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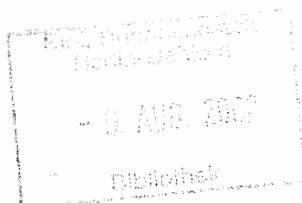
2002

**EU-Beurteilungsbericht Eisen(III)phosphat
Rechtliche Regelungen der Europäischen Union
zu Pflanzenschutzmitteln und deren Wirkstoffen
Band D 33**

Review Report ferric phosphate
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 33

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Inhalt / Contents

Vorwort / Preface

Richtlinie 2001/87/EG der Kommission

Commission Directive 2001/87/EC

Review Report SANCO/3035/99-rev. 4 (final)

Summary Report of the Meeting of the Standing Committee on Plant Health held on
29 June 2001

Bereits erschienene Beurteilungsberichte / Already published Review Reports

Heft / Report	Band / Volume Wirkstoff / Active Substance	Berichterstattender Mitgliedstaat Rapporteur Member State
59/2000	D1: Fluroxypyr	Deutschland Germany
60/2000	D2: Azimsulfuron	Italien Italy
61/2000	D3: Kresoxim-methyl	Belgien Belgium
65/2000	D4: Azoxystrobin	Deutschland Germany
66/2000	D5: Spiroxamine	Deutschland Germany
69/2000	D6: Imazalil	Luxemburg Luxembourg
70/2000	D7: Prohexadion-calcium	Frankreich France
71/2000	D8: Metsulfuron-methyl	Frankreich France
73/2001	D9: Esfenvalerat	Portugal Portugal
74/2001	D10: Bentazon	Deutschland Germany
75/2001	D11: Triasulfuron	Frankreich France
78/2001	D12: Lambda-Cyhalothrin	Schweden Sweden
79/2001	D13: Amitrol	Frankreich France
80/2001	D14: Deiquat	Vereinigtes Königreich United Kingdom
81/2001	D15: Pyridat	Österreich Austria
82/2001	D16: Chlozolinat	Griechenland Greece
83/2001	D17: Lindan	Österreich Austria
84/2001	D18: Monolinuron	Vereinigtes Königreich United Kingdom
85/2001	D19: Permethrin	Irland Ireland
86/2001	D20: Pyrazophos	Niederlande The Netherlands
87/2001	D21: Quintozen	Griechenland Greece
88/2001	D22: Tecnazen	Vereinigtes Königreich United Kingdom
89/2001	D23: Zineb	Italien Italy

Heft / Report	Band / Volume Wirkstoff / Active Substance	Berichterstattender Mitgliedstaat Rapporteur Member State
90/2001	D24: Thiabendazol	Spanien Spain
91/2001	D25: Fenhexamid	Vereinigtes Königreich United Kingdom
92/2001	D26: Glyphosat	Deutschland Germany
97/2002	D27: 2,4-D	Griechenland Greece
99/2002	D28: Thifensulfuron-methyl	Frankreich France
100/2002	D29: Flupyr-sulfuron-methyl	Frankreich France
101/2002	D30: Paecilomyces fumosoroseus	Belgien Belgium
102/2002	D31: Isoproturon	Deutschland Germany
105/2002	D32: Acibenzolar-S-methyl	Frankreich France

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 33. Heft dieser Reihe (Band D 33) 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 Berichtersteller ist, ebenfalls beim Saphir Verlag gegen Erstattung der Unkosten bezogen werden. Für Eisen(III)phosphat war Deutschland Berichtersteller.

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) <i>wird zur Zeit bearbeitet</i>
68/2000	Band B: Verordnungen und Protokolle zur Wirkstoffprüfung (4. Auflage, Stand 01. Juli 2000) <i>wird zur Zeit bearbeitet</i>
	Band C: <i>wird zur Zeit bearbeitet</i>

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 33th report belonging to this series (Volume D 3) 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 ferric phosphate Germany 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 (3 rd Edition, date: 1 November 1997) <i>in progress</i>
68/2000	Volume B: Regulations and Protocols regarding the Evaluation of Active Substances (4 th Edition, date: 1 July 2000) <i>in progress</i>
	Volume C: <i>in progress</i>

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 (%)	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-ylmethyl)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 (%)	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 widmen 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 (pymetrozine) 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, pymetrozine 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.

