COMMISSION DIRECTIVE 2005/53/EC

of 16 September 2005

amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl 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 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]), establishes 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 chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl.

(2) For those active substances the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifiers. By Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member State for the implementation of Regulation (EEC) No 3600/92 ([3]), the following rapporteur Member States were designated, which in turn submitted the relevant assessment reports and recommendations to the Commission in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92. For chlorothalonil the rapporteur Member State was the Netherlands, and all relevant information was submitted on 31 January 2000. For chlorotoluron, the rapporteur Member State was Spain and all relevant information was submitted on 7 May 1999. For cypermethrin the rapporteur Member State was Belgium and all relevant information was submitted on 25 October 1999. For daminozide the rapporteur Member State was the Netherlands and all relevant information was submitted on 30 July 1999. For thiophanate-methyl, the rapporteur Member State was Germany and all relevant information was submitted on 21 November 1997.

(3) The assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health.

(4) The reviews of all active substances were finalised on 15 February 2005 in the format of the Commission review reports for chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl.

(5) The review of chlorothalonil, chlorotoluron and cypermethrin did not reveal any open questions to be addressed by the Scientific Committee on Plants or the European Food Safety Authority (EFSA) which has taken over the role of the latter.

(6) The review of daminozide revealed a number of open questions which were addressed by the EFSA. The Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR Panel) of the EFSA was asked to comment on the mechanism of action of the carcinogenic response of rodents to 1,1-dimethylhydrazide (UDMH) and to indicate whether or not a threshold could be derived for this effect. If yes, it was requested to indicate this value. The PPR Panel, having regard to the submitted questions, concluded ([4]) that, on the basis of the available data, it is not possible to identify the mechanism responsible for the carcinogenic action of UDMH in rodents. There is no *in vitro* evidence of genotoxicity of pure and oxidation-protected UDMH and *in vivo* studies are not available. In addition, the PPR Panel noted an apparent discrepancy in that daminozide long-term studies did not give rise to carcinogenicity in rats and mice at doses that should have produced internal doses of metabolically-formed UDMH at least one order of magnitude higher than those proven to be effective on direct testing. In addition, methylation

([1]) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).

([2]) OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 27).

([3]) OJ L 107, 28.4.1994, p. 8. Regulation as last amended by Regulation (EC) No 2230/95 (OJ L 225, 22.9.1995, p. 1).

([4]) Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request from the Commission related to the evaluation of daminozide in the context of Council Directive 91/414/EEC (*The EFSA Journal* (2004), 61, 1-27), adopted on 11 May 2004.

of N7 guanine was found to be 50-fold higher in one study following oral administration of UDMH to rats, when compared to the corresponding data for daminozide. Thus, the PPR Panel considered that any conclusion on the mechanism of carcinogenicity of orally administered UDMH should be regarded to include a degree of uncertainty. The PPR Panel concluded that the weight of evidence is against a genotoxic mechanism.

Among possible non-genotoxic mechanisms, altered regulation of cell proliferation or hormonal imbalance are plausible alternatives to genotoxicity, but these mechanisms have not been specifically investigated and thus a more definitive conclusion on the mechanism involved is not possible at the moment. In experimental testing of UDMH for carcinogenicity in rats and mice, no effects were observed at 0,09 mg/kg bw/day and 1,41 mg/kg bw/day, respectively.

If the observed UDMH carcinogenicity is due to a non-genotoxic mechanism, the above indicated doses should be considered to be toxicological thresholds. However, taking together the uncertainties associated with the mechanism and the possibility that UDMH in greenhouse conditions may form oxidised derivatives that might be genotoxic, the PPR Panel is of the opinion that any use of these doses as thresholds should be undertaken only with due caution. The opinion was taken into consideration by the Standing Committee that concluded that the use of daminozide is acceptable under the specified conditions.

(7) The review of thiophanate-methyl revealed a number of open questions which were addressed by the Scientific Committee on Plants. The Scientific Committee was asked to comment on the advisability of establishing an acceptable daily intake (ADI) and acceptable operator exposure level (AOEL) having regard particularly to the results of mutagenicity, carcinogenicity and reproductive studies for benomyl, carbendazim and thiophanate-methyl. The Committee [1] noted that carbendazim is the biologically active substance common to these three substances. Benomyl in particular, but also thiophanate-methyl, is metabolised to carbendazim and all three substances produce numerical chromosomal aberrations (aneuploidy) in mammalian cells, exposed *in vivo*. There is no evidence that any other form of damage to genetic material is induced by any of these substances. Carcinogenicity is not a concern. The known effects of these fungicides upon reproduction are explicable by interaction with the microtubules of the spindle apparatus. The mechanism of aneuploidy induction is well understood and consists of inhibition of polymerisation of tubulin, the protein that is essential for the segregation of chromosomes during cell division: it does not involve any interaction with DNA. Since multiple copies of tubulin molecules are present in proliferating cells, in the presence of low concentration of the fungicides a limited number of tubulin molecules will be affected and consequently no toxicological adverse effects will ensue. Consequently, a clear no adverse effect level is recognisable and both an ADI and an AOEL can be established.

