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Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen
Band D 39

Review Report Pyraflufen-ethyl
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 39

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Vorwort

Für neue Wirkstoffe werden die EU-Mitgliedstaaten in den Richtlinien zur Aufnahme der Wirkstoffe in Anhang I verpflichtet, den nach Abschluss aller Prüfungen erstellten Beurteilungsbericht (Review Report) mit allen Anlagen (mit Ausnahme von vertraulichen Informationen im Sinne von Artikel 14 der Richtlinie 91/414/EWG) allen Interessierten zur Verfügung zu stellen oder auf besonderen Antrag zugänglich zu machen. Für alte Wirkstoffe ergibt sich diese Verpflichtung für die Mitgliedstaaten bereits aus Artikel 7 Absatz 6 Unterabsatz 2 der Verordnung (EWG) Nr. 3600/92.

Die Mitgliedstaaten und die Europäische Kommission haben vereinbart, dass die Beurteilungsberichte, einschließlich der zum Teil sehr umfangreichen Hintergrunddokumente, vorzugsweise beim berichterstattenden Mitgliedstaat angefordert oder eingesehen werden sollen.

Die Biologische Bundesanstalt stellt die Beurteilungsberichte als Berichte aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft als Band D in der Reihe "Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen" über den Saphir Verlag gegen Erstattung der Unkosten zur Verfügung. Das vorliegende 29. Heft dieser Reihe (Band D 39) enthält nicht die Hintergrunddokumente A, B und C des Beurteilungsberichtes. Diese können bei Bedarf bei der BBA eingesehen oder für die Wirkstoffe, für die Deutschland Berichterstatter ist, ebenfalls beim Saphir Verlag gegen Erstattung der Unkosten bezogen werden. Für Pyraflufen-ethyl war Belgien Berichterstatter.

In der Reihe "Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen" sind bisher erschienen:

Heft	**Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen**
35/97	Band A: Richtlinie 91/414/EWG und diesbezügliche Protokolle (3. Auflage, Stand: 01. November 1997) *wird zur Zeit bearbeitet*
68/2000	Band B: Verordnungen und Protokolle zur Wirkstoffprüfung (4. Auflage, Stand 01. Juli 2000) *wird zur Zeit bearbeitet*
	Band C: *wird zur Zeit bearbeitet*

Preface

According to the Directives for the inclusion of active substances in Annex I with regard to new active substances, EU-Member States are obliged to keep available or make available on special request the review report which is prepared after completion of all evaluations including its appendices (excluding confidential information, in accordance with article 14 of Directive 91/414/EEC) to all interested parties. For existing active substance this obligation for Member States already arises from article 7 (6) subparagraph 2 of Regulation (EEC) No 3600/92.

Member States and the European Commission agreed that requests of review reports including their background documents which are partly very voluminous, shall preferably be addressed to the Rapporteur Member State.

The Federal Biological Research Centre makes available review reports as reports from the Federal Biological Research Centre for Agriculture and Forestry, Volume D of the series "Legal Regulations of the European Union for Plant Protection Products and their Active Substances" via Saphir Verlag against reimbursement of expenses. The present 39th report belonging to this series (Volume D 39) does not include background documents A, B and C of the review report. If the need arises, their inspection at the BBA is possible or they may be also obtained from Saphir Verlag against reimbursement of expenses, however, only for active substances with Germany as Rapporteur Member State. For pyraflufen-ethyl Belgium acted as Rapporteur Member State.

In the series Legal Regulations of the European Union for Plant Protection Products and their Active Substances the following Reports have been published:

Report	**Legal Regulations of the European Union for Plant Protection Products and their Active Substances**	
35/97	Volume A:	Directive 91/414/EEC and respective Protocols (3rd Edition, date: 1 November 1997) *in progress*
68/2000	Volume B:	Regulations and Protocols regarding the Evaluation of Active Substances (4th Edition, date: 1 July 2000) *in progress*
	Volume C:	*in progress*

RICHTLINIE 2001/87/EG DER KOMMISSION

vom 12. Oktober 2001

zur Änderung des Anhangs I der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln zur Aufnahme der Wirkstoffe Acibenzolar-s-methyl, Cyclanilide, Eisen(III)-phosphat, Pymetrozin und Pyraflufen-ethyl

DIE KOMMISSION DER EUROPÄISCHEN GEMEINSCHAFTEN —

gestützt auf den Vertrag zur Gründung der Europäischen Gemeinschaft,

gestützt auf die Richtlinie 91/414/EWG des Rates vom 15. Juli 1991 über das Inverkehrbringen von Pflanzenschutzmitteln [1], zuletzt geändert durch die Richtlinie 2001/49/EG der Kommission [2], insbesondere auf Artikel 6 Absatz 1,

in Erwägung nachstehender Gründe:

(1) Die Behörden Frankreichs haben am 15. Oktober 1996 gemäß Artikel 6 Absatz 2 der Richtlinie 91/414/EWG (im Folgenden „die Richtlinie" genannt) einen Antrag von Novartis — jetzt Syngenta — auf Aufnahme des Wirkstoffs Acibenzolar-s-methyl (CGA 245704) in Anhang I der Richtlinie erhalten. Mit der Entscheidung 97/865/EG der Kommission [3] wurde bestätigt, dass die Unterlagen „vollständig" sind und somit grundsätzlich die Anforderungen der Anhänge II und III der Richtlinie hinsichtlich der Daten und Informationen erfüllen.

(2) Die Behörden Griechenlands haben am 27. März 1996 einen Antrag von Rhône Poulenc Agrochimie SA (jetzt Aventis CropScience) für Cyclanilide (RPA 090946) erhalten. Dieser Antrag wurde mit der Entscheidung 97/137/EG der Kommission [4] für vollständig erklärt.

(3) Deutschland hat am 27. August 1998 einen Antrag von der W. Neudorff GmbH KG für Eisen(III)-phosphat erhalten. Dieser Antrag wurde mit der Entscheidung 1999/43/EG der Kommission [5] für vollständig erklärt.

(4) Deutschland hat darüber hinaus am 4. September 1996 einen Antrag von Novartis für Pymetrozin (CGA 215 944) erhalten. Dieser Antrag wurde mit der Entscheidung 97/865/EG für vollständig erklärt.

(5) Belgien hat am 16. Juni 1997 einen Antrag von Nihon Nohyaku Co. Ltd für Pyraflufen-ethyl erhalten. Dieser Antrag wurde mit der Entscheidung 98/242/EG der Kommission [6] für vollständig erklärt.

(6) Die Auswirkungen dieser fünf Wirkstoffe auf die menschliche Gesundheit und auf die Umwelt wurden gemäß Artikel 6 Absätze 2 und 4 der Richtlinie für die von dem jeweiligen Antragsteller vorgeschlagenen Anwendungen geprüft. Die Bericht erstattenden Mitgliedstaaten haben der Kommission jeweils am 17. Dezember 1998 (Acibenzolar-s-methyl), 11. Februar 1998 (Cyclanilide), 30. Juli 1999 (Eisen(III)-phosphat), 28. Mai 1998 (Pymetrozin) und 8. Juli 1999 (Pyraflufen-ethyl) einen Entwurf des Bewertungsberichts über die Wirkstoffe übermittelt.

(7) Die Entwürfe der Bewertungsberichte wurden von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses für Pflanzenschutz geprüft. Diese Prüfung wurde am 29. Juni 2001 in Form einzelner Beurteilungsberichte der Kommission für Acibenzolar-s-methyl, Cyclanilide, Eisen(III)-phosphat, Pymetrozin und Pyraflufen-ethyl abgeschlossen.

(8) Die Unterlagen und die aus den Prüfungen hervorgegangenen Informationen wurden dem Wissenschaftlichen Ausschuss „Pflanzen" übermittelt. Was Acibenzolar-s-methyl und Eisen(III)-phosphat angeht, so wurden dem Ausschuss keine besonderen Fragen vorgelegt. Der Ausschuss war der Auffassung, dass im Hinblick auf eine mögliche Aufnahme dieser Wirkstoffe in Anhang I der Richtlinie keine Anmerkungen zu machen sind [7]. Er wies darauf hin, dass dies nur als ein Hinweis darauf verstanden werden sollte, dass keine offensichtlichen Gründe für Anmerkungen vorliegen.

