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EU-Beurteilungsbericht Pymetrozin

Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen Band D 38

Review Report Pymetrozine
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 38

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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 38. Heft dieser Reihe (Band D 38) 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 Pymetrozin war Deutschland 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*
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	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 38th report belonging to this series (Volume D 38) 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 pymetrozine 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 (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

Pymetrozine

7455/VI/98-FINAL

2 July 2002

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

Review report for the active substance pymetrozine

Finalised in the Standing Committee on Plant Health at its meeting on 29 June 2001 in view of the inclusion of pymetrozine 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 pymetrozine, 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, German authorities received on 4 September 1996 an application from Novartis Agro GmbH (representative of Novartis Crop Protection AG, now Syngenta AG), hereafter referred to as the applicant, for the inclusion of the active substance pymetrozine (CGA 215944) in Annex I to the Directive. German authorities indicated to the Commission on 18 March 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 pymetrozine 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 29 May 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 97/865/EC[1] of 5 December 1997 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 28 May 1998 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 pymetrozine in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States on 14 April 1998 as well as to Novartis Agro GmbH being the sole applicant on 23 April 1998.

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 September 1998 to January 1999.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 18 May 1999.

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 September 1999 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 L 351, 23.12.1997, p.67.

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. In its opinion[2] the Committee assessed the significance of certain effects observed in the long-term study and acute neurotoxiocity study with rats in the context of deriving an Acceptable Daily Intake and an Acute Reference Dose for consumers.

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 pymetrozine in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing pymetrozine 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.

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

[3] OJ L276, 19.10.2001, p.17

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 pymetrozine 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 pymetrozine 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:

- insecticide for fruits, vegetables, potatoes, oilseeds, hops, ornamentals and tobacco

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 pymetrozine 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 3.5 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). The National Estimated Short Term Intake (NESTI) for toddlers is up to 21% of the Acute Reference Dose (ARfD), based on the UK intake data. This intake value reflects the evaluated 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 pymetrozine are given in Appendix I.

The active substance shall have a minimum purity of 950 g/kg technical product.

The review has established that for the active substance notified by the applicant (Novartis Agro GmbH), 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 pymetrozine

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:

- on the basis of current information only a maximum application rate of 450 g a.s./ha and a maximum number of three treatments per season at this rate, are acceptable. For higher application rates or number of treatments further data will be required, in particular in the fields of fate and behaviour in the environment and ecotoxicity (e.g. for terrestrial non-target arthropods),

- suitable risk management strategies should be considered to protect aquatic organisms.

- special attention should be given to the protection of operators.

8. List of studies to be generated

Certain data deficiencies were identified which will require the generation/submission of additional studies, to be submitted at Member State level, in order to support authorisations for use under certain conditions:

- Confirmation of the purity of the active substance after implementation of large scale, industrial production process.

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 monograph. 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.

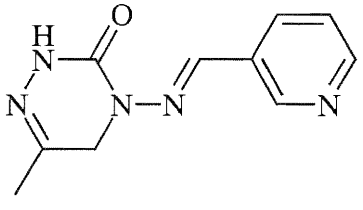
10. Updating of this review report

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 pymetrozine in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

PYMETROZINE

Common name (ISO)	Pymetrozine
Chemical name (IUPAC)	6-methyl-4-[(*E*)- (pyridin-3-ylmethylene)amino]-4,5-dihydro-2H -[1,2,4]-triazin-3 one
Chemical name (CA)	4,5-dihydro-6-methyl-4-[(*E*)- (3-pyridinylmethylene)amino]-1,2,4-triazin-3(2H)-one
CIPAC No	0593
CAS No	123312-89-0
EEC No	not available
FAO SPECIFICATION	not available
Minimum purity	950 g/kg
Molecular formula	$C_{10}H_{11}N_5O$
Molecular mass	217.2
Structural formula	

