two and a half years.

(13) 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 [2] 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.

(14) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 the Annex to Commission Implementing Regulation (EU) No 540/2011 [3] should be amended accordingly.

(15) Decision 2008/934/EC provides for the non-inclusion of bitertanol and the withdrawal of authorisations for plants protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning bitertanol in the Annex to that Decision. It is therefore appropriate to amend Decision 2008/934/EC accordingly.

(16) The Standing Committee on the Food Chain and Animal Health did not deliver an opinion. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance bitertanol, 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 bitertanol as an active substance by 30 June 2012.

[1] OJ L 353, 31.12.2008, p. 1.

[2] OJ L 366, 15.12.1992, p. 10.

[3] OJ L 153, 11.6.2011, p. 1.

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 bitertanol as either the only active substance or as one of several active substances, 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, where necessary, amend or withdraw the authorisation by 30 June 2014.

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

Amendments to Decision 2008/934/EC

The line concerning bitertanol in the Annex to Decision 2008/934/EC is deleted.

Article 5

Entry into force and date of 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, 8 December 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Common name, identification numbers	IUPAC name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Bitertanol CAS No: 55179-31-2 CIPAC No: 386	(1*RS*,2*RS*;1*RS*,2*SR*)-1-(biphenyl-4-yloxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol (20:80 ratio of (1*RS*,2*RS*)- and (1*RS*,2*SR*)-isomers)	≥ 970 g/kg (A≥ 80, B≤ 20) *RS* + *SR* 80 – 90 % *RR* + *SS* 10 – 20 %	1 January 2012	30 June 2015	PART A Only uses as fungicide for seed treatment may be authorised. Member States shall ensure that authorisations provide that seed coating be performed exclusively in professional seed treatment facilities and that these facilities apply the best available techniques to exclude the release of dust clouds during storage, transport and application. 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 bitertanol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 October 2011 shall be taken into account. In this overall assessment Member States: (a) shall pay particular attention to the risk to operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate; (b) shall pay particular attention to the dietary exposure of consumers to the residues of triazole derivative metabolites (TDMs); (c) shall pay particular attention to the risk to birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the toxicological relevance of the impurities BUE 1662, thus referred to for confidentiality reasons, and 3-chlorophenoxy compound; (2) the acute and short-term risk to granivorous birds; (3) the long-term risk to granivorous mammals; (4) residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin;

Common name, identification numbers	IUPAC name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
					(5) the possible impact of the variable isomer-ratio in the technical material and of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and the environmental risk assessment. The applicant shall submit to the Commission, the Member States and the Authority the information set out in point (1) by 30 June 2012, the information set out in points (2), (3) and (4) by 31 December 2013 and the information set out in point (5) two years after the adoption of specific guidance.

[1] Further details on identity and specification of active substance are provided in the review report.

ANNEX II

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

Number	Common name, identification numbers	IUPAC name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'21	Bitertanol CAS No: 55179-31-2 CIPAC No: 386	(1*RS*,2*RS*;1*RS*,2*SR*)-1-(biphenyl-4-yloxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol (20:80 ratio of (1*RS*,2*RS*)- and (1*RS*,2*SR*)-isomers)	≥ 970 g/kg (A ≥ 80, B ≤ 20) *RS* + *SR* 80 – 90 % *RR* + *SS* 10 – 20 %	1 January 2012	30 June 2015	PART A Only uses as fungicide for seed treatment may be authorised. Member States shall ensure that authorisations provide that seed coating be performed exclusively in professional seed treatment facilities and that these facilities apply the best available techniques to exclude the release of dust clouds during storage, transport and application. 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 bitertanol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 October 2011 shall be taken into account. In this overall assessment Member States: (a) shall pay particular attention to the risk to operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate; (b) shall pay particular attention to the dietary exposure of consumers to the residues of triazole derivative metabolites (TDMs); (c) shall pay particular attention to the risk to birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the toxicological relevance of the impurities BUE 1662, thus referred to for confidentiality reasons, and 3-chlorophenoxy compound; (2) the acute and short-term risk to granivorous birds; (3) the long-term risk to granivorous mammals; (4) residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin;

Number	Common name, identification numbers	IUPAC name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
						(5) the possible impact of the variable isomer-ratio in the technical material and of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and the environmental risk assessment. The applicant shall submit to the Commission, the Member States and the Authority the information set out in point (1) by 30 June 2012, the information set out in points (2), (3) and (4) by 31 December 2013 and the information set out in point (5) two years after the adoption of specific guidance.'

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