(9) In seiner Stellungnahme [8] über Cyclanilide hat der Ausschuss seine Auffassung hinsichtlich bestimmter Auswirkungen auf Mäuse und Kaninchen dargelegt und eine Neubewertung betreffend den Abbau des Bodenmetaboliten 2,4-Dichloranilin empfohlen. Die Empfehlungen des Ausschusses wurden berücksichtigt.

(10) In seiner Stellungnahme [9] über Pymetrozin hat der Ausschuss bestimmte Auswirkungen im Zusammenhang mit der Festlegung einer duldbaren täglichen Aufnahmemenge und einer akuten Referenzdosis für Verbraucher bewertet.

(11) In seiner Stellungnahme [10] über Pyraflufen-ethyl ist der Ausschuss zu dem Schluss gekommen, dass ein im Allgemeinen vernachlässigbares Risiko einer Grundwasserkontamination bei der Grundverbindung und ihren Abbauprodukten besteht. Unter extremen Bedingungen sollte jedoch der Verbleib bestimmter Abbauprodukte sorgfältig geprüft werden.

[1] ABl. L 230 vom 19.8.1991, S. 1.
[2] ABl. L 176 vom 29.6.2001, S. 61.
[3] ABl. L 351 vom 23.12.1997, S. 67.
[4] ABl. L 52 vom 22.2.1997, S. 20.
[5] ABl. L 14 vom 19.1.1999, S. 30.
[6] ABl. L 96 vom 28.3.1998, S. 45.

[7] Bericht über die Plenarsitzung des Wissenschaftlichen Ausschusses „Pflanzen" vom 7. März 2001 (Acibenzolar-s-methyl).
Bericht über die Plenarsitzung des Wissenschaftlichen Ausschusses „Pflanzen" vom 4. Juni 2001 (Eisen(III)-phosphat).
[8] Stellungnahme des Wissenschaftlichen Ausschusses „Pflanzen" hinsichtlich der Bewertung von Cyclanilide im Zusammenhang mit der Richtlinie 91/414/EWG über das Inverkehrbringen von Pflanzenschutzmitteln. SCP/CYCLAN/002-endg. vom 11. Dezember 2000.
[9] Stellungnahme des Wissenschaftlichen Ausschusses „Pflanzen" hinsichtlich der Bewertung von Pymetrozin im Zusammenhang mit der Richtlinie 91/414/EWG über das Inverkehrbringen von Pflanzenschutzmitteln. SCP/PYMETR/002-endg. vom 31. Januar 2001.
[10] Stellungnahme des Wissenschaftlichen Ausschusses „Pflanzen" hinsichtlich der Bewertung von Pyraflufen-ethyl im Zusammenhang mit der Richtlinie 91/414/EWG über das Inverkehrbringen von Pflanzenschutzmitteln. SCP/PYRA/-endg. vom 7 März 2001.

(12) Untersuchungen haben ergeben, dass davon ausgegangen werden kann, dass die betreffenden Wirkstoffe enthaltende Pflanzenschutzmittel im Allgemeinen die Anforderungen gemäß Artikel 5 Absatz 1 Buchstaben a) und b) und Absatz 3 der Richtlinie erfüllen, insbesondere hinsichtlich der geprüften und in den Beurteilungsberichten der Kommission behandelten Anwendungen. Daher sollten die betreffenden Wirkstoffe in Anhang I der Richtlinie aufgenommen werden, damit Pflanzenschutzmittel mit den betreffenden Wirkstoffen in allen Mitgliedstaaten gemäß den Bestimmungen der genannten Richtlinie zugelassen werden können.

(13) Nach der Aufnahme ist den Mitgliedstaaten eine angemessene Frist einzuräumen, um die Bestimmungen der Richtlinie über Pflanzenschutzmittel, die Acibenzolar-s-methyl, Cyclanilide, Eisen(III)-phosphat, Pymetrozin und Pyraflufen-ethyl enthalten, umzusetzen und insbesondere innerhalb dieser Frist bereits bestehende vorläufige Zulassungen zu überprüfen bzw. spätestens vor Ablauf der Frist neue Zulassungen gemäß der Richtlinie zu erteilen. Für Pflanzenschutzmittel, die einen der betreffenden Wirkstoffe und andere in Anhang I aufgeführte Wirkstoffe enthalten, kann auch eine längere Frist erforderlich sein.

(14) Der Beurteilungsbericht ist erforderlich für die ordnungsgemäße Umsetzung bestimmter Teile der einheitlichen Grundsätze gemäß Anhang VI der Richtlinie durch die Mitgliedstaaten, soweit sich diese Grundsätze auf die Bewertung der Angaben beziehen, die zwecks Aufnahme des Wirkstoffs in Anhang I der Richtlinie vorgelegt wurden. Es ist daher vorzuschreiben, dass die Mitgliedstaaten die endgültigen Beurteilungsberichte (mit Ausnahme von vertraulichen Informationen im Sinne des Artikels 14 der Richtlinie) allen Interessierten zur Einsicht zur Verfügung stellen oder zugänglich machen. Muss ein Beurteilungsbericht aktualisiert werden, um technischen und wissenschaftlichen Entwicklungen Rechnung zu tragen, so sollten die Bedingungen für die Aufnahme des betreffenden Wirkstoffs in Anhang I der Richtlinie in Übereinstimmung mit der Richtlinie ebenfalls geändert werden.

(15) Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz —

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

Die Tabelle in Anhang I der Richtlinie 91/414/EWG wird gemäß dem Anhang der vorliegenden Richtlinie geändert.

Artikel 2

(1) Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens 31. März 2002 nachzukommen. Sie unterrichten die Kommission unverzüglich davon.

Bei Erlass dieser Vorschriften nehmen die Mitgliedstaaten in den Vorschriften selbst oder durch einen Hinweis bei der amtlichen Veröffentlichung auf diese Richtlinie Bezug. Die Mitgliedstaaten regeln die Einzelheiten der Bezugnahme.

(2) Hinsichtlich der Beurteilung und Entscheidungsfindung gemäß den einheitlichen Grundsätzen von Anhang VI der Richtlinie 91/414/EWG wird der in Absatz 1 festgesetzte Zeitraum jedoch auf der Grundlage von Unterlagen, die die Anforderungen von Anhang III derselben Richtlinie erfüllen, für vorläufige Zulassungen von Pflanzenschutzmitteln, die Acibenzolar-s-methyl, Cyclanilide, Eisen(III)-phosphat, Pymetrozin und Pyraflufen-ethyl enthalten, bis zum 31. März 2003 verlängert.

(3) Bei Pflanzenschutzmitteln, die Acibenzolar-s-methyl, Cyclanilide, Eisen(III)-phosphat, Pymetrozin oder Pyraflufen-ethyl zusammen mit einem anderen in Anhang I der Richtlinie 91/414/EWG aufgeführten Wirkstoff enthalten, wird der Zeitraum gemäß Absatz 1 jedoch insoweit verlängert, als die Vorschriften der Richtlinie über die Änderung des genannten Anhangs I eine längere Umsetzungsfrist vorsehen, um den Wirkstoff in den Anhang aufzunehmen.

(4) Die Mitgliedstaaten stellen die Beurteilungsberichte für Acibenzolar-s-methyl, Cyclanilide, Eisen(III)-phosphat, Pymetrozin und Pyraflufen-ethyl (mit Ausnahme von vertraulichen Informationen im Sinne des Artikels 14 der Richtlinie) allen Interessierten zur Einsicht zur Verfügung oder machen sie gegebenenfalls auf besonderen Antrag zugänglich.

Artikel 3

Diese Richtlinie tritt am 1. November 2001 in Kraft.