Melting point	217 °C
Boiling point	thermal decomposition at about 190 °C
Appearance	White odourless powder
Relative density	1.37 (relative density has no dimension)
Vapour pressure	< $4.2 \cdot 10^{-6}$ Pa at 25 °C
Henry's law constant	< $3.0 \cdot 10^{-6}$ $Pa \cdot m^3 \cdot mol^{-1}$
Solubility in water	pH 5: 320 mg/l (25 °C) pH 7: 270 mg/l (25 °C) pH 9: 270 mg/l (25 °C)
Solubility in organic solvents	At 25 °C: n-hexane: < 1 mg/l toluene: 34 mg/l dichloromethane: 1200 mg/l ethanol: 2400 mg/l n-octanol: 450 mg/l acetone: 94 mg/l ethyl acetate: 1200 mg/l
Partition co-efficient (log P_{OW})	pure water: -0.18 pH 5: -0.24 pH 7: -0.19 pH 9: -0.20
Hydrolytic stability (DT_{50})	At 25 °C: pH 5: 5.0 - 12 d pH 7: 616 - 800 d pH 9: 510 - 1210 d
Dissociation constant	4.06 at 20 °C
Quantum yield of direct photo-transformation in water at ε >290 nm	0.31 at 313 nm
Flammability	Not flammable
Explosive properties	Not explosive
UV/VIS absorption (max.)	ε = 20500 at 299.2 nm
Photostability (DT_{50})	4.3 - 6.8 d at pH 7 and 25 °C

APPENDIX II

END POINTS AND RELATED INFORMATION

PYMETROZINE

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	High bioavailability (appr. 90 %) within 24 h
Distribution:	Uniformly distributed
Potential for accumulation:	No evidence for accumulation
Rate and extent of excretion:	Rapid and extensive (appr. 90 %) within 48 h, mainly via urine (52 – 74 %) within 24 h
Metabolism in animals:	Extensively metabolised (appr. 90 %); oxidation reactions at the methyl substitute & the triazine-methylene group, and cleavage reactions between the triazine and the pyridine ring systems
Toxicologically significant compounds:	Parent compound and metabolites

Acute toxicity

Rat LD_{50} oral:	> 5000 mg/kg bw
Rat LD_{50} dermal:	> 2000 mg/kg bw
Rat LC_{50} inhalation:	> 1.8 mg/l air (4 h; nose only; aerosol)
Skin irritation:	Non-irritant
Eye irritation:	Non-irritant
Skin sensitization (test method used and result):	Non-sensitising (M&K)

Short term toxicity

Target / critical effect:	Liver, testes, red blood cells
Lowest relevant oral NOAEL / NOEL:	1 y & 90-d dog studies: 100 ppm (3 mg/kg bw/d)
Lowest relevant dermal NOAEL / NOEL:	1000 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL:	not required

Genotoxicity

No evidence of genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect:	Liver
Lowest relevant NOAEL:	2 y rat: 100 ppm (3.7 mg/kg bw/d)
Carcinogenicity:	Increased incidences of liver tumors, rats and mice

Reproductive toxicity

Target / critical effect - Reproduction:	Delayed development of pups at parental toxic dosages
Lowest relevant reproductive NOAEL / NOEL:	200 ppm (10 mg/kg bw/d)
Target / critical effect - Developmental toxicity:	Variations at maternal toxic dosages
Lowest relevant developmental NOAEL / NOEL:	Rabbit: 10 mg/kg bw/d

Delayed neurotoxicity

No evidence of a specific neurotoxic potential

Other toxicological studies

Inducer of xenobiotic metabolising enzymes; Stimulation of hepatocyte cell proliferation; Weak tumour promoting potential for the thyroid

Medical data

Currently limited: new active substance. no detrimental effects in manufacturing personnel.

Summary

	Value	Study	Safety factor
ADI:	0.03 mg/kg bw	dog, 90d & 1yr studies	100
AOEL systemic:	0.03 mg/kg bw/d	dog, 90d & 1yr studies	100
ARfD (acute reference dose):	0.1 mg/kg bw/d	rabbit, developmental tox. study; rat, 28-d gavage study	100

Dermal absorption

< 6 % at lowest dose tested

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

Non-extractable residues after 100 days:

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

3 - 15 % (20 - 25 °C) (after 90 ...92 days)	
21 - 61 % (20 -25 °C) (after 90 ...92 days)	
Code	*Laboratory:* (% of applied; silt loam, loamy sand, and/or sandy loam)
CGA 359009	9 – 34 % after 7 d, 13 – 54 % after 14 d, 3 – 28 % after 90 d
CGA 363430	0 – 10 % after 14d, 4 – 9 % after 150d
CGA 363431	7–24 % after 29/30d, 10 – 20 % after 90d
CGA 294849	8 – 11 % after 60d, 6 – 11 % after 90 d, 13 % after 180 d (sand)
CGA 180777	13 – 17 % after 58 d, 1 – 2 % after 92 d

Supplemental studies

Anaerobic:

Sandy loam (0.3 % OM, pH 7.4): Mineralization: 0.3 - 1 % after 92 d, 2 – 6 % after 357 d Non-extractables: 11 – 19 % after 92 d, 6 – 15 % after 357 d Major metabolites (% of applied at maximum, total system): CGA 180777: 85 % after 357 d GS 23199: 15 % after 357 d CGA 249257: 13 % after 357 d Unknown I: 13 % after 273 d Unknown III: 12 % after 357 d

