Commission Directive 2009/77/EC of 1 July 2009 amending Council Directive 91/414/EEC to include chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron as active substances (Text with EEA relevance)

COMMISSION DIRECTIVE 2009/77/EC

of 1 July 2009

amending Council Directive 91/414/EEC to include chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron 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 chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron.

(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 chlorsulfuron and cyromazine the rapporteur Member State was Greece and all relevant information was submitted on 27 July 2007 and on 31 August 2007. For dimethachlor and penconazole the rapporteur Member State was Germany and all relevant information was submitted on 2 May 2007 and on 19 June 2007 respectively. For etofenprox the rapporteur Member State was Italy and all relevant information was submitted on 15 July 2005. For lufenuron the rapporteur Member State was Portugal and all relevant information was submitted on 20 September 2006. For tri-allate the rapporteur Member State was the United Kingdom and all relevant information was submitted on 6 August 2007. For triflusulfuron the rapporteur Member State was France and all relevant information was submitted on 26 July 2007.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 26 November 2008 for chlorsulfuron, on 17 September 2008 for cyromazine and for dimethachlor, on 19 December 2008 for etofenprox, on 30 September 2008 for lufenuron and triflusulfuron, on 25 September 2008 for penconazole and on 26 September 2008 for tri-allate 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 26 February 2009 in the format of the Commission review reports for chlorsulfuron, cyromazine, dimethachlor, lufenuron, penconazole, tri-allate and triflusulfuron and on 13 March 2009 for etofenprox.

(4) It has appeared from the various examinations made that plant protection products containing chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron 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.

(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 lufenuron, dimethachlor and chlorsulfuron the notifiers should be required to submit further information on the chemical specification of the active substances as manufactured. Furthermore, for cyromazine and penconazole it is appropriate to require that the notifiers submit further information on the fate and behaviour of the soil metabolite NOA 435343 (for cyromazine) and U1 (for penconazole) and on the risk to aquatic organisms. Moreover, it is appropriate as regards tri-allate, to require that the notifier submit further information on the primary plant metabolism, the fate and behaviour of the soil metabolite diisopropylamine, the potential for biomagnification in aquatic food chains, the risk to fish-eating mammals and the long-term risk to earthworms. In addition, it is appropriate for the etofenprox to require that the notifier submit further information on the risk to aquatic organisms, including the risk to sediment dwellers, further studies on the endocrine disruption potential in aquatic organisms (fish full life cycle study) and biomagnification. Finally, for dimethachlor, chlorsulfuron and triflusulfuron, the notifiers should be required to submit further information on the toxicological relevance of metabolites in case the substance is classified as carcinogenic category 3.

(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 chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron 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[(5)] 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 June 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 July 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 chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron as active substances by 30 June 2010.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole,

tri-allate and triflusulfuron 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 chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron 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 December 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 chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron 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 chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron as the only active substance, where necessary, amend or withdraw the authorisation 30 June 2014 at the latest; or

b in the case of a product containing chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusulfuron as one of several active substances, where necessary, amend or withdraw the authorisation by 30 June 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 January 2010.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 1 July 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[a]	Entry into force	Expiration of inclusion	Specific provisions
‘287	Chlorsulfuron CAS No 64902-72-3 CIPAC No 391	*1-(2-chlorophenylsulfonyl)-3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)urea*	≥ 950 g/kg Impurities: 2-Chlorobenzenesulfonamide (IN-A4097) not more than 5 g/kg and 4-methoxy-6-methyl-1,3,5-triazin-2-amine (IN-A4098) not more than 6 g/kg	1 January 2010	31 December 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 chlorsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food

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

						Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of aquatic organisms and non-target plants; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of the

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

						groundwater, when 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 by 1 January 2010. If chlorsulfuron is classified as carcinogenic category 3 in accordance with point 4.2.1 of Annex VI to Directive 67/548/EEC, the