Artikel 4

Diese Richtlinie ist in alle Mitgliedstaaten gerichtet.

Brüssel, den 12. Oktober 2001

Für die Kommission

David BYRNE

Mitglied der Kommission

ANHANG

IN DIE TABELLE IN ANHANG I DER RICHTLINIE 91/414/EWG AUFZUNEHMENDE EINTRÄGE

Nr.	Gebräuchliche Bezeichnung, Kennnummern	IUPAC-Bezeichnung	Reinheit (1)	Inkrafttreten	Aufnahme befristet bis	Besondere Bedingungen
„20	Acibenzolar-s-methyl CAS Nr. 135158-54-2 CICAP Nr. 597	Benzo[1,2,3]tiadiazol-7-carbothioat-s-methyl	970 g/kg	1. November 2001	31. Oktober 2011	Nur Verwendungen als Pflanzenaktivator dürfen zugelassen werden Der Beurteilungsbericht wurde vom Ständigen Ausschuss für Pflanzenschutz am 29. Juni 2001 abgeschlossen
21	Cyclanilide CAS Nr. 113136-77-9 CICAP Nr. 586	Nicht verfügbar	960 g/kg	1. November 2001	31. Oktober 2011	Nur Verwendungen als Wachstumsregler dürfen zugelassen werden Der Höchstgehalt der Verunreinigung 2,4-Dichloroanilin (2,4-DCA) im hergestellten Wirkstoff sollte sich auf 1 g/kg belaufen Der Beurteilungsbericht wurde vom Ständigen Ausschuss für Pflanzenschutz am 29. Juni 2001 abgeschlossen
22	Eisen(III)-phosphat CAS Nr. 10045-86-0 CICAP Nr. 629	Eisen(III)-phosphat	990 g/kg	1. November 2001	31. Oktober 2011	Nur Verwendungen als Molluscizid dürfen zugelassen werden Der Beurteilungsbericht wurde vom Ständigen Ausschuss für Pflanzenschutz am 29. Juni 2001 abgeschlossen
23	Pymetrozin CAS Nr. 123312-89-0 CICAP Nr. 593	(*E*)-6-methyl-4-[(pyridin-3-ylmethylen)amino]-4,5-dihydro-2H-[1,2,4]-triazin-3-one	950 g/kg	1. November 2001	31. Oktober 2011	Nur Verwendungen als Insektizid dürfen zugelassen werden Bei der Entscheidungsfindung gemäß den einheitlichen Grundsätzen müssen die Mitgliedstaaten dem Schutz von Wasserorganismen besondere Aufmerksamkeit widmen Der Beurteilungsbericht wurde vom Ständigen Ausschuss für Pflanzenschutz am 29. Juni 2001 abgeschlossen

Nr.	Gebräuchliche Bezeichnung, Kennnummern	IUPAC-Bezeichnung	Reinheit (1)	Inkrafttreten	Aufnahme befristet bis	Besondere Bedingungen
24	Pyraflufen-ethyl CAS Nr. 129630-19-9 CICAP Nr. 605	Ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetat	956 g/kg	1. November 2001	31. Oktober 2011	Nur Verwendungen als Herbizid dürfen zugelassen werden Bei der Entscheidungsfindung gemäß den einheitlichen Grundsätzen müssen die Mitgliedstaaten dem Schutz von Algen und Wasserpflanzen besondere Aufmerksamkeit wirdmen und sollten gegebenenfalls Maßnahmen zur Risikominderung treffen Der Beurteilungsbericht wurde vom Ständigen Ausschuss für Pflanzenschutz am 29. Juni 2001 abgeschlossen

(1) Weitere Einzelheiten hinsichtlich der Identität und Spezifikation des Wirkstoffs sind dem Beurteilungsbericht zu entnehmen."

COMMISSION DIRECTIVE 2001/87/EC

of 12 October 2001

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymetrozine and pyraflufen-ethyl 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 2001/49/EC [2], and in particular Article 6(1) thereof,

Whereas:

(1) In accordance with Article 6(2) of Directive 91/414/EEC (hereinafter referred to as 'the Directive') France received on 15 October 1996 an application from Novartis (now Syngenta) for the inclusion of the active substance acibenzolar-s-methyl (CGA 245704) in Annex I to the Directive. By Commission Decision 97/865/EC [3] it was confirmed that the dossier was 'complete' i.e. it could be considered as satisfying, in principle, the data and information requirements of Annex II and Annex III to the Directive.

(2) Greece received a similar application on 27 March 1996 from Rhône Poulenc Agrochimie SA (now Aventis CropScience), concerning cyclanilide (RPA 090946). This application was declared complete by Commission Decision 97/137/EC [4].

(3) On 27 August 1998, Germany received an application from W. Neudorff GmbH KG, concerning ferric phosphate. This application was declared complete by Commission Decision 1999/43/EC [5].

(4) Germany also received on 4 September 1996 an application from Novartis concerning pymetrozine (CGA 215944). By Commission Decision 97/865/EC this application was declared complete.

(5) On 16 June 1997, Belgium received an application from Nihon Nohyaku Co. Ltd, concerning pyraflufen-ethyl. This application was declared complete by Commission Decision 98/242/EC [6].

(6) For these five 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 the Directive, for the uses proposed by the respective applicant. The nominated rapporteur Member States, submitted draft assessment reports concerning the substances to the Commission on 17 December 1998 (acibenzolar-s-methyl), 11 February 1998 (cyclanilide), 30 July 1999 (ferric phosphate), 28 May 1998 (pymethrozine) and 8 July 1999 (pyraflufen-ethyl), respectively.

(7) The draft assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. The reviews were finalised on 29 June 2001 in the format of the individual Commission review reports for acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymethrozine and pyraflufen-ethyl.

(8) The dossier and the information from each of the reviews were submitted to the Scientific Committee for Plants. As regards acibenzolar-s-methyl and ferric phosphate, no specific questions were addressed to the Committee. The Committee considered that there were no issues that it wished to raise regarding the active substances in the context of a possible inclusion in Annex I to the Directive [7]. The Committee noted that absence of comment should only be interpreted as an indication of no obvious reasons necessitating comment.

(9) In its opinion [8] concerning cyclanilide the Committee provided its interpretation of certain effects observed in mice and rabbits and recommended a reassessment of the degradation of the soil metabolite 2,4-dichloraniline. The recommendations of the Committee have been taken into consideration.

(10) In its opinion [9] on pymetrozine the Committee assessed certain effects in the context of deriving an acceptable daily intake and an acute reference dose for consumers.

(11) In its opinion [10] on pyraflufen-ethyl the Committee concluded that there is generally negligible risk of groundwater contamination for the parent compound and its breakdown products. However, under extreme conditions the fate of certain breakdown products should be assessed carefully.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 176, 29.6.2001, p. 61.
[3] OJ L 351, 23.12.1997, p. 67.
[4] OJ L 52, 22.2.1997, p. 20.
[5] OJ L 14, 19.1.1999, p. 30.
[6] OJ L 96, 28.3.1998, p. 45.

[7] Minutes of the plenary meeting of the Scientific Committee for Plants from 7 March 2001 (acibenzolar-s-methyl).
Minutes of the plenary meeting of the Scientific Committee for Plants from 4 June 2001 (ferric phosphate).

[8] Opinion of the Scientific Committee for Plants regarding the evaluation of cyclanilide in the context of Directive 91/414/EEC concerning the placing of plant protection products on the market. SCP/CYCLAN/002-final dated 11 December 2000.

[9] Opinion of the Scientific Committee for Plants regarding the evaluation of pymetrozine in the context of Directive 91/414/EEC concerning the placing of plant protection products on the market. SCP/PYMETR/002-final dated 31 January 2001.

[10] Opinion of the Scientific Committee for Plants regarding the evaluation of pyraflufen-ethyl in the context of Directive 91/414/EEC concerning the placing of plant protection products on the market. SCP/PYRA/-final dated 7 March 2001.