Soil photolysis:

Xenon lamp, silt loam:
Major metabolite: CGA 359009, 29 - 34 % after 3 - 7 d
Overall DT_{50}: 1.6 - 4.3 d at corresponding midsummer sunlight irradiation at 40 °N latitude

Remarks:

None

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):

DT_{50lab} (d) (20 °C, aerobic):
Pymetrozine:

Median	Range	n	r^2 (median)	r^2 (range)
4	2 – 23	6	0.973	0.943 - 0.990

Metabolite	*ModelMaker*
CGA 359009	9 – 35 (2 soils)
CGA 363430	23 – 119 (2 soils)
CGA 363431	53 – 145 (2 soils)
CGA 180777	8 – 10 (1 soil)

DT_{90}lab (20 °C, aerobic):

DT_{90lab} (d) (20 °C, aerobic):
Pymetrozine:

Median	Range	n	r^2 (median)	r^2 (range)
32	20-122	6	0.973	0.943 - 0.990

Metabolite	*ModelMaker*
CGA 359009	28 – 117 (2 soils)
CGA 363430	76 – 397 (2 soils)
CGA 363431	176 – 481 (2 soils)
CGA 180777	25 – 32 (1 soil)

DT_{50}lab (10 °C, aerobic):

DT_{50lab} (10°C, aerobic):
Pymetrozine: 4 – 11 d, calculated with PESTLA and PELMO from experimental data obtained at 20 °C, assuming DT50 (20 °C) between 2 and 5 days!
Assuming the worst case DT50 of 23 d at 20 °C, the calculated DT50 (10 °C) is expected to be in the range of 50 days.
Using the Q_{10} factor of 2.3 DT50 (10 °C) are calculated to be in the range of 5 – 12 days; assuming the worst case DT50 of 23 d at 20 °C, the calculated DT50 (10 °C, Q_{10}) is expected to be 53 days.

DT_{50}lab (20 °C, anaerobic):

DT_{50lab} (25°C, anaerobic): 69 - 707 d

Field studies (country or region)

DT_{50f} from soil dissipation studies:	DT_{50f}: State location: France, Germany, Switzerland; single and multiple treatment Median: 14 d Range: 2 – 69 d (7 values)
DT_{90f} from soil dissipation studies:	DT_{90f}: State location: France, Germany, Switzerland; single and multiple treatment Median: 185 d; Range: 55 – 288 d (7 values)
Soil accumulation studies:	no data required
Soil residue studies:	Not required (cf. soil dissipation studies)

Remarks:
e.g. effect of soil pH on degradation rate

Concentrations of the major metabolites in field dissipa of a radio-labelled WP25 formulation:	
Code	*Field dissipation (460 and 500 g as/ha)* (% of applied; mg/kg equivalents of as; Switzerland; sandy loam)
CGA 359009	14 % after 34 d (maximum; = 0.060 mg/kg), 11 % after 82 d (= 0.046 mg/kg), 4 % after 368 d (= 0.013 mg/kg)
CGA 363430	< 10 % (< 0.05 mg/kg)
CGA 363431	< 10 % (< 0.05 mg/kg)
CGA 294849	< 1.5 % after 34 d (= 0.012 mg/kg)
CGA 180777	< 10% (< 0.05 mg/kg)

Adsorption/desorption

K_f / K_{OC}:
Soil type

402	1291	518	307	246	1394	5833	7875	3080	1500
Loamy Sand	Sand	Silt loam	Clay loam	Humic soil	Sand	Sandy loam	Loam	Silty clay Loam	Loam
Org. C (%)	0.76	0.43	2.40	4.39	19.34	0.47	0.24	0.24	0.88	2.06
pH	7.0	5.7	5.7	7.1	6.6	5.6	5.7	7.0	7.9	7.1

pH dependence: no

Mobility

Laboratory studies:

Column leaching:

Soil type:	Sand	Loamy sand	Silt loam	Sand	Sandy loam	Loam	Silty clay loam
org. C (%):	0.43	0.76	1.39	0.47	0.24	0.24	0.88
pH:	5.7	7.0	5.7	5.6	5.7	7.0	7.9
% AR in leachate:	0.4	0.4	0.2	<0.8	<0.8	<0.8	<0.8

Aged residue leaching:

Soil type:	Silt loam	Loamy sand	Sand	Sandy loam	Loam	Silty clay loam
org. C (%):	2.7	2.2	0.47	0.24	0.24	0.88
pH:	7.0	7.2	5.6	5.7	7.0	7.9
ageing period (d)	5	5	30	30	30	30
% AR in leachate:	0.1-0.2	0.1-0.4	<0.8-4.3	<0.8-1.0	<0.8-3.2	<0.8
consisting of e.g.:						
- pymetrozine			0.3-0.4			
- CGA 294849			≤ 2.6%		1.9%	

Field studies:

Lysimeter/Field leaching studies:	Not required based on evidence from aged column leaching studies.
Remarks:	None

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	pH 5, 25 °C: DT_{50} 5.0 – 12.1 d pH 7, 25 °C: stable pH 9, 25 °C: stable
Major metabolites:	Major metabolites exceeding 10 %: CGA 300407, up to 63 % after 30 d , hydrolytically stable CGA 215525, up to 40-48 % after 32-35 d , hydrolytically stable
Photolytic degradation:	Xenon lamp, pH 7, 25 °C: half-life of pymetrozine equivalent to 12-h day of latitude 40 °N: 4.3 ... 6.8 d
Major metabolites:	Major metabolites exceeding 10 % (40°N, summer sunlight): CGA 300407, up to 92% after 32d CGA 215525, up to 71% after 18d , 57 % after 38 d CGA 249257, up to 21% after 38d

Biological degradation

Readily biodegradable:	No (pymetrozine, CGA 215525, CGA 249257)
Water/sediment study:	Pond / Rhine river
DT_{50} water:	5.2 - 6.3 d / 5.3 - 6.6 d
DT_{90} water:	57 – 69 d / 58 – 72 d
DT_{50} whole system:	50 - 115 d / 86 - 118 d
DT_{90} whole system:	not determinable / not determinable
Distribution in water / sediment systems (active substance)	Incubation time (d): 7 / 14 / 28 / 120 Pymetrozine Water: 34-41 / 18-32 / 8.3-15 / 1.7-2.6 Sediment: 44-51 / 49-54 / 48-64 / 39-45
Distribution in water / sediment systems (metabolites)	No metabolite > 10 % in water or sediment
Accumulation in water and/or sediment:	There is no accumulation potential in the water phase because the elimination of pymetrozine of more than 90 % is given within one year even after 3 direct water treatments and under worst case conditions. Since about 25 – 37 % of applied were found as parent in the sediment after one year, an accumulation of pymetrozine in the sediment cannot be absolutely excluded after applications annually repeated at the same location, however, should not be expected taking into account the compliance with the allowed buffer zone distances, the dilution by water turn-over and the rapid photolysis in water. Further relevant endpoints for the risk assessment: - Mineralization after 344 d: 29 – 32 % - Non-extractable residues after 344 d: 21 – 23 %

Degradation in the saturated zone	No data required
Remarks:	None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	< 4.2 ·10^{-6} Pa at 25 °C
Henry's law constant:	< 3.0 ·10^{-6} Pa·m^3·mol^{-1}

Photolytic degradation

Direct photolysis in air:	Not required
Photochemical oxidative degradation in air DT_{50}:	tropospherical half-life: 27 h chemical lifetime in troposphere: 40 h (according to Atkinson, reaction with OH radicals, concentration: 1.5 · 10^6 OH/cm^3)
Volatilisation:	From plant surfaces: about 18 % from wheat within 24 h From soil: up to 11 % within 24 h
Remarks:	None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	5820 mg as/kg bw
Acute toxicity to birds:	LD50 > 2000 mg/kg bw
Dietary toxicity to birds:	LC50 > 5200 ppm
Reproductive toxicity to birds:	NOEL 300 ppm
Long term oral toxicity to mammals:	NOEL 200 ppm (reproductive toxicity rat)

Aquatic Organisms

Acute toxicity fish:	LC50 (96 h) > 100 mg/l (*Oncorhynchus mykiss*)
Long term toxicity fish	NOEC (90 d) > 11.7 mg/l (*Oncorhynchus mykiss*)
Bioaccumulation fish:	Study not necessary, log P_{ow} < 3
Acute toxicity invertebrate:	EC50 (48 h) 87 mg/l (*Daphnia magna*)
Chronic toxicity invertebrate:	NOEC (21 d) 0.025 mg/l (*Daphnia magna*)
Acute toxicity algae:	EC50 (72 h) 21.6 mg/l (*S. capricornutum*)
Chronic toxicity sediment dwelling organism:	NOEC (30 d) 0.313 mg/l 25 WP formulation (*Chironomus riparius*)
Chronic toxicity Lemna	NOEC (14 d) > 109 mg/L

