COMMISSION DIRECTIVE 2003/84/EC

of 25 September 2003

amending Council Directive 91/414/EEC to include flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate and silthiofam 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]), as last amended by Commission Directive 2003/79/EC ([2]), and in particular Article 6(1) thereof,

Whereas:

(1) In accordance with Article 6(2) of Directive 91/414/EEC the authorities of France received on 15 February 1994 an application from Rhône-Poulenc Agro France (now Bayer CropScience) for the inclusion of the active substance flurtamone in Annex I to Directive 91/414/EEC. Commission Decision 1996/341/EC ([3]) confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(2) France received an application under Article 6(2) of Directive 91/414/EEC on 1 February 1996 an application from Bayer AG (now Bayer CropScience) concerning flufenacet (former name: fluthiamide). This application was declared complete by Commission Decision 97/362/EC ([4]).

(3) Germany received an application under Article 6(2) of Directive 91/414/EEC on 14 December 1998 from Hoechst Schering AgrEvo GmbH (now Bayer CropScience) concerning iodosulfuron (as parent substance of iodosulfuron-methyl-sodium). This application was declared complete by Commission Decision 1999/392/EC ([5]).

(4) Germany received an application under Article 6(2) of Directive 91/414/EEC on 16 April 1999 from BASF AG concerning dimethenamid-p. This application was declared complete by Commission Decision 1999/555/EC ([6]).

(5) Ireland received an application under Article 6(2) of Directive 91/414/EEC on 26 May 1999 from Zeneca Agrochemicals (now Syngenta) concerning picoxystrobin. This application was declared complete also by Commission Decision 1999/555/EC.

(6) The United Kingdom received an application under Article 6(2) of Directive 91/414/EEC on 5 March 1996 from ISK Biosciences Europe SA concerning fosthiazate. This application was declared complete by Commission Decision 97/362/EC.

(7) Ireland received an application under Article 6(2) of Directive 91/414/EEC on 14 December 1998 from Monsanto Crop Protection concerning silthiofam (former name: silthiopham). This application was declared complete by Commission Decision 1999/392/EC.

(8) For those active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The nominated rapporteur Member States submitted a draft assessment report concerning the substance to the Commission on 21 May 1997 (flurtamone), 6 January 1998 (flufenacet), 30 May 2000 (iodosulfuron), 26 September 2000 (dimethenamid-p), 11 June 2001 (picoxystrobin), 18 March 1998 (fosthiazate), and 2 October 2000 (silthiofam).

(9) The draft assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 4 July 2003 in the format of the Commission review report for flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate and silthiofam.

(10) The review of iodosulfuron, dimethenamid-p, picoxystrobin and silthiofam did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.

(11) For flurtamone, the documents and information were also submitted to the Scientific Committee for Plants for separate consultation. The Scientific Committee for Plants was consulted twice, mainly to assess the potential leaching of two metabolites of the active substance, 3-trifluoromethylbenzoic acid (TFMBA) and trifluoroacetic acid (TFAA). In a first opinion ([7]), the Scientific Committee recommended with respect to TFMBA the inclusion of soils with pH values between 7 and 8 in the sorption studies with this metabolite. As regards the

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 228, 12.9.2003, p. 11.
([3]) OJ L 130, 31.5.1996, p. 20.
([4]) OJ L 152, 11.6.1997, p. 31.
([5]) OJ L 148, 15.6.1999, p. 44.
([6]) OJ L 210, 10.8.1999, p. 22.