⁽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.

⁽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.

- (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 (%)	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-ylmethylene)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-mhyprazol-3-yl)-4-fluorophenoxyacetate	956 g/kg	1 November 2001	31 October 2011	<p>Only uses as a herbicide may be authorised.</p> <p>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.</p> <p>Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001.</p>

(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

Ferric phosphate
SANCO/3035/99-rev. 4
8 March 2002

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

Review report for the active substance ferric phosphate

Finalised in the Standing Committee on Plant Health at its meeting on 29 June 2001 in view of the inclusion of ferric phosphate 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 ferric phosphate, 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 German authorities received on 27 August 1998 an application from W. Neudorff GmbH KG, hereafter referred to as the applicant, for the inclusion of the active substance ferric phosphate in Annex I to the Directive. German authorities indicated to the Commission on 21 September 1998 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 ferric phosphate 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 15 October 1998, 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 1999/43/EC¹ of 22 December 1999 that these requirements were satisfied.

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 Germany 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.

Germany submitted to the Commission on 30 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 ferric phosphate 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 W. Neudorff GmbH KG being the sole 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

¹ OJ No L14, 19.01.1999, p.30.

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. No specific questions were addressed to the Committee. Following an exchange of views the Committee noted 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 Directive². The Committee reiterated its earlier statements that absence of comment should only be interpreted as an indication of no obvious reasons necessitating comment.

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/EC³ concerning the inclusion of ferric phosphate in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing ferric phosphate 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 ferric phosphate 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

² Minutes of the plenary of the Scientific Committee on Plants from June 4, 2001

³ OJ L 276; 19.October 2001 p17

implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each ferric phosphate containing plant protection product for which Member States will grant or review the authorisation.

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

- Molluscicide against slugs in Brassica vegetables, lettuce, strawberries and ornamentals.

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 ferric phosphate in foodstuffs

The review has established that no harmful effects on human or animal health will be arising from the proposed uses.

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.

5. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of ferric phosphate are given in Appendix I.

The active substance shall have a minimum purity of **990** g/kg technical product.

The review has established that for the active substance notified by the applicant (W. Neudorff GmbH KG), 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 ferric phosphate

No further studies were identified which were at this stage considered necessary in relation to the inclusion of ferric phosphate in Annex I under the current inclusion conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions.

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 ferric phosphate 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 assessment 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 ferric phosphate in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

Ferric phosphate

Common name (ISO)	Ferric phosphate
Development Code	E 33
Chemical name (IUPAC)	Ferric phosphate
Chemical name (CA)	Ferric phosphate
CIPAC No	629
CAS No	10045-86-0
EEC No	233-149-7
FAO SPECIFICATION	Not available, Food Chemical Codex quality.
Minimum purity	990 g/kg
Molecular formula	FePO ₄ · 4 H ₂ O
Molecular mass	222.9 (150.82, anhydrous)
Structural formula	$\text{Fe}^{3+} \left[\begin{array}{c} \text{O} \\ \parallel \\ \text{O}-\text{P}-\text{O} \\ \\ \text{O} \end{array} \right]^{3-} \quad \text{Fe}^{3+} \left[\begin{array}{c} \text{O} \\ \parallel \\ \text{O}-\text{P}-\text{O} \\ \\ \text{O} \end{array} \right]^{3-} \quad \times 4 \text{H}_2\text{O}$