Honeybees

Acute oral toxicity:	LD50: > 117 µg/bee (as) 171 µg/bee (formulation)
Acute contact toxicity:	LD 50: > 200 µg/bee (as) 100 µg/bee (formulation)

Other arthropod species

Typhlodromus pyri	17.4 % effect on total lifecyle (0.6 kg as/ha 250 WP formulation)
Aphidius colemani	95.2 % effect on adults (0.6 kg as/ha 250 WP formulation)
Chrysopa carnea	42.2 % effect on larvae (1.0 kg as/ha 250 WP formulation) 34.6 % effect on larvae (0.2 kg as/ha 250 WP formulation)
Orius insidiosus	56.2 % effect on larvae (0.6 kg as/ha 250 WP formulation)
Aleochara bilineata	4.1 % effect on parasitation (total lifecyle) (1.0 kg as/ha 250 WP formulation)
Poecilus cupreus	0 % effect on adults (0.6 kg as/ha 250 WP formulation)
Aphidius matricariae and Aphidoletis aphidimyza	A semi-field test was conducted in the glasshouse with 350 g as/ha, not according to validated test methods. The application rate tested was too low compared to the number of applications in the field and even with this rate the results do not indicate that the risk is acceptable.
Aphidius colemani	A semi-field test was done in tomato with up to 0.450 kg as/ha. The test does presents the realistic exposure rates in the field.

Earthworms

Acute toxicity:	LC50 > 250 mg as/kg dry weight substrate
Reproductive toxicity:	$NOEC_{reproduction}$ 0.450 kg as/ha (corresponding to 1.39 mg as/kg)
Effects in the field	no effect up to 3 x 0.45 kg/ha

Soil micro-organisms

Nitrogen mineralization:	No effects up to 6.66 mg/kg substrate
Carbon mineralization:	No effects up to 6.66 mg/kg substrate

Appendix III

PYMETROZINE

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

A.1 Identity

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	Date of submission
IIA-1.10	Birk, R.	1998	Z-Isomer of Pymetrozine in Technical Material. Novartis Crop Protection AG, Switzerland. GLP/GEP: no Published: no	1998
IIA-1.9	Hunston, R.	1998	Statement concerning the Minimum Purity of Pymetrozine. Novartis Crop Protection AG, Switzerland. GLP/GEP: no Published: no	1998

A.2 Physical and chemical properties

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	Date of submission
IIIA-2.8.1; IIIA-2.8.2	Rodler, M.	1996	Report on Physico-Chemical Stability, Dissolution Rate of Water soluble Bag. Novartis Crop Protection AG, Switzerland. Project 40245. GLP/GEP: yes Published: no	1998

A.3 Further information

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	Date of submission
IIIA-4.6.1	Wochner, F.	1998	Procedures for Destruction or Decontamination of the Plant Protection Product and its Packaging. Novartis Crop Protection AG, Switzerland. GLP/GEP: no Published: no	1998

A.4 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	Date of submission
IIA-4.2.1	Smal, M.A.	1997	Validated Analytical Method CGA 215944, Determination of Pymetrozine (CGA 215944) in Fruit and Vegetables by HPLC. Novartis Animal Health Australasia PTY Ltd , Australia. Analytical Procedure No. 259A.00 GLP/GEP: -- Published: no	1998
IIA-4.2.1	Tribolet, R.	1998	Independant Laboratory Validation of the Method REM 154.04 Battelle, Geneva Research Centres, Switzerland. Special Report 531/98 GLP/GEP: -- Published: no	1999
IIA-4.2.1	Tribolet, R.	1998	Validation of Analytical Method AG-644 by Analysis of Fortified Animal Tissues, Milk and Eggs Specimens for Pymetrozine and Evaluation of Recoveries. Novartis Crop Protection AG, Switzerland. Report on Special Study 107/98 GLP/GEP: -- Published: no	1998
IIA-4.2.2	Tribolet, R.	1998	Confirmatory Technique - Soil. Novartis Crop Protection AG, Switzerland. Appendix n°1 of Analytical Method REM 154.03 GLP/GEP: -- Published: no	1999
IIA-4.2.3	Tribolet, R.	1998	Pymetrozine (CGA 215944) - Water - Determination of Parent Compound by High Performance Liquid Chromatography. Novartis Crop Protection AG, Switzerland . Residue Method REM 154.06 GLP/GEP: -- Published: no	1998