(12) It has appeared from the various examinations made that plant protection products containing any of the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a), (b) and (3) of the Directive, in particular with regard to the uses which were examined and detailed in the respective 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.

(13) After inclusion, a reasonable period is necessary to permit Member States to implement the provisions of the Directive on plant protection products containing acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymetrozine or pyraflufen-ethyl and in particular to review, within this period, existing provisional authorisations or to grant, by the end of this period at the latest, new authorisations in accordance with the provisions of the Directive. A longer period may also be required for plant protection products containing any of the active substances concerned and other active substances included in Annex I.

(14) The review report is required for the proper implementation by the Member States, of several sections of the uniform principles laid down in Annex VI to the Directive, where those principles refer to the evaluation of the data which were submitted for the purpose of the inclusion of the active substance in Annex I to the Directive. It is, therefore, appropriate to provide that the finalised review reports (except for confidential information in the meaning of Article 14 of the Directive) are kept available or made available by the Member States for consultation by any interested parties. If a review report has to be updated to take account of technical and scientific developments, the conditions for the inclusion of the active substance concerned in Annex I to the Directive should also be amended in accordance with the Directive.

(15) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The table in Annex I to Directive 91/414/EEC shall be amended as set out in the Annex hereto.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive, at the latest by 31 March 2002. They shall forthwith inform the Commission thereof.

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.

2. However, with regard to evaluation and decision-making pursuant to 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, the period laid down in the first paragraph is extended for existing provisional authorisations of plant protection products containing acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymetrozine or pyraflufen-ethyl to 31 March 2003.

3. However for plant protection products containing acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymetrozine or pyraflufen-ethyl together with another active substance which is in Annex I to Directive 91/414/EEC, the period referred to in paragraph 1 is extended to the extent that a longer implementation period is provided for by the provisions laid down in the Directive amending Annex I to Directive 91/414/EEC to include the substance in the Annex.

4. Member States shall keep available the review reports for acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymetrozine and pyraflufen-ethyl (except for confidential information within the meaning of Article 14 of the Directive) for consultation by any interested parties or shall make it available to them on specific request.

Article 3

This Directive shall enter into force on 1 November 2001.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 12 October 2001.

For the Commission

David BYRNE

Member of the Commission

ANNEX

ENTRIES TO BE INSERTED IN 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
'20	Acibenzolar-s-methyl CAS No 135158-54-2 CIPAC No 597	Benzo[1,2,3]thiadiazole-7-carbothioic acid S-methyl ester	970 g/kg	1 November 2001	31 October 2011	Only uses as a plant activator may be authorised. Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001.
21	Cyclanilide CAS No 113136-77-9 CIPAC No 586	Not available	960 g/kg	1 November 2001	31 October 2011	Only uses as a plant growth regulator may be authorised. The maximum content of the impurity 2,4-dichloroaniline (2,4-DCA) in the active substance as manufactured should be 1 g/kg. Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001.
22	Ferric phosphate CAS No 10045-86-0 CIPAC No 629	Ferric phosphate	990 g/kg	1 November 2001	31 October 2011	Only uses as a molluscicide may be authorised. Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001
23	Pymetrozine CAS No 123312-89-0 CIPAC No 593	(*E*)-6-methyl-4-[(pyridin-3-ylmetylene)amino]-4,5-dihydro-2H-[1,2,4]-triazin-3 one	950 g/kg	1 November 2001	31 October 2011	Only uses as an insecticide may be authorised. In decision-making according to the uniform principles Member States must pay particular attention to the protection of aquatic organisms. Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
24	Pyraflufen-ethyl CAS No 129630-19-9 CIPAC No 605	Ethyl-2-chloro-5-(4-chloro-5-difluoromethoxy-1-mhypyrazol-3-yl)-4-fluorophenoxyacetate	956 g/kg	1 November 2001	31 October 2011	Only uses as a herbicide may be authorised. In decision-making according to the uniform principles Member States must pay particular attention to the protection of algae and aquatic plants and should apply, where appropriate, risk mitigation measures. Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001.

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

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Food Safety: plant health, animal health and welfare, international questions
E1 - Plant health

COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

Review report for the active substance pyraflufen-ethyl

Finalised in the Standing Committee on Plant Health at its meeting on 29 June 2001 in view of the inclusion of Pyraflufen-ethyl in Annex I of Directive 91/414/EEC.

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance pyraflufen-ethyl, made in the context of the work provided for in Articles 5 and 6 of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the Belgian authorities received on 16 June 1997 an application from Nihon Nohyaku Co. Ltd., hereafter referred to as the applicant, for the inclusion of the active substance Pyraflufen-ethyl in Annex I to the Directive. Belgian authorities indicated to the Commission on 2 December 1997 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on Pyraflufen-ethyl was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on Plant Health in the meeting of the working group 'legislation' thereof on 16 December 1997, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 98/242[1] of 20 March 1998 that these requirements were satisfied.

[1] OJ No L96, 28.03.1998, p.45.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that Belgium would, as rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to the Commission as soon as possible and at the latest within a period of one year.

Belgium submitted to the Commission on 8 July 1999 the report of its detailed scientific examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of Pyraflufen-ethyl in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States as well as to Nihon Nohyaku Co. Ltd. being the applicant on 20 September 1999.

The Commission organised further an intensive consultation of specialised scientific experts from a representative number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines :

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, from November 1999 to July 2000.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 15 June 2001.

The dossier, draft assessment report and the peer review report (i.e. full report) including in particular an outline resumé of the remaining technical questions, were referred to the Standing Committee on Plant Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from July 2000 to June 2001, and was finalised in the meeting of the Standing Committee on 29 June 2001.

The present review report contains the conclusions of this final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

These documents were also submitted to the Scientific Committee for Plants for separate consultation. The report of this Committee was formally adopted on 7 March 2001. (SCP/PYRA/final [2]).

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive 2001/87/EC[3] concerning the inclusion of Pyraflufen-ethyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing Pyraflufen-ethyl they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to the applicant.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated possession of regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing Pyraflufen-ethyl will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each Pyraflufen-ethyl containing plant protection product for which Member States will grant or review the authorisation.

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[2] Opinion of the scientific Committee on Plants regarding the inclusion of pyraflufen-ethyl in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. Opinion adopted 7 March 2001.

[3] OJ L276, 19.10.2001, p.17

Furthermore, these conclusions were reached within the framework of the following uses which were proposed and supported by the sole submitter:

- herbicide use in cereals

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

4. Specific conclusions which are highlighted in this evaluation

4.1 Residues of pyraflufen-ethyl in foodstuffs

The review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI) for a 60 kg adult is 0.033 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This low intake value reflects the current limited use pattern for this active substance.

4.2 Exposure of operators, workers and bystanders

The review has identified acceptable exposure scenarios for operators, workers and bystanders, which require, however, confirmation for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

4.3 Ecotoxicology

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 7 of this report.

5. Identity and Physical/chemical properties

The identity and the main physical/chemical properties of Pyraflufen-ethyl are given in Appendix I.

The active substance shall have a minimum purity of 956 g/kg technical product.

The review has established that for the active substance notified by the applicant (Nihon Nohyaku Co. Ltd.), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

6. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints as identified during the evaluation process are listed in Appendix II.

7. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing pyraflufen-ethyl

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term (within 12 months at the latest) attention from the Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- Member States must pay particular attention to the protection of algae and aquatic plants and should apply, where appropriate, risk mitigation measures.
- The acid metabolite (designated as E1) has a potential for leaching which might require particular attention in vulnerable areas to ensure protection of groundwater.

8. List of studies to be generated

No further studies were identified which were considered at this stage, and under the current inclusion conditions necessary in relation to the inclusion of Pyraflufen-ethyl in Annex I.

9. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the applicant has claimed data protection and which are not present in the original dossier neither mentioned in the draft review report. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the time this review report was prepared; but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

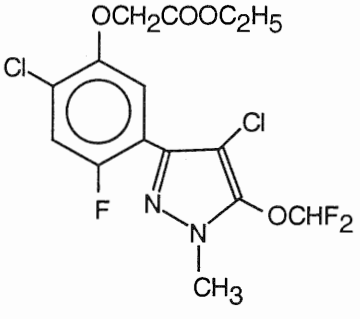
10. Updating of this review report

The technical information in this report may require periodic updating to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on Plant Health, in connection with any amendment of the inclusion conditions for Pyraflufen-ethyl in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

Pyraflufen-ethyl

Common name (ISO)	Pyraflufen-ethyl
Chemical name (IUPAC)	Ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetate
Chemical name (CA)	Ethyl 2-chloro-5-[4-chloro-(5-difluoromethoxy)-1methyl-1*H*–pyrazol-3-yl]-4-fluorophenoxyacetate
CIPAC No	605
CAS No	129630-19-9
EEC No	Not allocated
FAO SPECIFICATION	No FAO specification
Minimum purity	956 g/kg
Molecular formula	$C_{15}H_{13}Cl_2F_3N_2O_4$
Molecular mass	413.18
Structural formula	

Melting point	126.4-127.2 °C (99.4% purity)
Boiling point	Not determinable due to decomposition above its melting point (99.4% purity).
Appearance	Fine white powder, without significant odour (99.4% purity); Fine cream coloured powder (some claying present), without significant odour (97.7% purity)
Relative density	1.565 at 24 °C (99.4% purity)
Vapour pressure	1.6 10^{-8} Pa (25°C) 4.3 10^{-9} Pa (20°C)
Henry's law constant	2.2 10^{-5} Pa.m^3/mol (20°C)
Solubility in water	pH 7, 20°C: 0.082 mg/l
Solubility in organic solvents	at 20°C (97.7% purity): n-heptane: 234 mg/l p-xylene: 41.7 to 43.5 g/l 1,2-dichloromethane:100 to 111 g/l methanol: 7.39 g/l acetone: 167 to 182 g/l ethyl acetate: 105 to 111 g/l
Partition co-efficient (log P_{ow})	pH 7, ambient temperature: log Pow = 3.49
Hydrolytic stability (DT_{50})	pH 4: hydrolytically stable pH 9: rapid hydrolysis (DT50 at 50°C < 2.4 h) pH 7, 25°C: DT50 = 13.1 d
Dissociation constant	Not applicable
Quantum yield of direct photo-transformation in water at e >290 nm	f = 1.07%
Flammability	Not highly flammable.
Explosive properties	Not explosive.
UV/VIS absorption (max.)	l= 203 nm : e = 28700 l.mol^{-1}.cm^{-1} l= 243 nm : e = 12800 l.mol^{-1}.cm^{-1} l= 291 nm : e = 5900 l.mol^{-1}.cm^{-1} No further maxima between 291 and 700 nm.
Photostability in water (DT50)	pH 5, 20°C, Xenon lamp : DT50 = 30 h

APPENDIX II

END POINTS AND RELATED INFORMATION

Pyraflufen-ethyl

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid, dose-dependent; 56 % (urine + bile) after low dose within 2 days.
Distribution:	At 6 h, highest residues in GI tract, liver and excretory organs.
Potential for accumulation:	No accumulation
Rate and extent of excretion:	95-100 % in 24 h (70 % via feces ; 30% urinary)
Toxicologically significant compounds:	Parent compound, metabolites E1 and E9 Metabolism in plants and animals is similar.
Metabolism in animals:	Ester hydrolysis; N-demethylation < 1% absorbed dose eliminated unchanged

Acute toxicity

Rat LD50 oral:	> 5000 mg/kg bw
Rat LD50 dermal:	>2000 mg/kg bw
Rat LC50 inhalation:	> 5.03 mg/l
Skin irritation:	Non-irritant
Eye irritation:	Non-irritant
Skin sensitization (test method used and result):	Not sensitising (Maximisation test)

Short term toxicity

Target / critical effect:	Liver, kidney, red blood cells
Lowest relevant oral NOAEL / NOEL:	200 ppm (20 mg/kg bw/d) 90 day mouse (satellite group in 78 wk study)
Lowest relevant dermal NOAEL / NOEL:	No data, not necessary
Lowest relevant inhalation NOAEL / NOEL:	No data, not necessary

Genotoxicity	Not genotoxic

Long term toxicity and carcinogenicity

Target / critical effect:	Red blood cells and liver in mice, urinary and biliary tract in rats.

Lowest relevant NOAEL:	200 ppm (20 mg/kg bw/d) 2 year mice study 400 ppm (20 mg/kg bw/d) 2 year rat study
Carcinogenicity:	Increased incidence of hepatocellular adenomas in mice at hepatotoxic doses, not carcinogenic in rats. Classification and labelling not appropriate.

Reproductive toxicity

Target / critical effect - Reproduction:	Reduced body weight gain of pups during lactation at parental toxic doses.
Lowest relevant reproductive NOAEL / NOEL:	NOAELsyst.tox = 1000 ppm (70.8 mg/kg bw/d) NOAELreprotox = 1000ppm (70.8 mg/kg bw/d)
Target / critical effect - Developmental toxicity:	Implantation loss and retardations in rabbits at maternally toxic doses (mortality).
Lowest relevant developmental NOAEL / NOEL:	20 mg/kg bw/d

Delayed neurotoxicity	No data, not necessary
Other toxicological studies	Accumulation of porphyrins in all organs except skin and Harderian glands. Inhibitor of some liver P450 dependent activities ; inhibitor of catalase. Induction of liver single cell necrosis followed by mitosis.
Medical data	No detrimental effects on health were found in participating personnel in manufacturing of pyraflufen-ethyl.

Summary

	Value	Study	Safety factor
ADI:	0.2 mg/kg bw/d	NOAEL from 2 year rat, mice study	100
AOEL systemic:	0.112 mg/kg bw/d	90 day satellite groups of 78 wk mouse carcinogenicity study	100 x 56%
AOEL inhalation:	Not necessary		
AOEL dermal:	Not necessary		
ARfD (acute reference dose):	0.2 mg/kg bw/d	Same basis as ADI and AOEL supported by rabbit teratogenesis study.	100

Dermal absorption	No studies; dermal absorption not higher than oral absorption (56%).

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	2.53%
Non-extractable residues after 100 days:	17%
Relevant metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	E-1 (max 94% at d 1), E-2 (max 14-19%), E-3 (max 56-69%), Structure of unknown2 (10%) is rather similar to the a.s. and the 3 main metabolites.

Supplemental studies

Anaerobic:	E-1 major degradation product (max 99%) E-2 (max 28%) 2.04% bound residue 0.2% mineralization
Soil photolysis:	No photodegradation : DT50 = 299 d
Remarks:	None

Rate of degradation

Laboratory studies

DT50lab (20 °C, aerobic):	a.s.: < 0.5 d (4 values) E-1: 16-53 d (4 values) E-2: 6-11 d (3 values) E-3: 153-496 d (3 values)
DT90lab (20 °C, aerobic):	a.s.: 0.8-4.0 d (4 values) E-1: 52-175 d (4 values) E-2: 20-36 d (3 values) E-3: 509-1648 d (3 values)
DT50lab (10 °C, aerobic):	a.s.: 1 d (1 value) E-1: 328 d (1 value)
DT50lab (20 °C, anaerobic):	a.s.: 1 d (1 value) E-1: 191 d (1 value) E-2: 392 d (1 value)

Field studies (country or region)

DT50f from soil dissipation studies:	a.s., spring: 1-7 d (4 sites in FR, UK, DE) a.s., fall: 1-3 d (4 sites in FR, UK, DE) E-1, spring: 11-44 d (4 sites in FR, UK, DE) E-1, fall: 35-71 d (4 sites in FR, UK, DE)
DT90f from soil dissipation studies:	a.s., spring: 3-23 d (4 sites in FR, UK, DE) a.s., fall: 3-10 d (4 sites in FR, UK, DE) E-1, spring: 121-345 d (4 sites in Fr, UK, DE) E-1, fall: 115-236 d (4 sites in Fr, UK, DE) Max level E-2: 0.01 mg /kg soil Max level E-3: 0.01-0.05 mg /kg soil
Soil accumulation studies:	Not required
Soil residue studies:	Not required