Melting point	Does not melt - degrades into ferric oxide, Fe ₂ O ₃ , at a temperature near 500°C.
Boiling point	Ferric Phosphate is a solid which degrades into ferric oxide, Fe ₂ O ₃ , at a temperature near 500°C. It loses water above 140°C.
Appearance	Dry powder, white to buff.
Relative density	2.87 g/ml (20°C)
Vapour pressure	Non-volatile.
Henry's law constant	Not applicable.
Solubility in water	pH 7: 1.86 x 10 ⁻¹² g/l (25 °C) With decreasing pH, the solubility increases.
Solubility in organic solvents	Ferric phosphate is insoluble in organic solvents.
Partition co-efficient (log P_{ow})	Not applicable (ferric phosphate is practically insoluble).
Hydrolytic stability (DT₅₀)	Not applicable (ferric phosphate is practically insoluble in water).
Dissociation constant	Not applicable (ferric phosphate is practically insoluble in water).
Quantum yield of direct photo-transformation in water at λ >290 nm	Not applicable (ferric phosphate is practically insoluble in water).
Flammability	Non-flammable.
Explosive properties	Non-explosive.
UV/VIS absorption (max.)	Not applicable (ferric phosphate is practically insoluble in water).
Photostability in water (DT₅₀)	Not applicable (ferric phosphate is practically insoluble in water).

APPENDIX II

END POINTS AND RELATED INFORMATION

Ferric phosphate

1 Toxicology and metabolism

Bridging concept (Ferric phosphate: lower toxicity than Ferrous sulphate and other Iron salts expected)

Ferric phosphate: No studies submitted for the a.s., animal studies submitted with the preparation (1% FePO₄). Very poor bio-availability, extremely low solubility in water and lipids, not volatile, but corrosive. No residues in food resulting from proposed uses and no relevant operator exposure expected.

Ferrous sulphate: Extensive human data available, higher bioavailability than FePO₄, better soluble in water and lipids than FePO₄.

Definition of the Residues

Residues relevant to worker safety

None.

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:

Poor bioavailability. Approximately 10% of dietary iron absorbed, influenced by dietary and host-related factors.

Distribution:

Widely distributed, highest residues in liver, absorption to specific transport proteins (e.g. haemoglobin).
--

Potential for accumulation:

No potential for accumulation under normal physiological conditions.
--

Rate and extent of excretion:

Low iron excretion under normal physiological conditions.

Toxicologically significant compounds:

Iron.

Metabolism in animals:

Ferric phosphate dissociates into trivalent iron-cations and phosphate-anions, iron is separately absorbed as ferrous ions.

Acute toxicity

Rat LD ₅₀ oral:	Ferric phosphate: no data Single doses of Ferrous (II) sulphate equivalent to 200 – 250 mg elemental iron/kg bw cause severe toxic reactions in children. Ferric (III) sulphate: 1487 mg/kg bw (Harmful).
Rat LD ₅₀ dermal:	Ferric phosphate: no relevant acute dermal toxicity; Ferric (III) sulphate: >2000 mg/kg bw.
Rat LC ₅₀ inhalation:	Ferric phosphate: no data (not volatile) Ferric (III) sulphate >1.1 mg/l
Skin irritation:	Ferric phosphate: no data; <i>in-vitro</i> test (irritation) required.
Eye irritation:	Ferric phosphate: no data; <i>in-vitro</i> test (corrosion) required.
Skin sensitization (test method used and result):	Ferric phosphate: no indication of sensitising potential; natural constituent of human diet; Ferric (III) sulphate: no indication of sensitisation.

Short term toxicity

Target / critical effect:	Iron salts (acute – subchronic): gastrointestinal tract, liver, CNS, cardiovascular system.
Lowest relevant oral NOAEL / NOEL:	52 mg FePO ₄ per day (18 month, children)
Lowest relevant dermal NOAEL / NOEL:	Not applicable, no studies required.
Lowest relevant inhalation NOAEL / NOEL:	Not applicable, no studies required.

Genotoxicity

No mutagenic potential.

Long term toxicity and carcinogenicity

Target / critical effect:	Iron salts; liver, pancreas, cardiovascular system, endocrine system.
Lowest relevant NOAEL:	300 mg Fe/day (oral long-term therapeutic dose level)
Carcinogenicity:	No evidence of a carcinogenic potential (based on the bridging concept).