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	Date of submission
IIA-4.2.3	Tribolet, R.	1998	Validation of Method REM 154.06 by Analysis of Fortified Water Specimens for Pymetrozine (CGA 215944) and Evaluation of Recoveries. Novartis Crop Protection AG, Switzerland. Report on Special Study 104/9 GLP/GEP: -- Published: no	1998
IIA-4.2.1	Tribolet, R.	1999	Pymetrozine - Citrus – Determination of Parent Compound by High Performance Liquid Chromatography. Novartis Crop Protection AG, Switzerland. Residue Method REM 154.08 GLP/GEP: -- Published: no	1999
IIA-4.2.1	Tribolet, R.	1999	Validation of Method REM 154.08 on Lemons (Fruit and Juice) by Analysis of Fortified Specimens for Pymetrozine and Evaluation of Recoveries. Novartis Crop Protection AG, Switzerland. Report on Special Study 110/98 GLP/GEP: -- Published: no	1999
IIA-4.2.1	Tribolet, R.	1999	Confirmatory Technique – Plants. Novartis Crop Protection AG, Switzerland. Appendix I to Analytical Method REM 154.04. GLP/GEP: -- Published: no	1999

A.5 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	Date of submission
IIA-5.7 IIA-5.8	Ferkany, J.W.M.	1997	An Acute Neurotoxicity Study with CGA-215944 Technical in Rats. Oread Biosafety Incorporated, Farmington, Connecticut, USA. A108-017 GLP/GEP: yes Published: no	1998
IIA-5.3.2	Gerspach, R.	1992	3-Month Range Finding Toxicity Study in Mice (Administration in Food) - 1st Amendment. Novartis Crop Protection AG, Switzerland. Amendment to the Final Report Report 901478 GLP/GEP: no Published: no	1998
IIA-5.3.2	Kitazawa, T.	1998	Pymetrozine : 4-Week Oral Feeding Study in Rats (Effects on Testis) (translation from Japanese). The Institute of Environmental Toxicology, Japan. IET 97-0133 GLP/GEP: no Published: no	1998
IIA-5.3.1	Kitazawa, T.	1998	Pymetrozine : 4-Week Oral Feeding Study in Rats (Effects on Seminiferous Epithelial Cycle in Testis) (translation from Japanese). The Institute of Environmental Toxicology, Japan. IET 97-0133A GLP/GEP: no Published: no	1998
IIA-5.3.1	Kitazawa, T.	1998	Pymetrozine : 4-Week Oral Feeding Study in Rats (Effects on Thyroid and Testis) (translation from Japanese). The Institute of Environmental Toxicology, Japan. IET 97-0134 GLP/GEP: no Published: no	1998
IIA-5.1	Mewes, K.E.	1999	Dermal absorption of [Pyridine-5-14C] CGA 215944 Formulated as WP 25 (A-8811 B) in the Rat Novartis Crop Protection AG, Switzerland. Study 001AM06 GLP/GEP: yes Published: no	1999

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	Date of submission
IIA-5.7 IIA-5.8	Weiler, M.S.	1997	13-Week Dietary Neurotoxicity Study with CGA-215944 Technical in Rats. Covance laboratories Inc., Madison, Wisconsin, USA. 6804-100 GLP/GEP: yes Published: no	1998
IIA-5.4.2	Ogorek, B.	1998	Micronucleus Test, Mouse (OECD Conform). Novartis Crop Protection AG, Switzerland. 982052 GLP/GEP: yes Published: no	1998
IIA-5.1	Okada, M.	1998	Study on the Biological Fate of Pymetrozine – Absorption, Distribution and Metabolism in Rats (translation from Japanese). Kashima Laboratory, Japan. 7L845 GLP/GEP: no Published: no	1998
IIA-5.1	Okada, M.	1998	Study on the Biological Fate of Pymetrozine - Absorption, Distribution and Metabolism in Dogs (translation from Japanese). Kashima Laboratory, Japan. 7L846 GLP/GEP: no Published: no	1998