Remarks: e.g. effect of soil pH on degradation rate	None

Adsorption/desorption

Kf / Koc: Kd pH dependence:	Koc (a.s., HPLC) = 1949 Kf (E-1, 3 soils) = 2.21-3.02; Koc = 81-197 Kf (E-2, 3 soils) = 26.15-52.68; Koc = 1424-2179 Kf (E-3, 3 soils) = 52.24-114.62; Koc = 3098-4354 No

Mobility

Laboratory studies:

Column leaching:	0.2 % RR in the leachate
Aged residue leaching:	0.5 % RR in the leachate

Field studies:

Lysimeter/Field leaching studies:	Not required

Remarks:	None

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	a.s. (pH 7, 25°C): 13.1 d a.s. hydrolytically stable at pH 4, rapidly hydrolyzed at pH 9.
Relevant metabolites:	The only hydrolysis product E-1 is stable at pH 4-7-9.
Photolytic degradation:	a.s. (20°C): 30 h (major degradate : PD1) E-1 (25°C): 22.1 h E-2 (25°C): 8.7 h E-3 (25°C): 29.1 h
Relevant metabolites:	E-1, E-2

Biological degradation

Readily biodegradable:	No
Water/sediment study:	
DT50 water:	a.s.: 1-2 h, E-1 = 50-100 d,
DT90 water:	a.s.: 4-7 h
DT50 whole system:	a.s.: 2-2h
DT90 whole system:	a.s.: 6-7 h
Distribution in water / sediment systems (active substance)	a.s. mainly in water phase
Distribution in water / sediment systems (metabolites)	E-1: mainly in water phase (83-94% after 1 d, 11-42% after 100 d) E-2: mainly in sediment phase (20-54% after 100 d) E-3: mainly in sediment phase (6-7% after 100 d)
Accumulation in water and/or sediment:	No

Degradation in the saturated zone	Not required
Remarks:	None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	1.6 10-8 Pa (25°C) 4.3 10-9 Pa (20°C)
Henry's law constant:	2.2 10-5 Pa.m3/mol (20°C)

Photolytic degradation

Direct photolysis in air:	DT50 : 11.3 h
Photochemical oxidative degradation in air DT50:	Latitude: 52° N Season: June DT50 : 33 h
Volatilisation:	No volatilisation from plant surfaces or soil.

Remarks:	None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 > 5000 mg/kg bw
Acute toxicity to birds:	LD50 > 2000 mg/kg bw
Dietary toxicity to birds:	LC50 > 5000 mg/kg food
Reproductive toxicity to birds:	NOEC = 50 mg a.s./kg food
Reproductive toxicity to mammals:	NOAEL= 1000 mg a.s./kg food (70.8 mg/kg bw/d)

Aquatic Organisms

Acute toxicity fish:	a.s.: LC50 > 100 µg/l (96 h; *Oncorhynchus mykiss)* E-1: LC50 > 100 000 µg/l (96 h; *Lepomis macrochirus*) EXP31279A*: LC 50 > 60 000 µg/l (96 h; *Oncorhynchus mykiss*)
Long term toxicity fish:	E-1: NOEC = 10 000 µg/l (36 d; *Pimephales promelas*)
Bioaccumulation fish:	a.s.: BCF is not relevant (DT50 = 2h) E-1: BCF = 2.4
Acute toxicity invertebrate:	a.s. : EC50 > 100 µg/l (48 h; *Daphnia magna*) E-1: EC50 > 120 000 µg/l (48 h; *D. magna*) EXP31279A*: EC50 > 15 000 µg/l (48 h; *D. magna*)
Chronic toxicity invertebrate:	E-1: NOEC = 100 000 µg/l (21 d; *D. magna*)
Acute toxicity algae:	a.s. : EC50 = 0.23 µg/l (72 h; *Selenastrum capricornutum*) E-1: EC50 = 2.2 µg/l (72 h; *S. capricornutum*) E-2: EC50 = 0.16 µg/l (72 h; *S. capricornutum)* EXP31279A*: EC50 = 0.48 µg/l (72 h; *S. capricornutum*)
Chronic toxicity sediment dwelling organism:	Not required
Acute toxicity aquatic plants:	E-1: EC50 = 2.6 µg/l (14 d; *Lemna gibba*)

*EXP31279A (SC containing 9 g/l pyraflufen-ethyl and 500 g/l bifenox)

Honeybees

Acute oral toxicity:	LD50 > 100 µg/bee
Acute contact toxicity:	LD50 > 100 µg/bee

Other arthropod species

	1.33 l formulation /ha
Aphidius rhopalosiphi	Beneficial capacity: 2.1 % effect (adults; formulation, 1.33 l/ha)
Typhlodromus pyri	Beneficial capacity: 100 % effect (protonymphs; formulation, 1.33 l/ha)
Pardosa amentata	Mortality: 29.4 % (adults; formulation, 1.33 l/ha)
Poecilus cupreus	Mortality: 3.3 % (adults; formulation, 1.33 l/ha)
Chrysoperla carnea	Beneficial capacity: 32.6 % effect (24 h old larvae; formulation, 1.33 l/ha)
Coccinella septempunctata	Beneficial capacity: 33.04 % effect (3 d old larvae; formulation, 1.33 l/ha)
Typhlodromus pyri	Mortality: 42.7 % effect Reproduction: no effect (protonymphs; formulation, 5 % of 1.33 l/ha)
Extended laboratory test: *Hypoaspis aculeifer (Acari, Laelapidae)*	Mortality: 2 % Egg production: 25 % (protonymphs; formulation, 1.5 l/ha) Mortality: 4 % Egg production: 0.3 % (protonymphs; formulation, 4 % of 1.5 l/ha)

Earthworms

Acute toxicity:	LC 50 > 1000 mg a.s./kg soil
Reproductive toxicity:	Not required

Soil micro-organisms

Nitrogen mineralization:	Negligible effects at 20 and 100 g a.s./ha (1.5 and 7.4 times the application rate of 13.5 g a.s./ha)
Carbon mineralization:	Negligible effects at 20 and 100 g a.s./ha (1.5 and 7.4 times the application rate of 13.5 g a.s./ha)

APPENDIX III

Pyraflufen-ethyl

List of studies which were submitted during the evaluation process and were not cited in the draft assessment report:

New references submitted after completion of the monograph.

Author(s)	Year	Annex IIA Point Title Company, Report No.	GLP GEP Y/N	Published or not Y/N	Owner
Stumpf, K.	2000	Annex IIA.4.2.2 Proposed Analytical Method for Pyraflufen-ethyl (ET-751) and Metabolites E-1, E-2 and E-3 in Soil Using GC/NPD 26 April 2000 Aventis CropScience, report n°: PSR00/006	Y	N	ACS
Tran Thanh Phong, J.	1999	Annex IIA.2.15 Determination of the oxidizing properties of technical pyraflufen-ethyl-first amendment 25 November 1999 Rhone Poulenc, report n°: 99-267-EC	Y	Y	RPA
Ulf, Lührs	1999	Annex IIA.8.3.2 Effects of EXP 31279A on the predatory mite *Thyphlodromus pyri* Scheuten (Acari, Phytoseiidae) in the Laboratory 13 April 1999 Rhone Poulenc , report n°: C008209	Y	N	RPA
Pascual, Juan	1999	Annex IIA.8.3.2 An extended laboratory study to evaluate the effect of EXP31279A on the predaceous mite *Hypoaspis aculeifer* Canestrini (Acari, Laelapidae) 15 December 1999 Rhone Poulenc, report n°: RP001HAE	Y	N	RPA
Kudo, M.	1996	Annex IIA.1/IIIA.1 Identity of the active substance and plant protection product Nihon Nohyaku, Document J	Y	N	NN
Kudo, M.	1997	Annex IIA.1.11 Analytical Profile of Batches of ET-751 Technicals 12 February 1997 Nihon Nohyaku, report n°: GE-23 96-0154	Y	N	NN