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

						Member States concerned shall request the submission of further information on the relevance of the metabolites IN-A4097, IN-A4098, IN-JJ998, IN-B5528 and IN-V7160 with respect to cancer and ensure that the notifier provides that information to the Commission within six months from the notification of the classification decision concerning that substance.
288	Cyromazine CAS No 66215-27-8 CIPAC No 420	*N-cyclopropyl-1,3,5-triazine-2,4,6-triamine*	≥ 950 g/kg	1 January 2010	31 December 2019	PART A Only uses as insecticide in greenhouses may be authorised. PART B In assessing applications to

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

						authorise plant protection products containing cyromazine for uses other than in tomatoes, 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

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

						uniform principles of Annex VI, the conclusions of the review report on cyromazine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 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/

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

						or climatic conditions, — the protection of aquatic organisms, — the protection of pollinators. 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 of the soil metabolite NOA 435343 and on the risk to aquatic organisms. They shall ensure that the notifier at whose request cyromazine has been included in this Annex provide such information

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

						to the Commission by 31 December 2011 at the latest.	
289	Dimethachlor CAS No 50563-36-5 CIPAC No 688	*2-chloro-N-(2-methoxyethyl)-6'-xylidide*	≥ 950 g/kg Impurity *2,6-*dimethylaniline: Not more than 0,5 g/kg	1 January 2010	31 December 2019	PART A	Only uses as herbicide in application max. of 1,0 kg/ha only every third year on the same field may be authorised.
						PART B	For the implementation of the uniform principles of Annex VI, the conclusions of the review report on dimethachlor, and in particular Appendices

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

						I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 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,

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

						— the protection of aquatic organisms and non-target plants; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk

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

						mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from metabolites CGA 50266, CGA 354742, CGA 102935 and SYN 528702 in vulnerable zones, where appropriate. The Member States concerned shall — ensure that the notifier submits to the Commission further studies on the specification by 1 January 2010. If dimethachlor is classified as carcinogenic

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

						category 3 in accordance with point 4.2.1 of Annex VI to Directive 67/548/EEC, the Member States concerned shall request the submission of further information on the relevance of the metabolites CGA 50266, CGA 354742, CGA 102935 and SYN 528702 with respect to cancer and ensure that the notifier provides that information to the Commission within six months from the notification of the classification decision concerning that substance.

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

290	Etofenprox CAS No 80844-07-1 CIPAC No 471	*2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether*	≥ 980 g/kg	1 January 2010	31 December 2019	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 etofenprox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall

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

						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; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied

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

						where appropriate, — the protection of bees and non-target arthropods; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate. The Member States concerned shall — ensure that the notifier submits to the Commission further information on the risk to aquatic organisms including the risk

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

						— to sediment dwellers and biomagnification, the submission of further studies on the endocrine disruption potential in aquatic organisms (fish full life cycle study). They shall ensure that the notifiers provide such studies to the Commission by 31 December 2011.	
291	Lufenuron CAS No 103055-07-8 CIPAC No 704	*(RS)-1-[2,5-dichloro-4-(1,1,2,3,3,3-hexafluoro-propoxy)-phenyl]-3-(2,6-difluorobenzoyl)-urea*	≥ 970 g/kg	1 January 2010	31 December 2019	PART A Only indoor uses or use in outdoor bait stations as insecticide may be authorised. PART B For the	

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

						implementation of the uniform principles of Annex VI, the conclusions of the review report on lufenuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States must pay

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

						particular attention to: — the high persistency in the environment and the high risk for bioaccumulation and shall ensure that the use of lufenuron has no adverse long-term effects on non-target organisms, — the protection of birds, mammals, soil non-target organisms, bees, non-target arthropods, surface waters and aquatic organisms in

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

							vulnerable situations. The Member States concerned shall — ensure that the notifier submits to the Commission further studies on the specification by 1 January 2010.
292	Penconazole CAS No 66246-88-6 CIPAC No 446	*(RS) 1-[2-(2,4-dichloro-phenyl)-pentyl]-1H-[1,2,4] triazole*	≥ 950 g/kg	1 January 2010	31 December 2019	PART A	Only uses as fungicide in greenhouses may be authorised.
						PART B	For the implementation of the uniform principles of Annex VI, the conclusions of the review report on

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

						penconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 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