Reproductive toxicity

Target / critical effect – Reproduction:	No indication of reproductive toxicity (iron supplementation in pregnant women on a routine basis).
Lowest relevant reproductive NOAEL / NOEL:	50 mg Fe/day (therapeutic dose in pregnant women)
Target / critical effect – Developmental toxicity:	No indication of developmental toxicity (iron supplementation in pregnant women on a routine basis).
Lowest relevant developmental NOAEL / NOEL:	50 mg Fe/day (therapeutic dose in pregnant women)

Delayed neurotoxicity

No relevant neurotoxic effects of ferric phosphate: no data required.

Other toxicological studies

No studies submitted, not required.

Medical data

Ingestion of Ferrous sulphate tablets by children: 20-60 mg elemental iron/kg bw is moderately toxic, 200-250 mg elemental iron /kg bw is life threatening.

Summary

	Value	Study	Safety factor
ADI (PMTDI, iron):	0.8 mg/kg bw/d	JECFA has 1983 allocated a Provisional maximum tolerable daily intake for man.	---
ADI (MTDI, phosphate):	70 mg/kg bw/d	JECFA has 1982 allocated a maximum tolerable daily intake for man.	---
AOEL systemic (PMTDI, iron):	0.8 mg/kg bw/d	JECFA has 1983 allocated a Provisional maximum tolerable daily intake for man.	---
ArfD (acute reference dose):	Not required.	Not necessary.	---

Dermal absorption

No relevant dermal absorption of FePO₄ is expected (extremely low solubility in water and lipids). No study available for FeSO₄.

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Definition of the Residues

Residues relevant to the environment

None.

Route of degradation

Aerobic:

Mineralization after 100 days:

Not applicable.

Non-extractable residues after 100 days:

Not applicable.

Relevant metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)

Not applicable.

Supplemental studies

Anaerobic:

Not applicable.

Soil photolysis:

Not applicable.

Remarks:

None.

Rate of degradation

Laboratory studies

DT₅₀lab (20 °C, aerobic):

Not applicable.

DT₉₀lab (20 °C, aerobic):

Not applicable.

DT₅₀lab (10 °C, aerobic):

Not applicable.

DT₅₀lab (20 °C, anaerobic):

Not applicable.

Field studies (country or region)

DT_{50f} from soil dissipation studies:

Not applicable.

DT_{90f} from soil dissipation studies:

Not applicable.

Soil accumulation studies:

Not applicable.

Soil residue studies:

Not applicable.

Remarks:

e.g. effect of soil pH on degradation rate

None.

Adsorption/desorption

K_f / K_{oc} :

K_d

pH dependence:

Not applicable.

Mobility

Laboratory studies:

Column leaching:

Not applicable.

Aged residue leaching:

Not applicable.

Field studies:

Lysimeter/Field leaching studies:

Not applicable.

Remarks:

None.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

Not applicable.

Relevant metabolites:

Not applicable.

Photolytic degradation:

Not applicable.

Relevant metabolites:

Not applicable.

Biological degradation

Readily biodegradable:

Not applicable.

Water/sediment study:

Not applicable.

DT₅₀ water:

DT₉₀ water:

DT₅₀ whole system:

DT₉₀ whole system:

Distribution in water / sediment systems
 (active substance)

Distribution in water / sediment systems
 (metabolites)

Accumulation in water and/or sediment:

Not applicable.

Degradation in the saturated zone

Not applicable.

Remarks:

None.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

Non-volatile.

Henry's law constant:

Not applicable.

Photolytic degradation

Direct photolysis in air:

Not applicable.

Photochemical oxidative degradation in air

Not applicable.

DT₅₀:

Volatilisation:

Not applicable.

Remarks:

None.

3 Ecotoxicology

Definition of the Residues

Residues of ecotoxicological relevance

None.

Terrestrial Vertebrates

Acute toxicity to mammals:

LD₅₀ >5000 mg/kg bw (formulation Ferramol Schneckenkorn)

Acute toxicity to birds:

LD₅₀ >2000 mg/kg bw (formulation Ferramol Schneckenkorn)

Dietary toxicity to birds:

No data provided.
Not required.