Author(s)	Year	Annex IIA Point Title Company, Report No.	GLP GEP Y/N	Published or not Y/N	Owner
Souvignet-bairrère, J. / Stumpf, K.	2000	Annex IIA.6.3 Storage stability in wheat grain and straw and wheat or barley shoot over a time period of 18 months at about -18°C. Pyraflufen-ethyl (ET-751) code : AE F116624 report n°: PSROO/004	Y	N	ACS
Quintelas, G.	2000	Annex IIA.6.3 Stability of ET-751 in wheat (grain, straw and shoot) after storage at -18°C. Study n° : RPA/P6-036	Y	N	RPA
Quintelas, G.	2000	Annex IIA.6.3 Stability of E-I in wheat (grain and straw) and barley (shoot) after storage at -18°C. Study n°: RPA/96-051	Y	N	RPA
Clarke, D.E.	1998	Annex IIA.6.6 [^{14}C]-ET-751 : A confined Rotational Crop Study using Radishes, lettuces and barley. Report n° : C007850	Y	Y	NN

The abbreviations ACS (Aventis Crop Sciences) , RPA (Rhône-Poulenc Agro), NN (Nihon Nohyaku) refer to one dossier (Joint submission of the dossier by RPA and NN, afterwards merging of RPA in ACS)

SUMMARY REPORT
OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH
HELD ON 29 JUNE 2001 IN STOCKHOLM

President : G. Del Bino
All Member States were present.

1 **Examination and possible vote on a draft Commission Directive concerning the inclusion of Pyraflufen in Annex 1 to Council Directive 91/414/EEC** (Sanco/1524/2001 rev. 6; Review Report Sanco/3039/99 rev. 8).

The Commission presented the Review Report in document 3039/99 rev. 8. The Committee took note of the Review Report.

The following declaration was made:

Commission: At the adoption of the Uniform Principles by Council in 1997, the Council and Commission agreed to the following declaration:

"The Council and the Commission note that application of this Directive is without prejudice to the legislation in force concerning the protection of workers. The Council and the Commission state that this principle will be unequivocally clarified in Directive 91/414/EEC on the occasion of the first amendment of that Directive. The Commission intends to submit a proposal for such amendment within one year from the date of notification of this Directive."

The Commission can for its part confirm its agreement with this declaration (subject to adequate adaptation of the deadline in the declaration).

The Commission presented the draft Directive.

Vote : favourable opinion by unanimity.

The substance is a new active substance to be used as herbicide.

The measures on which the Committee has given its opinion are subject to the appropriate procedures for formal adoption by the Commission.

A CHECCHI LANG
Director

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C3 - Management of scientific committees II; scientific co-operation and networks

SCIENTIFIC COMMITTEE ON PLANTS

SCP/PYRAF/002-Final
28 March 2001

OPINION ON THE EVALUATION OF PYRAFLUFEN-ETHYL [ET-751] IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

(Opinion expressed by the Scientific Committee on Plants, 7 March 2001)

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1. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE EVALUATION OF PYRAFLUFEN-ETHYL [ET-751] IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC CONCERNINGTHE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

(Opinion expressed by the Scientific Committee on Plants, 7 March 2001)

2. TERMS OF REFERENCE

The Scientific Committee on Plants (SCP) is requested to respond to the following question in the context of the Commission' work on the implementation of Council Directive 91/414/EEC concerning the placing of plant protection products on the market.

In the context of the proposed uses, can the Committee comment on the risk of ground water contamination in particular in relation to metabolite E1?

3. BACKGROUND

Pyraflufen-ethyl [ET-751] is a new active substance (a.s.) in the context of Council Directive 91/414/EEC[1]. The draft Commission Directive for the inclusion of pyraflufen-ethyl in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market was submitted to the Committee for opinion. The Committee had been supplied with documentation comprising a draft evaluation report (monograph) prepared by the Rapporteur Member States (Belgium) based on a dossier submitted by the notifier (Nihon Nohayaku), a review report prepared by the Commission and the Recommendations of the ECCO[2] Peer Review Programme.

Pyraflufen-ethyl is a new herbicide of the peroxidizing herbicides. Pyraflufen is effective against broad-leaved weeds. It is intended for use in cereal crops at a rate ranging from 9 to 13.5 g a.s./ha in association with other herbicides.

4. OPINION

QUESTION:

"In the context of the proposed uses, can the Committee comment on the risk of ground water contamination in particular in relation to metabolite E1?"

[1] OJ N° L 230, 19. 8.1991, p. 1.
[2] European Commission Co-ordination.

OPINION OF THE COMMITTEE:

The Committee concludes that groundwater concentrations of the metabolite E1 will usually be lower than 0.01 µg/l although values in the range from 0.01 to 0.1 µg/l cannot be excluded in exceptional cases (for two out of nine realistic worst-case scenarios values in range from 0.01 to 0.04 µg/l were found). It is unlikely that concentrations of E1 will exceed 0.1 µg/l. There is negligible risk of groundwater contamination for the parent compound and groundwater concentrations for other metabolites are expected to be considerably lower than those estimated for E1. The Committee concludes, that exposure to E1 through drinking water does not pose any significant health risk to humans.

SCIENTIFIC BACKGROUND ON WHICH OPINION IS BASED:

4.1 Soil metabolism and degradation rates

In soil, the parent compound pyraflufen-ethyl is rapidly degraded showing half-lives that are usually shorter than 1 day. In an aerobic soil metabolism study, the following metabolites were detected:

- E1: 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazole-3yl)-4-fluorophenoxyacetic acid
- E2: 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazole-3yl)-4-fluorophenol
- E3: 4-chloro-3-(4-chloro-2-fluoro-5-methoxyphenyl)-5-difluoromethoxy-1-methylpyrazole
- E9: 2-chloro-5-(4-chloro-5-difluoromethoxylpyrazole-3yl)-4-fluorophenoxyacetic acid.

Pyraflufen-ethyl was practically completely degraded into E1 metabolite. E1 metabolite was to a large extent degraded into metabolite E2 and to a minor extent into metabolite E9. Metabolite E2 was almost completely degraded into metabolite E3. In the aerobic soil metabolism studies, soil bound residues were formed in percentages ranging from 15-17% and cumulative amounts of CO_2 ranged from 2 to 9%. The maximum levels and half-lives of E1, E2 and E3 in laboratory studies with aerobic soils are given in the following table.

	max. percentage (%)	half-life (days) at 20°C
E1	78	16 – 53
E2	39	6 – 11
E3	69	158 – 442

The half-lives of E2 and E3 given in this table were measured in studies in which either E2 or E3 was added to the soil. It was not attempted to derive half-lives of E2 and E3 from metabolism studies with the parent compound. However, the results of studies with the parent compound are not consistent with the half-lives of 6-11 days reported above for E2: in studies with the parent compound the percentage E2 after 100 days was 7, 12, 30 and 39% in four different soils.

4.2 Sorption of pyraflufen-ethyl and its soil metabolites

The K_{OC}[3] of pyraflufen-ethyl was estimated to be larger than 1000 l/kg. Sorption studies with three soils were carried out for the E1, E2 and E3 metabolites and results are summarised in the following table.

	K_{OM}[4] (l/kg)
E1	47- 112
E2	823-1245
E3	1791-2488

The K_{OM} measurements of E1 indicated that the sorption is a decreasing function of pH as is shown by the following table:

pH-H_2O	K_{OM} (l/kg) of E1
5.2	112
6.7	58
7.6	47

This dependency between pH and K_{OM} was expected in view of the COOH-group in the molecular structure of E1.

