DIRECTIVES

COMMISSION DIRECTIVE 2009/11/EC

of 18 February 2009

amending Council Directive 91/414/EEC to include bensulfuron, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad as active substances

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Whereas:

(1) Commission Regulations (EC) No 451/2000 ([2]) and (EC) No 1490/2002 ([3]) lay down the detailed rules for the implementation of the third stage 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 includes bensulfuron, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad.

(2) For those active substances the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 451/2000 and (EC) No 1490/2002 for a range of uses proposed by the notifiers. Moreover, those Regulations designate the rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 10(1) of Regulation (EC) No 1490/2002. For bensulfuron the rapporteur Member State was Italy and all relevant information was submitted on 11 September 2006. For sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate the rapporteur Member State was Greece and all relevant information was submitted on 7 December 2005. For tebufenpyrad the rapporteur Member State was Germany and all relevant information was submitted on 12 March 2007.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 26 September 2008 for bensulfuron, on 30 September 2008 for sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate and on 23 October 2008 for tebufenpyrad in the format of the EFSA Scientific Reports ([4]). These reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 2 December 2008 in the format of the Commission review reports for sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad and on 8 December 2008 in the format of the Commission review reports for bensulfuron.

(4) It has appeared from the various examinations made that plant protection products containing bensulfuron, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad 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 with regard to the uses which were examined and detailed in the Commission review reports. It is therefore appropriate to include these active substances in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances can be granted in accordance with the provisions of that Directive.

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 55, 29.2.2000, p. 25.
([3]) OJ L 224, 21.8.2002, p. 23.

([4]) *EFSA Scientific Report (2008) 178, Conclusion regarding the peer review of the pesticide risk assessment of the active substance bensulfuron (finalised 26 September 2008).*
EFSA Scientific Report (2008) 191, Conclusion regarding the peer review of the pesticide risk assessment of the active substance sodium (5-nitroguaiacolate, o-nitrophenolate, p-nitrophenolate) (finalised 30 September 2008).
EFSA Scientific Report (2008) 192, Conclusion regarding the peer review of the pesticide risk assessment of the active substance tebufenpyrad (finalised 23 October 2008).

(5) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore, the notifier should be required to submit further information on the chemical specification, information to further address the route and rate of degradation of bensulfuron under aerobic flooded soil conditions and information to address the relevance of metabolites for the consumer risk assessment. Furthermore, it is appropriate to require that sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate should be subjected to further testing for confirmation of the risk assessment for groundwater and such studies should be presented by the notifier. Finally, it is appropriate as regards tebufenpyrad, to require the notifier to submit information confirming that no relevant impurities are present and addressing further the risk to insectivorous birds.

(6) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(7) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing authorisations of plant protection products containing bensulfuron, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations, in accordance with the provisions of Directive 91/414/EEC. By way of derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.

(8) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 [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.

(9) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(10) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 30 April 2010 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 May 2010.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing bensulfuron, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad as active substances by 30 April 2010.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to bensulfuron, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13 of that Directive.

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

2. By way of derogation from paragraph 1, for each authorised plant protection product containing bensulfuron, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 October 2009 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning bensulfuron, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad respectively. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

(a) in the case of a product containing bensulfuron, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad as the only active substance, where necessary, amend or withdraw the authorisation by 30 April 2014 at the latest; or

(b) in the case of a product containing bensulfuron, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad as one of several active substances, where necessary, amend or withdraw the authorisation by 30 April 2014 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 4

This Directive shall enter into force on 1 November 2009.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 18 February 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'276	Bensulfuron CAS No 83055-99-6 CIPAC No 502.201	*α-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-o-toluic acid (bensulfuron)* *methyl α-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-o-toluate (bensulfuron-methyl)*	≥ 975 g/kg	1 November 2009	31 October 2019	PART A Only uses as a herbicide PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on bensulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to the following: — the protection of aquatic organisms; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of the groundwater, where the active substance is applied in regions with vulnerable soil and/or climatic conditions. The Member States concerned shall ensure that the notifier submits to the Commission: — further studies on the specification, — information to further address the route and rate of degradation of bensulfuron-methyl under aerobic flooded soil conditions, — information to address the relevance of metabolites for the consumer risk assessment. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
277	Sodium 5-nitroguaiacolate CAS No 67233-85-6 CIPAC number not allocated	*Sodium 2-methoxy-5-nitrophenolate*	≥ 980 g/kg	1 November 2009	31 October 2019	PART A Only use as plant growth regulator may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the protection of the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further studies to address the risk to groundwater. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
278	Sodium o-nitrophenolate CAS No 824-39-5 CIPAC number not allocated	*Sodium 2-nitrophenolate; sodium o-nitrophenolate*	≥ 980 g/kg *The following impurities are of toxicological concern:* *Phenol* *Max content: 0,1 g/kg* *2,4 dinitrophenol* *max content: 0,14 g/kg* *2,6 dinitrophenol* *max content: 0,32 g/kg*	1 November 2009	31 October 2019	PART A Only use as plant growth regulator may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the protection of the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further studies to address the risk to groundwater. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
279	Sodium p-nitrophenolate CAS No 824-78-2 CIPAC number not allocated	*Sodium 4-nitrophenolate; sodium p-nitrophenolate*	≥ 998 g/kg *The following impurities are of toxicological concern:* *Phenol* *max content: 0,1 g/kg* *2,4 dinitrophenol* *max content: 0,07 g/kg* *2,6 dinitrophenol* *max content: 0,09 g/kg*	1 November 2009	31 October 2019	PART A Only use as plant growth regulator may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the protection of the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further studies to address the risk to groundwater. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
280	Tebufenpyrad CAS No 119168-77-3 CIPAC No 725	*N-(4-tert-butylbenzyl)-4-chloro-3-ethyl-1-methylpyrazole-5-carboxamide*	≥ 980 g/kg	1 November 2009	31 October 2019	PART A Only uses as acaricide and insecticide may be authorised. PART B In assessing applications to authorise plant protection products containing tebufenpyrad in formulations other than water soluble bags Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on tebufenpyrad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms and must ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate, — the protection of insectivorous birds and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. The Member States concerned shall ensure that the notifier submits to the Commission: — further information confirming that no relevant impurities are present, — information to further address the risk to insectivorous birds. They shall ensure that the notifier provides such information to the Commission by 31 October 2011.'

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