DIRECTIVES

COMMISSION DIRECTIVE 2009/37/EC

of 23 April 2009

amending Council Directive 91/414/EEC to include chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin 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 chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin.

(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 chlormequat and teflubenzuron the rapporteur Member State was the United Kingdom and all relevant information was submitted on 27 April 2007 and 6 August 2007 respectively. For copper compounds the rapporteur Member State was France and all relevant information was submitted on 7 June 2007. For propaquizafop the rapporteur Member State was Italy and all relevant information was submitted on 22 September 2005. For quizalofop-P the rapporteur Member State was Finland and all relevant information was submitted on 1 February 2007 (variant quizalofop-P-ethyl) and 2 May 2007 (variant quizalofop-P-tefuryl). For zeta-cypermethrin the rapporteur Member State was Belgium and all relevant information was submitted on 10 July 2006.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 29 September 2008 for chlormequat and teflubenzuron, on 30 September 2008 for copper compounds and zeta-cypermethrin and on 26 November 2008 for propaquizafop and quizalofop-P 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 23 January 2009 in the format of the Commission review reports for chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin.

(4) It has appeared from the various examinations made that plant protection products containing chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in

[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) 179, Conclusion regarding the peer review of the pesticide risk assessment of the active substance chlormequat (finalised 29 September 2008).
EFSA Scientific Report (2008) 187, Conclusion regarding the peer review of the pesticide risk assessment of the active substance copper compounds (finalised 30 September 2008).
EFSA Scientific Report (2008) 204, Conclusion regarding the peer review of the pesticide risk assessment of the active substance propaquizafop (finalised 26 November 2008).
EFSA Scientific Report (2008) 205, Conclusion regarding the peer review of the pesticide risk assessment of the active substance quizalofop-P (finalised 26 November 2008).
EFSA Scientific Report (2008) 184, Conclusion regarding the peer review of the pesticide risk assessment of the active substance teflubenzuron (finalised 29 September 2008).
EFSA Scientific Report (2008) 196, Conclusion regarding the peer review of the pesticide risk assessment of the active substance zeta-cypermethrin (finalised 30 September 2008).

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.

(5) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore, for chlormequat the notifier should be required to submit further information on the fate and behaviour (adsorption studies to be performed at 20 °C, recalculation of the predicted concentrations in groundwater, surface water and sediment), the monitoring methods for determination of the substance in animal products and water, and the risk to aquatic organisms, birds and mammals. Furthermore for copper compounds, the notifier should be required to submit further information on the risk from inhalation and on the risk assessment for non-target organisms, soil and water. Moreover, it is appropriate as regards propaquizafop, to require that the notifier submit information on the relevant impurity Ro 41-5259 and on the risk to aquatic organisms and to non-target arthropods. In addition, it is appropriate as regards quizalofop-P, to require that the notifier submit further information on the risk to non-target arthropods. Finally, it is appropriate for the zeta-cypermethrin to require that the notifier submit further information as regards the fate and behaviour (aerobic degradation in soil), the risk to birds (long-term risk), aquatic organisms and non-target arthropods.

(6) Moreover, with regard to copper compounds, copper occurs in nature and is an essential micronutrient. Copper accumulates in soil and the level of copper in soil can be affected not only by applications of plant protection products but also from animal husbandry and from the application of manure. Therefore, it is necessary that Member States initiate monitoring programmes in vulnerable areas, where the contamination of the soil compartment by copper is of concern, in order to set, where appropriate, limitations such as maximum application rates.

(7) Articles 5(4) and 6(1) of Directive 91/414/EEC provide that inclusion of a substance into Annex I may be subject to restrictions. In the case of copper compounds, the risk assessment revealed eco-toxicological concerns, a restriction on the inclusion period is deemed necessary to allow Member States to review after a shorter period plant protection products already on the market containing copper. Moreover, copper compounds are currently subject to evaluation in the framework of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [1], as well as to evaluation in the framework of Regulation (EC) No 1907/2006 of the European Parliament and of the Council [2] concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). As with all substances included in Annex I to Directive 91/414/EEC, the status of copper compounds could be reviewed under Article 5(5) of that Directive in the light of any new data becoming available.

(8) 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.

(9) 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 chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin 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.

(10) 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 [3] 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.

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

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3.
[3] OJ L 366, 15.12.1992, p. 10.

(12) 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 31 May 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 June 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 chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin as active substances by 31 May 2010.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin 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.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron, zeta-cypermethrin 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 30 November 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 chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin 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 chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin as the only active substance, where necessary, amend or withdraw the authorisation by 31 May 2014 at the latest; or

(b) in the case of a product containing chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin as one of several active substances, where necessary, amend or withdraw the authorisation by 31 May 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 December 2009.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 23 April 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
'281	Chlormequat CAS No 7003-89-6 (chlormequat) CAS No 999-81-5 (chlormequat chloride) CIPAC No 143 (chlormequat) CIPAC No 143.302 (chlormequat chloride)	*2-chloroethyltrimethyl-ammonium (chlormequat)* *2-chloroethyltrimethyl-ammonium chloride (chlormequat chloride)*	≥ 636 g/kg Impurities: 1,2-dichloroethane: max 0,1 g/kg (on the dry chlormequat chloride content). Chloroethene (vinylchloride): max 0,0005 g/kg (on the dry chlormequat chloride content).	1 December 2009	30 November 2019	PART A Only uses as plant growth regulator on cereals may be authorised. PART B In assessing applications to authorise plant protection products containing chlormequat for uses other than in rye and triticale, notably as regards the exposure of consumers, 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 chlormequat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of birds and mammals. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further information on the fate and behaviour (adsorption studies to be performed at 20 °C, recalculation of the predicted concentrations in groundwater, surface water and sediment), the monitoring methods for determination of the substance in animal products and water, and the risk to aquatic organisms, birds and mammals. They shall ensure that the notifier at whose request chlormequat has been included in this Annex provide such information to the Commission by 30 November 2011 at the latest.