4.3 Field persistence of pyraflufen-ethyl and its soil metabolites

Eight field persistence studies were carried out at four sites in Germany, France and UK. At each site pyraflufen-ethyl was applied both in spring and autumn at a rate of 200 g/ha to small plots of bare soil (5 x 7 m; three replicates). Soil was sampled up to 1 year after application (the number of samples and their surface area were not reported). The DT_{50}[5] values found for pyraflufen-ethyl ranged from 1-7 days and those found for E1 ranged from 11 to 44 days after spring application and from 35-71 days after autumn application. The DT_{90}[6] values found for E1 were 121-345 days after spring application and 115-236 days after autumn application. The metabolite E2 was not detected after spring application (detection limit 0.01 mg/kg) and its maximum content in soil was 0.02 mg/kg after autumn application. Maximum contents of the metabolite E3 were 0.05 mg/kg after spring application and 0.07 mg/kg after autumn application. These contents were measured in 5-cm thick layers. Assuming a dry bulk density

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[3] Organic carbon adsorption coefficient.
[4] Organic matter adsorption coefficient.
[5] Period required for 50% dissipation.
[6] Period required for 90% dissipation.

of 1.4 kg/l, a content of 0.07 mg/kg in a 5-cm layer corresponds with about 50 g/ha of E3 which implies that E3 was formed in significant fractions of the applied amount in the field.

4.4 Leaching to groundwater

No lysimeter study was conducted because reported PEC[7] groundwater calculations for the German Hamburg scenario did not result in concentrations of E1, E2 and E3 exceeding 0.1 µg/l.

The Committee conducted PEC groundwater calculations for the FOCUS[8] scenarios (FOCUS 2000) with the PEARL model version 1.1.1 considering only the E1 metabolite because concentrations of the E2 and E3 metabolites can be expected to be lower. The calculations were based on the following model input:

- Pyraflufen-ethyl was applied to soil 15 days after emergence of winter wheat at a rate of 10.1 g/ha (based on a dose of 13.5 g/ha assuming 25% crop interception; see Table 2.14 of FOCUS, 2000).

- The K_{OM} of pyraflufen-ethyl was estimated to be 1150 l/kg and its half-life 1 day.

- The K_{OM} of E1 was estimated for each FOCUS scenario via considering the pH-H_2O of each FOCUS topsoil and selecting the K_{OM} value (47, 58 or 112 l/kg) whose pH value was closest to that of the FOCUS topsoil.

- The percentage formed of E1 out of the parent compound was estimated to be 100%.

- The half-life of E1 in top soil at 20°C and matric pressure of -10 kPa was estimated to be 39 days via averaging the half-lives of four soils (19, 20, 24 and 93 days) as derived from laboratory studies (the DT_{50} values found in the field persistence studies were not used because the Committee could not assess the acceptability of these data for this purpose; moreover, they were more or less consistent with the laboratory degradation rates). The moisture correction of all half-lives had to be based on Table 5.2 of FOCUS (2000) because the definition of maximum water holding capacity was not clear in the reported studies. The half-life of 93 days was based on a study with one soil at two temperatures (half-lives of 53 days at 20°C and of 328 days at 10°C) assuming the default value of 54 kJ/mol for the Arrhenius activation energy as recommended by FOCUS (2000). There was no need to include a pH-dependency of the half-lives in the calculations (the half-life/pH combinations were 20 days - 4.9, 19 days - 5.8, 93 days - 6.3, and 24 days - 7.8).

Calculated 80th percentile groundwater concentrations of E1 for the nine FOCUS groundwater scenarios were 0.000, 0.000, 0.001, 0.001, 0.002, 0.003, 0.007, 0.010 and 0.038 µg/l. These scenarios should be viewed collectively as representing realistic worst-cases for major agricultural areas in the EU (FOCUS, 2000).

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[7] Predicted Environmental Concentration.
[8] Forum for the Co-ordination of pesticide fate models and their use.

4.5 Toxicological assessment

E1 is a major metabolite of pyraflufen-ethyl in rats, therefore its toxicity is covered by the toxicological testing of the parent compound.

When considering the human risk, the Committee has compared the worst-case exposure scenario of humans to E1 through drinking water with the provisional acceptable daily intake (ADI) value of pyraflufen-ethyl, 0.2 mg/kg bw/day. The calculated concentration of E1 in ground water due to leaching through the soil will usually be below 0.01 µg/l although values in the range of 0.01 µg/l and 0.04 µg/l cannot be excluded in exceptional cases (for two out of worst case scenarios, values from 0.01 µg/l and 0.04 µg/l [10-40 ng/l] were found). Assuming an average intake of water of 2 l/day, a maximum intake of 80 ng of E1 /day can be expected. This would result, assuming a 70 kg average man, in a maximum daily intake of 1.1 ng/kg bw, indicating a safety margin of 1.8×10^5 with respect to the provisional ADI[9]. The Committee, therefore, concludes that exposure to E1 through drinking water does not pose any significant health risk to humans.

5. REFERENCES

FOCUS (2000). FOCUS groundwater scenarios in the EU review of active substances. EC Document Sanco/321/2000 rev.2, 197 pp.

6. DOCUMENTS MADE AVAILABLE TO THE COMMITTEE

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2. Pyraflufen-ethyl: Evaluation table -Doc. SANCO/3038/99 rev. 0 - 03.07.00 (SCP/PYRAF/003 submitted by DG SANCO, 18 December 2000).
3. Pyraflufen-ethyl: List of end points (SCP/PYRAF/004 submitted by DG SANCO, 18 December 2000).
4. Pyraflufen-ethyl: Effects on non target species (SCP/PYRAF/005 submitted by DG SANCO, 18 December 2000).
5. Pyraflufen-ethyl: Residues (SCP/PYRAF/006 submitted by DG SANCO, 18 December 2000).
6. Pyraflufen-ethyl: Draft Review report for the active substance pyraflufen-ethyl 23 June 2000 (SCP/PYRAF/007 submitted by DG SANCO, 18 December 2000).
7. Pyraflufen-ethyl: Impacts on human and animal health (SCP/PYRAF/008 submitted by DG SANCO, 18 December 2000).
8. Pyraflufen-ethyl: Danish comments – 14-07-2000 (SCP/PYRAF/009 submitted by DG SANCO, 18 December 2000).

[9] Acceptable daily intake.

9. Pyraflufen-ethyl: Fate and behaviour (SCP/PYRAF/010 submitted by DG SANCO, 18 December 2000).

10. Pyraflufen-ethyl: draft evaluation report (monograph) prepared by Belgium as Rapporteur Member State (Volumes 1 to 4) – June 1999.

7. ACKNOWLEDGEMENTS

The Committee wishes to acknowledge the contributions of the following working groups that prepared the initial draft opinion.

Environmental assessment WG: Prof. Hardy (Chairman) and Committee members: Mr. Koepp, Prof. Leszkowicz, Prof. Papadoupoulou Mourkidou, Dr. Sherratt, Prof. Silva Fernandes, invited experts: Dr. Boesten, Dr. Carter, Dr. Forbes, Dr. Hart and Dr. Luttik.

Toxicology: Prof. Maroni (Chairman) and Committee Members: Dr. Delcour-Firquet, Prof. Leszkowicz, Dr. Meyer, Dr Moretto, Prof. Petzinger, Prof. Savolainen, Prof. Silva Fernandes, Dr. Speijers, and invited expert Dr. Fait, Dr. McGregor.

Berichte aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft erscheinen seit 1995 in zwangloser Folge.

Heft 95, 2002: Pflanzenschutz im ökologischen Landbau – Probleme und Lösungsansätze. Fünftes Fachgespräch am 28. Juli 2001 in Kleinmachnow. Hinreichende Wirksamkeit von Pflanzenschutzmitteln im ökologischen Landbau. Saat- und Pflanzgut für den ökologischen Landbau. Bearbeitet von PD Dr. habil. Stefan Kühne und Britta Friedrich, 177 S.

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