(8) It has appeared from the various examinations made that plant protection products containing chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl 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 report. It is therefore appropriate to include this active substance in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

(9) 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.

(10) 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 chlorothalonil, chlorotoluron, cypermethrin, daminozide or thiophanate-methyl 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 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.

[1] Opinion of the Scientific Committee on Plants (SCP/BENOMY/002 — final, SCP/CARBEN/002 — final, SCP/THIOPHAN/002 — final) of 23 March 2001 regarding the evaluation of benomyl, carbendazim and thiophanate-methyl in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Opinion adopted by the Scientific Committee on Plants on 7 March 2001).

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

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

(13) 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 August 2006 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 September 2006.

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 chlorothalonil, chlorotoluron, cypermethrin, daminozide or thiophanate-methyl as active substances by 31 August 2006.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl are met, with the exception of those identified in part B of the entries concerning those active substances, 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 derogation from paragraph 1, for each authorised plant protection product containing chlorothalonil, chlorotoluron, cypermethrin, daminozide or thiophanate-methyl 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 28 February 2006 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 entries in Annex I to that Directive concerning chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl. 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 chlorothalonil, chlorotoluron, cypermethrin, daminozide or thiophanate-methyl as the only active substance, where necessary, amend or withdraw the authorisation by 28 February 2010 at the latest; or

(b) in the case of a product containing chlorothalonil, chlorotoluron, cypermethrin, daminozide or thiophanate-methyl as one of several active substances, where necessary, amend or withdraw the authorisation by 28 February 2010 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 March 2006.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 16 September 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

The following entries 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
'102	Chlorothalonil CAS No 1897-45-6 CIPAC No 288	Tetrachloroisophthalonitrile	985 g/kg — Hexachlorobenzene: not more than 0,01 g/kg — Decachlorobiphenyl: not more than 0,03 g/kg	1 March 2006	28 February 2016	PART A Only uses as fungicide may be authorised PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on chlorothalonil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account In this overall assessment Members States must pay particular attention to the protection of: — aquatic organisms, — groundwater, in particular with regards to the active substance and its metabolites R417888 and R611965 (SDS46851), when the substance is applied in regions with vulnerable soil and/or climate conditions Conditions of use should include risk mitigation measures, where appropriate
103	Chlorotoluron (unstated stereochemistry) CAS No 15545-48-9 CIPAC No 217	3-(3-chloro-p-tolyl)-1,1-dimethylurea	975 g/kg	1 March 2006	28 February 2016	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 chlorotoluron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Conditions of authorisation should include risk mitigation measures, where appropriate

No	Common name, identification numbers	IUPAC Name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
104	Cypermethrin CAS No 52315-07-8 CIPAC No 332	(RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate (4 isomer pairs: cis-1, cis-2, trans-3, trans-4)	900 g/kg	1 March 2006	28 February 2016	PART A Only uses as insecticide may be authorised PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cypermethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account. In this overall assessment — Member States must pay particular attention to the protection of aquatic organisms, bees and non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate, — Member States must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate
105	Daminozide CAS No 1596-84-5 CIPAC No 330	N-dimethylaminosuccinamic acid	990 g/kg Impurities: — N-nitrosodimethylamine: not more than 2,0 mg/kg — 1,1-dimethylhydrazide: not more than 30 mg/kg	1 March 2006	28 February 2016	PART A Only uses as growth regulator in non-edible crops may be authorised PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on daminozide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the safety of operators and workers after re-entry. Conditions of authorisation should include protective measures, where appropriate

No	Common name, identification numbers	IUPAC Name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
106	Thiophanate-methyl (unstated stereo-chemistry) CAS No 23564-05-8 CIPAC No 262	Dimethyl 4,4'-(o-phenylene)bis(3-thioallophanate)	950 g/kg	1 March 2006	28 February 2016	PART A Only uses as fungicide may be authorised PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on thiophanate-methyl , and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of aquatic organisms, earthworms and other soil macro-organisms. Conditions of authorisation should include risk mitigation measures, where appropriate'

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