A.6 Residue data

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	Date of submission
IIA-6.1	Campbell, D.D.	1998	Residue Test Report – Test System Pome Fruit – Apples. Novartis Crop Protection, Inc., USA. Field Test Number 0W-IR-627-96 GLP/GEP: yes Published: no	1998
IIA-6.1	Campbell, D.D.	1998	Residue Test Report – Test System Pome Fruit – Apples. Novartis Crop Protection, Inc., USA. Field Test Number 05-IR-004-96 GLP/GEP: yes Published: no	1998
IIA-6.1	Campbell, D.D.	1998	CGA293343 and CGA215944 – Magnitude of the Residues in or on Crop Subgroup 1C : Tuberous and Corn Vegetables. Novartis Crop Protection, Inc., USA. ABR-97107 GLP/GEP: yes Published: no	1998
IIA-6.5.2.1	Campbell, D.D.	1998	CGA 215944, WP 50, Potatoes (Processing), USA Novartis Crop Protection Inc., Greensboro, United States Study Report No. MW-IR-513-96 integrated in ABR-97107 (Interim Report) GLP/GEP: yes Published: no	1999
IIA-6.5.2.1	Campbell, D.D.	1998	CGA 215944, WP 50, Potatoes (Processing), USA Novartis Crop Protection Inc., Greensboro, United States Study Report No. OW-IR-621-96 integrated in ABR-97107 (Interim Report) GLP/GEP: yes Published: no	1999
IIA-6.6	Fleischmann, T.J.	1998	Study on Confined Rotational Crops After Soil Application of Triazine-^{14}C-CGA215944 and Pyridine-^{14}C-CGA215944. Novartis Crop Protection, Inc., USA. ABR-97018 GLP/GEP: yes Published: no	1999
IIA-6.1	Joseph, T.A.	1996	Residue Test Report – Test System Tomatoes. Novartis Crop Protection, Inc., USA. Field Test Number 07-IR-003-94 GLP/GEP: yes Published: no	1998

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	Date of submission
IIA-6.1	Joseph, T.A.	1996	Residue Test Report – Test System Tomatoes. Novartis Crop Protection, Inc., USA. Field Test Number 02-IR-016-94 GLP/GEP: yes Published: no	1998
IIA-6.1	Joseph, T.A.	1996	Residue Test Report – Test System Hot Peppers. Novartis Crop Protection, Inc., USA. Field Test Number 02-IR-018-94 GLP/GEP: yes Published: no	1998
IIA-6.1	Joseph, T.A.	1996	Residue Test Report – Test System Sweet Peppers. Novartis Crop Protection, Inc., USA. Field Test Number 07-IR-004-94 GLP/GEP: yes Published: no	1998
IIA-6.3.2.4	Joseph, T.A.	1998	CGA 215944, WP 50, Fruiting Vegetables, Tomatoes, USA Novartis Crop Protection Inc., Greensboro, United States Study Report No. ABR-97137 GLP/GEP: yes Published: no	1999
IIA-6.1	Leuthold, U.	1998	Pymetrozine – White Monograph, B-6 : Statement on Plant Metabolism. Novartis Crop Protection AG, Switzerland. GLP/GEP: no Published: no	1998
IIA-6.1; IIA-6.4	Leuthold, U.	1999	Comments concerning the reporting and evaluation tables of ECCO 70. Novartis Crop Protection AG, Switzerland. GLP/GEP: no Published: no	1999
IIA-6.3; IIA-6. 5	Scherrer, P.	1999	Tier I – Addendum / Section 4 – Annex II A, Residues in or on Treated Products, Food and Feed Novartis Crop Protection AG, Switzerland. GLP/GEP: no Published: no	1999
IIA-6.3; IIA-6.5	Leuthold, U.	1999	Tier II – Addendum / Section 4 – Annex II, Residues in or on Treated Products, Food and Feed Novartis Crop Protection AG, Switzerland. GLP/GEP: no Published: no	1999

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	Date of submission
IIA-6.3.2.1	Maffezzoni, M.	1996	CGA 215944, WP 25, A-8811 B, Peaches, France Ciba-Geigy SA, Rueil-Malmaison, France Final report No. OI95307/LD24 GLP/GEP: yes Published: no	1999
IIA-6.3.2.1	Maffezzoni, M.	1996	CGA 215944, WP 25, A-8811 B, Peaches, France Ciba-Geigy SA, Rueil-Malmaison, France Final report No. OI95307/FP93 GLP/GEP: yes Published: no	1999
IIA-6.3.2.2	Pointurier, R.	1999	CGA 215944, WP 25, A-8811 B, Eggplant (greenhouse), France (North) ADME - Bioanalysis, Aigues-Vives, France Final report No. 9831801 GLP/GEP: yes Published: no	1999
IIA-6.3.2.2	Pointurier, R.	1999	CGA 215944, WP 25, A-8811 B, Eggplant (greenhouse), France (North) ADME - Bioanalysis, Aigues-Vives, France Final report No. 9831802 GLP/GEP: yes Published: no	1999
IIA-6.3.2.3	Pointurier, R.	1999	CGA 215944, WP 25, A-8811 B, Sweet Peppers, France (South) ADME - Bioanalysis, Aigues-Vives, France Study Report No. 9831601 GLP/GEP: yes Published: no	1999
IIA-6.3.2.3	Pointurier, R.	1999	CGA 215944, WP 25, A-8811 B, Sweet Peppers, France (South) ADME - Bioanalysis, Aigues-Vives, France Study Report No. 9831604 GLP/GEP: yes Published: no	1999
IIA-6.3.2.3	Pointurier, R.	1999	CGA 215944, WP 25, A-8811 B, Sweet Peppers (greenhouse), France (North) ADME - Bioanalysis, Aigues-Vives, France Study Report No. 9831701 GLP/GEP: yes Published: no	1999
IIA-6.3.2.3	Pointurier, R.	1999	CGA 215944, WP 25, A-8811 B, Sweet Peppers (greenhouse), France (South) ADME - Bioanalysis, Aigues-Vives, France Study Report No. 9831702 GLP/GEP: yes Published: no	1999