Reproductive toxicity to birds:

No data provided.
Not required.

Short term oral toxicity to mammals:

52 mg FePO₄ per day (18 month, children)

Aquatic Organisms

Acute toxicity fish:

LC₅₀ >100 mg/L, NOEC > 100 mg/L (96 h;
Oncorhynchus mykiss)

Long term toxicity fish:

Not required.

Bioaccumulation fish:

Not relevant.

Acute toxicity invertebrate:

EC₅₀ > 100 mg/L, NOEC > 100 mg/L (48 h;
Daphnia magna)

Chronic toxicity invertebrate:

Not required.

Acute toxicity algae:

EC₅₀ >100 mg/L, NOEC > 100 mg/L (72 h;
Scenedesmus subspicatus)

Chronic toxicity sediment dwelling organism:

Not required.

Honeybees

Acute oral toxicity:

Not required.

Acute contact toxicity:

Not required.

Other arthropod species

Test species

Aphidius rhopalosiphi

Typhlodromus pyri

Aleochara bilineata

Poecilus cupreus

	% Effect
<i>Aphidius rhopalosiphi</i>	0 % mortality, 52.2 % parasitisation [adults; 1 kg as/ha; Ferramol Schneckenkorn (10 g as/kg)]
<i>Typhlodromus pyri</i>	6.6 % mortality, 0 % fertility [life cycle; 1 kg as/ha; Ferramol Schneckenkorn (10 g as/kg)]
<i>Aleochara bilineata</i>	5.5 % parasitisation [life cycle; 1 kg as/ha; Ferramol Schneckenkorn (10 g as/kg)]
<i>Poecilus cupreus</i>	3.3 % mortality, 16.25 % food uptake [adults; 1 kg as/ha; Ferramol Schneckenkorn (10 g as/kg)]

Earthworms

Acute toxicity:

Reproductive toxicity:

Acute toxicity:	LC ₅₀ > 10 mg as/kg soil LC ₅₀ > 1000 mg Ferramol Schneckenkorn/kg soil
Reproductive toxicity:	NOEC reproduction <i>Eisenia fetida</i> 5 g/m ² Ferramol Schneckenkorn NOEC weight <i>Lumbricus terrestris</i> 50 g/m ² Ferramol Schneckenkorn

Soil micro-organisms

Nitrogen mineralisation:

Carbon mineralisation:

Nitrogen mineralisation:	Not required.
Carbon mineralisation:	Not required.

APPENDIX III**FERRIC PHOSPHATE**

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

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIIA-2.7.3	Almond, D.S.	2000	Shelf Storage Stability of NEU 1165 M 13/06/2000 Eco-Care Technologies Inc., 10555 West Saanich Rd. Sidney, BC V8L 5L6, Canada, GLP/GEP: no Published: no

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA-5.2.1	Van Huygevoort, A. H. B. M.	2000	Assessment of acute oral toxicity with ferric phosphate in the rat NOTOX B.V., DD's Hertogenbosch, The Netherlands; Report Number: 272982, GLP/GEP: yes Published: no
IIA-5.2.4	Van Otterdijk, F. M.	2000	Primary skin irritation/corrosion study with Ferric phosphate in the rabbit NOTOX B.V., DD's Hertogenbosch, The Netherlands, Report Number: 287426 GLP/GEP: yes Published: no
IIA-5.2.5	Van Otterdijk, F. M.	2000	Acute eye irritation/corrosion study with Ferric phosphate in the rabbit NOTOX B.V., DD's Hertogenbosch, The Netherlands, Report Number: 287437 GLP/GEP: yes Published: no

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIIA- 10.6.1.2	Wachter, S.	2000	Assessment of Sublethal Effects of NEU 1165 M on <i>Lumbricus terrestris</i> L. in soil. Project No. 98031/01-NRLt 27/01/2000 GAB Biotechnologie GmbH, D-75223 Niefern-Öschelbronn, GLP/GEP: yes Published: no

**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 Ferric Phosphate in Annex 1 to Council Directive 91/414/EEC (Sanco/1792/2001 rev. 5; Review Report Sanco/3035/99-rev. 4).