([7]) Opinion of the Scientific Committee on Plants regarding the inclusion of flurtamone in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market (SCP/FLURT/004-Final, adopted on 18 December 1998).

metabolite TFAA, the Committee found the available data insufficient to assess the risk of contamination of groundwater. Subsequently, further studies were undertaken by the applicant for both metabolites. In its second opinion [1] the Scientific Committee concluded that concentrations of TFMBA leaching to groundwater from soils with pH above 5 may exceed 0,1 g/l in a small percentage of cases/situations. The Committee further concluded that the metabolite TFAA does not represent an unacceptable risk to aquatic organisms via groundwater but the toxicological information made available to the Committee was still insufficient. The recommendations of the Scientific Committee were taken into account during the further review and in this Directive and in the Review Report. After the missing information was subsequently delivered by the applicant and evaluated by the rapporteur Member State. The evaluation within the Standing Committee concluded that there would be no unacceptable influence of the metabolites TFMBA and TFAA on the environment if appropriate risk mitigation measures are applied.

(12) As regards flufenacet, the Scientific Committee for Plants was asked to comment on two degradation products (M2 and M4) of the active substance, which were detected in lysimeters leachates, and on the exposure of operators. In its opinion [2] the Committee found for the M2 and M4 metabolites that the risk to non-target terrestrial organisms were not yet adequately assessed and also identified other degradation products for which the risk to non-target organisms needed further evaluation. The Committee was of the opinion that operator risk assessment of flufenacet has been adequately addressed but noted that the sensitising potential of the formulation deserves proper attention. The recommendations of the Scientific Committee were taken into account during the further review and in this Directive and in the Review Report. After the missing information was subsequently delivered by the applicant and evaluated by the rapporteur Member State. The evaluation within the Standing Committee concluded that the risk by all identified degradation products for non-target organisms would be acceptable and that the sensitising risk would also be acceptable if appropriate risk mitigation measures are applied.

(13) As regards fosthiazate, the Scientific Committee was asked to comment on the potential for leaching to groundwater, on the risk to soil dwelling non-target organisms, on the risk to birds and wild mammals, and on the possible risk of organophosphate-induced delayed polyneuropathy (OPIDP) in humans following severe poisoning incidents. In its opinion [3] the Committee found that based on the available information no safe use scenario could be identified which poses no unacceptable risk to groundwater. The Committee noted that it is possible that lysimeter studies demonstrate lack of leaching for one or more use scenarios but none were reported. Also the risk of the different metabolites to soil organisms had not been sufficiently addressed. The Committee further considered that the potential for exposure of birds and wild mammals by all the routes mentioned above required further consideration. Finally, the Committee was of the opinion that NTE (neuropathy target esterase) inhibition by fosthiazate and its isomers had not been adequately assessed. The recommendations of the Scientific Committee were taken into account during the further review and in this Directive and in the Review Report. After the missing information was subsequently delivered by the applicant and evaluated by the rapporteur Member State and taking into account appropriate measures of risk mitigation measures, the evaluation within the Standing Committee concluded that no harmful effects are to be expected from NTE inhibition by fosthiazate and its isomers. The evaluation within the Standing Committee further concluded that the risk by the parent substances and the identified degradation products for the groundwater, soil organisms, birds and wild mammals would be acceptable if appropriate risk mitigation measures are applied.

(14) It has appeared from the various examinations made that plant protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) 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 flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate and silthiofam 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.

(15) After inclusion, Member States should be allowed a reasonable period to implement the provisions of Directive 91/414/EEC as regards plant protection products containing flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate and silthiofam and in particular to review existing provisional authorisations and, by the end of this period at the latest, to transform those authorisations into full authorisations, to amend them or to withdraw them in accordance with the provisions of Directive 91/414/EEC.

[1] Opinion of the Scientific Committee on Plants regarding the inclusion of flurtamone in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market (SCP/FLURT/018-Final, adopted on 26 January 2001).

[2] Opinion of the Scientific Committee on Plants on specific questions from the Commission concerning the evaluation of flufenacet [FOE 5043] in the context of Directive 91/414/EEC, (SCP/FLUFEN/002-Final, adopted 17 October 2001).

[3] Opinion on specific questions from the Commission concerning the evaluation of fosthiazate [IKKI-1145/TO-1145] in the context of Directive 91/414/EEC, (SCP/FOSTHIAZ/002-Final, adopted 20 December 2001).

