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COMMISSION DIRECTIVE 2002/48/EC

of 30 May 2002

amending Council Directive 91/414/EEC to include iprovalicarb, prosulfuron and sulfosulfuron as active substances

(OJ L 148, 6.6.2002, p. 19)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Decision 2009/685/EC of 2 September 2009	L 231	21	3.9.2009

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amending Council Directive 91/414/EEC to include iprovalicarb, prosulfuron and sulfosulfuron as active substances

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 2002/37/EC ([2]), and in particular Article 6(1) thereof,

Whereas:

(1) In accordance with Article 6(2) of Directive 91/414/EEC, Ireland received on 30 March 1998 an application from Bayer AG for the inclusion of the active substance iprovalicarb in Annex I to the Directive. By Commission Decision 98/512/EC ([3]) it was confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements laid down in Annexes II and III to Directive 91/414/EEC.

(2) France received a similar application on 14 May 1995 from Novartis, now Syngenta, concerning prosulfuron. This application was declared complete by Commission Decision 97/137/EC ([4]).

(3) Ireland received a similar application on 24 April 1997 from Monsanto concerning sulfosulfuron. This application was declared complete by Commission Decision 97/865/EC ([5]).

(4) For these three active substances, the effects on human health and the environment have been assessed, in accordance with Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The nominated rapporteur Member States submitted draft assessment reports concerning the substances to the Commission on 4 November 1999 (iprovalicarb), 18 January 1999 (prosulfuron), and 2 April 1998 (sulfosulfuron), respectively.

(5) 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 reviews were finalised on 26 February 2002 in the format of the Commission review reports for iprovalicarb, prosulfuron and sulfosulfuron.

(6) The dossier and the information from each of the reviews were submitted to the Scientific Committee for Plants. As regards iprovalicarb, the Committee was asked to comment on the acceptability of the risk of metabolite PMPA on earthworms and on the relevance to humans of tumours which were observed in rats after lifetime exposure to high doses. In two opinions ([6]) ([7]), the

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 117, 4.5.2002, p. 10.
([3]) OJ L 228, 15.8.1998, p. 35.
([4]) OJ L 52, 22.2.1997, p. 20.
([5]) OJ L 351, 23.12.1997, p. 67.
([6]) Opinion of the Scientific Committee on Plants on the evaluation of iprovalicarb in the context of Directive 91/414/EEC concerning the placing of plant protection products on the market (adopted 21 March 2001).
([7]) Opinion of the Scientific Committee on Plants on an additional question from the Commission on the evaluation of iprovalicarb (SZX 0722) in the context of Directive 91/414/EEC (adopted 28 November 2001).

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Committee identified the need for further data on earthworms, which were subsequently provided and assessed, and concluded that concerning the effects observed in rats sufficient safety margins exist to ensure protection of consumers and operators. The observations of the Scientific Committee were taken into consideration in formulating this Directive and the relevant review report.

(7) With respect to prosulfuron, the Committee was asked to comment on the acceptability of the risk of two breakdown products of the active substance to sediment dwelling organisms and on possible hormonal disruption effects observed in test animals. In its opinion [1] the Committee concluded that certain uterine and mammary changes, which were observed in rats after lifetime exposure are not considered relevant for human risk assessment of prosulfuron in the context of its intended uses. The Committee further commented that risks of the two breakdown products to sediment-dwelling species were not yet adequately assessed and noted that other persistent metabolites are formed in significant quantities in sediment-water tests which also did not appear to have been assessed. The pending information and assessments were subsequently provided and the observations of the Scientific Committee were taken into consideration in formulating this Directive and the relevant review report.

(8) With respect to sulfosulfuron the Committee was asked for its opinion on the occurrence of bladder tumours in the 18 months mouse study; to consider whether it would be appropriate to establish an acute reference dose for sulfosulfuron; to confirm that a sub-lethal study for earthworms is unnecessary, notwithstanding the persistence of the soil metabolites. In its opinion [2] the Committee considered that the lesions observed in mice do not predict a carcinogenic hazard to humans and saw no need to establish an acute reference dose. It was further concluded that no significant long term risks to earthworms are likely to arise. The Committee further highlighted the need to assess the potential environmental impact of three unidentified metabolites. This information was subsequently provided and the requested assessments were made.

(9) 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 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 the active substances concerned, can be granted in accordance with the provisions of the said Directive.

(10) The Commission review report is required for the proper implementation by the Member States, of several sections of the uniform principles laid down in Directive 91/414/EEC. It is, therefore, appropriate to provide that the finalised review reports, except for confidential information, should be kept

[1] Opinion of the Scientific Committee on Plants regarding the inclusion of prosulfuron (CGA 152005) in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market SCP/PROSULF/002-Final 21 June 2001.

[2] Opinion of the Scientific Committee on Plants regarding the evaluation of MON 37500 (sulfosulfuron) in the context of Directive 91/414/EEC concerning the placing of plant protection products on the market (SCP/SULFO/002-final dated 11 December 2000).

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available or made available by the Member States for consultation by any interested parties.

(11) 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 iprovalicarb, prosulfuron or sulfosulfuron 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.

(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 keep available the review reports for iprovalicarb, prosulfuron, and sulfosulfuron, except for confidential information within the meaning of Article 14 of Directive 91/414/EEC, for consultation by any interested parties or shall make it available to them on specific request.

Article 3

Member States shall adopt and publish by 31 December 2002 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 January 2003.

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 4

1. Member States shall review the authorisation for each plant protection product containing iprovalicarb, prosulfuron, or sulfosulfuron, 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 the authorisation in accordance with Directive 91/414/EEC before 31 December 2002.

2. Member States shall, for each authorised plant protection product containing iprovalicarb, prosulfuron, or sulfosulfuron, 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 1 July 2002, 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 thereto. On the basis of that

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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 31 December 2003 at the latest, they shall amend or withdraw the authorisation for each such plant protection product.

Article 5

This Directive shall enter into force on 1 July 2002.

Article 6

This Directive is addressed to the Member States.

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ANNEX

In Annex I the following rows are added to the end of the Table:

'No	Common name, identification numbers	IUPAC Name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
30	Iprovalicarb CAS No 140923-17-7 CICAP No 620	{2-Methyl-1-[1-(4-methylphenyl)ethyl-carbonyl] propyl}-carbamic acid isopropylester	950 g/kg (provisional specification)	1 July 2002	►M1 30 June 2012 ◄	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on iprovalicarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2002 shall be taken into account. In this overall assessment: — the specification of the technical material as commercially manufactured must be confirmed and supported by apporpriate analytical data. The test material used in the toxicity dossier should be compared and verified against this specification of the technical material, — Member States must pay particular attention to the protection of operators.
31	Prosulfuron CAS No 94125-34-5 CICAP No 579	1-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenylsulfonyl]-urea	950 g/kg	1 July 2002	►M1 30 June 2012 ◄	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on prosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2002 shall be taken into account. In this overall assessment Member States: — must carefully consider the risk to aquatic plants if the active substance is applied adjacent to surface waters. Risk mitigation measures should be applied where appropriate, — must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied where appropriate.
32	Sulfosulfuron CAS No 141776-32-1 CICAP No 601	1-(4,6-dimethoxypyrimidin-2-yl)-3-[2-ethanesulfonyl-imidazo[1,2-*a*]pyridine) sulfonyl]urea	980 g/kg	1 July 2002	►M1 30 June 2012 ◄	Only uses as a herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on sulforsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2002 shall be taken into account. In this overall assessment: — Member States must pay particular attention to the protection of aquatic plants and algae. Where apporpriate, risk mitigation measures should be applied, — Member States must pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditons.

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