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

						vulnerable soil and/ or climatic conditions. 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 of the soil metabolite U1. They shall ensure that the notifier at whose request penconazole has been included in this Annex provide such information to the Commission by 31 December 2011 at the latest.
293	Tri-allate CAS No 2303-17-5	*S-2,3,3-trichloroallyl*	≥ 940 g/kg	1 January 2010	31 December 2019	PART A Only uses as

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

	CIPAC No 97	*di-isopropyl (thiocarbamate)*	NDIPA (Nitroso-di-isopropylamine) max. 0,02 mg/kg				herbicide may be authorised.
						PART B	For the implementation of the uniform principles of Annex VI, the conclusions of the review report on tri-allate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken

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

						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 dietary exposure of consumers to residues of tri-allate in treated crops as well as in succeeding rotational crops and in products of

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

						animal origin — 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 potential for ground water contamination by the degradation products TCPSA when the active substance is applied in regions with vulnerable soil and/or climatic

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

						conditions. Conditions of authorisation must include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the notifier submits to the Commission: — further information to assess the primary plant metabolism, — further information on the fate and behaviour of the soil metabolite diisopropylamine, — further information on the potential for biomagnification in aquatic food chains,

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

							— information to further address the risk to fish-eating mammals and the long-term risk to earthworms. They shall ensure that the notifier provides such information to the Commission by 31 December 2011.
294	Triflusulfuron CAS No 126535-15-7 CIPAC No 731	*2-[4-dimethylamino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-ylcarbamoylsulfamoyl]-4-m-toluic acid*	≥ 960 g/kg N,N-dimethyl-6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine Max. 6 g/kg	1 January 2010	31 December 2019	PART A	Only uses as a herbicide in application on sugar and fodder beet at max 60 g/ha only every third year on the

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

							same field may be authorised. Foliage of treated crops may not be fed to livestock.
						PART B	For the implementation of the uniform principles of Annex VI, the conclusions of the review report on triflusulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain

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

						and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the dietary exposure of consumers to residues of metabolites IN-M7222 and IN-E7710 in succeeding rotational crops and in products of animal origin, — the protection of aquatic organisms and aquatic plants

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

						from the risk arising from triflusulfuron and the metabolite IN-66036 and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate, — the potential for ground water contamination by the degradation products IN-M7222 and IN-W6725 when the active substance is applied in regions with vulnerable soil

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

						and/ or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate. If triflusulfuron is classified as carcinogenic category 3 in accordance with point 4.2.1 of Annex VI to Directive 67/548/ EEC, the Member States concerned shall request the submission of further information on the relevance of the metabolites IN-M7222, IN-D8526 and IN-E7710 with respect to cancer. They shall ensure that the notifier provides that information

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

						to the Commission within six months from the notification of the classification decision concerning that substance.’

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

(**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) 201, Conclusion regarding the peer review of the pesticide risk assessment of the active substance chlorsulfuron (finalised 26 November 2008).*
EFSA Scientific Report (2008) 168, Conclusion regarding the peer review of the pesticide risk assessment of the active substance cyromazine (finalised 17 September 2008).
EFSA Scientific Report (2008) 169, Conclusion regarding the peer review of the pesticide risk assessment of the active substance dimethachlor (finalised 17 September 2008).
EFSA Scientific Report (2008) 213, Conclusion regarding the peer review of the pesticide risk assessment of the active substance etofenprox (finalised 19 December 2008).
EFSA Scientific Report (2008) 189, Conclusion regarding the peer review of the pesticide risk assessment of the active substance lufenuron (finalised 30 September 2008).
EFSA Scientific Report (2008) 175, Conclusion regarding the peer review of the pesticide risk assessment of the active substance penconazole (finalised 25 September 2008).
EFSA Scientific Report (2008) 195, Conclusion regarding the peer review of the pesticide risk assessment of the active substance triflusulfuron (finalised 30 September 2008).
EFSA Scientific Report (2008) 181, Conclusion regarding the peer review of the pesticide risk assessment of the active substance tri-allate (finalised 26 September 2008).

(**5**) OJ L 366, 15.12.1992, p. 10.