The Commission presented the Review Report in document Sanco/3035/99-rev. 4. The Committee took note of the Review Report.

The following declaration was made:

Commission: Same declaration as for cyclanilide.

The Commission presented the draft Directive.

Vote : favourable opinion by unanimity.

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

A CHECCHI LANG
Director

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

- Heft 87, 2001: EU-Beurteilungsbericht Quintozen. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 21.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.
- Heft 88, 2001: EU-Beurteilungsbericht Tecnazen. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 22.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.
- Heft 89, 2001: EU-Beurteilungsbericht Zineb. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 23.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.
- Heft 90, 2001: EU-Beurteilungsbericht Thiabendazol. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 24.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.
- Heft 91, 2001: EU-Beurteilungsbericht Fenhexamid. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 24.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.
- Heft 92, 2001: Liste der zugelassenen Pflanzenschutzmittel (Stand: 1. Juli 2001).
Bearbeitet von Dr. Achim Holzmann, 88 S.
- Heft 93, 2001: Pflanzenschutz im ökologischen Landbau.
PD Dr. habil. Stefan Kühne, Dr. Marga Jahn, Dr. Mario Wick und Dr. Holger Beer, 52 S.
- Heft 94, 2002: EU-Beurteilungsbericht Glyphosat. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 26.
Bearbeitet von Dr. Henning Bruno und Susanne Schaper, getr. Zählung.
- 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.
- Heft 96, 2002: Liste der zugelassenen Pflanzenschutzmittel (Stand: 1. Januar 2002).
Bearbeitet von Andreas Spinti, 74 S.
- Heft 97, 2002: EU-Beurteilungsbericht 2,4-D. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 27.
Bearbeitet von Dr. Martina Erdtmann-Vourliotis und Susanne Schaper, getr. Zählung.
- Heft 98, 2002: NEPTUN 2000 – Erhebung von Daten zum tatsächlichen Einsatz chemischer Pflanzenschutzmittel im Ackerbau Deutschlands. Dr. Dietmar Roßberg, Dr. Volkmar Gutsche, Dr. Siegfried Enzian und Dr. Mario Wick, 27 S., Anhang.
- Heft 99, 2002: EU-Beurteilungsbericht Thifensulfuron-methyl. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 28.
Bearbeitet von Dr. Martina Erdtmann-Vourliotis und Susanne Schaper, getr. Zählung.
- Heft 100, 2002: EU-Beurteilungsbericht Flupyrsulfuron-methyl. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 29.
Bearbeitet von Dr. Henning Bruno und Susanne Schaper, getr. Zählung.
- Heft 101, 2002: EU-Beurteilungsbericht *Paecilomyces fumosoroseus*. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 30.
Bearbeitet von Dr. Martina Erdtmann-Vourliotis, Dr. Axel Wilkening und Susanne Schaper, getr. Zählung.
- Heft 102, 2002: EU-Beurteilungsbericht Isoproturon. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 31.
Bearbeitet von Dr. Henning Bruno und Susanne Schaper, getr. Zählung.
- Heft 103, 2002: Zuständigkeiten bei der Prüfung und Zulassung von Pflanzenschutzmitteln und bei der EU-Wirkstoffprüfung.
Stand: Februar 2002. Bearbeitet von Edelgard Adam, 58 S.
- Heft 104, 2002: Pflanzenschutz im ökologischen Landbau – Probleme und Lösungsansätze.
Sechstes Fachgespräch am 26. Juni 2001 in Braunschweig. Abwehr von Wühlausschäden im ökologischen Landbau. Bearbeitet von Dr. Hans-Joachim Pelz, 109 S.
- Heft 105, 2002: EU-Beurteilungsbericht Acibenzolar-S-methyl. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 32.
Bearbeitet von Herbert Köpp und Susanne Schaper, getr. Zählung.