No	Common name, identification numbers	IUPAC name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
282	Copper compounds:			1 December 2009	30 November 2016	PART A
	Copper hydroxide CAS No 20427-59-2 CIPAC No 44.305	*Copper (II) hydroxide*	≥ 573 g/kg			Only uses as bactericide and fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing copper for uses other than on tomatoes in greenhouses, 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 copper compounds, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 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 which 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 operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate, — the protection of water and non-target organisms. In relation to these identified risks risk mitigation measures, such as buffer zones, should be applied where appropriate, — the amount of active substance applied and ensure that the authorised amounts, in terms of rates and number of applications, are the minimum necessary to achieve the desired effects.
	Copper oxychloride CAS No 1332-65-6 or 1332-40-7 CIPAC No 44.602	*Dicopper chloride trihydroxide*	≥ 550 g/kg			
	Copper oxide CAS No 1317-39-1 CIPAC No 44.603	*Copper oxide*	≥ 820 g/kg			
	Bordeaux mixture CAS No 8011-63-0 CIPAC No 44.604	*Not allocated*	≥ 245 g/kg			
	Tribasic copper sulphate CAS No 12527-76-3 CIPAC No 44.306	*Not allocated*	≥ 490 g/kg The following impurities are of toxicological concern and must not exceed the levels below: Lead max 0,0005 g/kg of copper content. Cadmium max 0,0001 g/kg of copper content. Arsenic max 0,0001 g/kg of copper content.			

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
						The concerned Member States shall request the submission of information to further address: — the risk from inhalation, — the risk assessment for non-target organisms and for soil and water. They shall ensure that the notifier at whose request copper compounds have been included in this Annex provides such information to the Commission by 30 November 2011 at the latest. Member States shall initiate monitoring programmes in vulnerable areas where the contamination of the soil compartment by copper is of concern, in order to set, where appropriate, limitations such as maximum application rates.
283	Propaquizafop CAS No 111479-05-1 CIPAC No 173	*2-isopropylidenamino-oxyethyl (R)-2-[4-(6-chloro-quinoxalin-2-yloxy)phenoxy]propionate*	≥ 920 g/kg Toluene maximum content 5 g/kg	1 December 2009	30 November 2019	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on propaquizafop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 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 which 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 operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment,

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
						— the protection of aquatic organisms and non-target plants and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate, — the protection of non-target arthropods and 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 on the relevant impurity Ro 41-5259, — information to further address the risk to aquatic organisms and to non-target arthropods. They shall ensure that the notifier provides such information to the Commission by 30 November 2011.
284	Quizalofop-P: Quizalofop-P-ethyl CAS No 100646-51-3 CIPAC No 641.202 Quizalofop-P-tefuryl CAS No 119738-06-6 CIPAC No 641.226	*ethyl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy] propionate* *(RS)-Tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy] propionate*	≥ 950 g/kg ≥ 795 g/kg	1 December 2009	30 November 2019	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on quizalofop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 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 which 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,

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
						— the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of non-target plants and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the notifier submits to the Commission further information on the risk to non-target arthropods. They shall ensure that the notifier provides such information to the Commission by 30 November 2011.
285	Teflubenzuron CAS No 83121-18-0 CIPAC No 450	1-(3,5-dichloro-2,4-difluorophenyl)-3-(2,6-difluorobenzoyl) urea	≥ 970 g/kg	1 December 2009	30 November 2019	PART A Only uses as insecticide in glasshouses (on artificial substrate or closed hydroponic systems) may be authorised. PART B In assessing applications to authorise plant protection products containing teflubenzuron for uses other than on tomatoes in greenhouses, 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 teflubenzuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to:

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
						— the operator and workers safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, where appropriate, — the protection of aquatic organisms. Releases from glasshouse application must be minimised and, in any case, should not have the potential to reach in significant levels water bodies in the vicinity, — the protection of bees which should be prevented from accessing the glasshouse, — the protection of pollinator colonies purposely placed in the glasshouse, — the safe disposal of condensation water, drain water and substrate in order to preclude risks to non-target organisms and contamination of surface water and groundwater. Conditions of authorisation shall include risk mitigation measures, where appropriate.
286	Zeta-cypermethrin CAS No 52315-07-8 CIPAC No 733	Mixture of the stereo-isomers (*S*)-α-cyano-3-phenoxybenzyl (1*RS*,3*RS*;1*RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2 dimethylcyclopropane-carboxylate where the ratio of the (*S*);(1*RS*,3*RS*) isomeric pair to the (*S*);(1*RS*,3*SR*) isomeric pair lies in the ratio range 45-55 to 55-45 respectively	≥ 850 g/kg Impurities: toluene: max 2 g/kg tars: max 12,5 g/kg	1 December 2009	30 November 2019	PART A Only uses as insecticide may be authorised. PART B In assessing applications to authorise plant protection products containing zeta-cypermethrin for uses other than in cereals, notably as regards the exposure of consumers to mPBAldehyde, a degradation product that may be formed during processing, 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 zeta-cypermethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account.

No	Common name, identification numbers	IUPAC name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
						In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, where appropriate, — the protection of birds, aquatic organisms, bees, non-target arthropods and non-target soil macro-organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further information on the fate and behaviour (aerobic degradation in soil), the long-term risk to birds, aquatic organisms and non-target arthropods. They shall ensure that the notifier at whose request zeta-cypermethrin has been included in this Annex provide such information to the Commission by 30 November 2011 at the latest.'

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