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

(17) 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 2004 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 July 2004.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall 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 review the authorisation for each plant protection product containing flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate or silthiofam to ensure that the conditions relating to these active substances set out in Annex I to Directive 91/414/EEC are complied with. Where necessary, they shall amend or withdraw authorisations in accordance with Directive 91/414/EEC by 30 June 2004 at the latest.

2. For each authorised plant protection product containing flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate or silthiofam 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 2004 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI, on the basis of a dossier satisfying the requirements of Annex III thereto. 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. Where necessary and by 30 June 2005 at the latest, they shall amend or withdraw the authorisation for each such plant protection product.

Article 4

This Directive shall enter into force on 1 January 2004.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 25 September 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX

In Annex I the following rows are added at the end of the table

No	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
'64	Flurtamone CAS No 96525-23-4	(RS)-5-methylamino-2-phenyl-4-(a,a,a-trifluoro-m-tolyl) furan-3 (2H)-one	960 g/kg	1 January 2004	31 December 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flurtamone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of algae and other aquatic plants. Risk mitigation measures should be applied where appropriate.
65	Flufenacet CAS No 142459-58-3 CIPAC No 588	4'-fluoro-N-isopropyl-2-[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yloxy]acetanilide	950 g/kg	1 January 2004	31 December 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flufenacet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of algae and aquatic plants, — should pay particular attention to the protection of operators. Risk mitigation measures should be applied where appropriate.
66	Iodosulfuron CAS No 185119-76-0 (parent) 144550-36-7 (iodosulfuron-methyl-sodium) CIPAC No 634 (parent) 634.501 (iodosulfuron-methyl-sodium)	4-iodo-2-[3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-ureidosulfonyl]benzoate	910 g/kg	1 January 2004	31 December 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on iodosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the potential of iodosulfuron and its metabolites for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of aquatic plants. Risk mitigation measures should be applied where appropriate.

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
67	Dimethenamid-p CAS No 163515-14-8 CIPAC No 638	S-2-chloro-N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)-acetamide	890 g/kg (preliminary value based on a pilot plant)	1 January 2004	31 December 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on dimethenamid-p, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the potential of the metabolites of dimethenamid-p for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of aquatic ecosystems, especially of aquatic plants. Risk mitigation measures should be applied where appropriate. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.
68	Picoxystrobin CAS No 117428-22-5 CIPAC No 628	Methyl (E)-3-methoxy-2-{2-[6-(trifluoromethyl) -2- pyridyloxymethyl]phenyl} acrylate	950 g/kg (preliminary value based on a pilot plant)	1 January 2004	31 December 2013	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on picoxystrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of soil organisms, — should pay particular attention to the protection of aquatic ecosystems. Risk mitigation measures should be applied where appropriate. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.
69	Fosthiazate CAS No 98886-44-3 CIPAC No 585	(RS)-S-sec-butyl O-ethyl 2-oxo-1,3-thiazolidin-3-ylphosphonothioate	930 g/kg	1 January 2004	31 December 2013	Only uses as nematicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fosthiazate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States:

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
						— should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of birds and wild mammals in particular if the substance is applied during the breeding season, — should pay particular attention to the protection of non-target soil organisms. Risk mitigation measures should be applied where appropriate. In order to mitigate the potential risk to small birds, product authorisations must require that a very high level of incorporation of granules into soil is achieved. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.
70	Silthiofam CAS No 175217-20-6 CIPAC No 635	N-allyl-4,5-dimethyl-2-(trimethylsilyl)thiophene-3-carboxamide	950 g/kg	1 January 2004	31 December 2013	Only uses as fungicide may be authorised. Uses other than seed treatments are currently not adequately supported by data. To support authorisations for such uses, data and information to prove their acceptability for consumers, operators and the environment will have to be generated and submitted to the Member States. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on silthiofam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of operators. Risk mitigation measures must be applied, where appropriate.

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