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	Date of submission
IIA-6.3.2.4	Pointurier, R.	1999	CGA 215944, WP 25, A-8811 B, Tomatoes (greenhouse), France (North) ADME - Bioanalysis, Aigues-Vives, France Study Report No. 9831901 GLP/GEP: yes Published: no	1999
IIA-6.3.2.6	Pointurier, R.	1999	CGA 215944, WP 25, A-8811 B, Melons, France (South) ADME - Bioanalysis, Aigues-Vives, France Study Report No. 9831201 GLP/GEP: yes Published: no	1999
IIA-6.3.2.6	Pointurier, R.	1999	CGA 215944, WP 25, A-8811 B, Melons, France (South) ADME - Bioanalysis, Aigues-Vives, France Study Report No. 9831202 GLP/GEP: yes Published: no	1999
IIA-6.1	Sandmeier, P.	1999	Final Report Metabolism of [Triazine-6-^{14}C]CGA215944 in Field Grown Tomato Plants Novartis Crop Protection AG, Switzerland. Study 98PSA51 GLP/GEP: yes Published: no	1999
IIA-6.3.2.3	Tack, T.	1998	CGA 215944, WG 50, A-9364 A, 25 WP, A-8811 B, Sweet peppers (glasshouse), United Kingdom Novartis Crop Protection UK Ltd., Whittlesford, United Kingdom Study Report No. IR2297 GLP/GEP: yes Published: no	1999
IIA-6.3.2.1	Tribolet, R.	1998	CGA 215944, WG 50, A-9364 A, Peaches, France (South) Novartis Crop Protection AG, Basel, Switzerland Final report No. 1159/97 GLP/GEP: yes Published: no	1999
IIA-6.3.2.1	Tribolet, R.	1998	CGA 215944, WG 50, A-9364 A, Peaches, France (South) Novartis Crop Protection AG, Basel, Switzerland Final report No. 1138/97 GLP/GEP: yes Published: no	1999

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	Date of submission
IIA-6.3.2.2	Tribolet, R.	1998	CGA 215944, WP 25, A-8811 B, Eggplant (greenhouse), Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 1053/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.2	Tribolet, R.	1998	CGA 215944, WP 25, A-8811 B, Eggplant (greenhouse), Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 1052/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.3	Tribolet, R.	1998	CGA 215944, WG 50, A-9364 A, Sweet peppers, Switzerland Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1110/97 GLP/GEP: yes Published: no	1999
IIA-6.3.2.4	Tribolet, R.	1998	CGA 215944, WG 50, A-9364 A, Tomatoes, Switzerland Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1112/97 GLP/GEP: yes Published: no	1999
IIA-6.3.2.5	Tribolet, R.	1998	CGA 215944, WG 50, A-9364 A, Cucumbers (glasshouse), Switzerland Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1111/97 GLP/GEP: yes Published: no	1999
IIA-6.3.2.6	Tribolet, R.	1998	CGA 215944, WG 50, A-9364 A, Melons, France Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1137/97 GLP/GEP: yes Published: no	1999
IIA-6.3.2.1	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Peaches, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 1061/98 GLP/GEP: yes Published: no	1999

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	Date of submission
IIA-6.3.2.1	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Peaches, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 1062/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.3	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Sweet Peppers (greenhouse), Spain Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1054/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.3	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Sweet Peppers (greenhouse), Spain Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1055/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.4	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Tomatoes (greenhouse), Netherlands Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1093/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.4	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Tomatoes, Switzerland Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1085/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.4	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Tomatoes, (greenhouse), Spain Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1058/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.4	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Tomatoes, (greenhouse), Spain Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1094/98 GLP/GEP: yes Published: no	1999

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	Date of submission
IIA-6.3.2.5	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Cucumbers (greenhouse), Netherlands Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1088/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.5	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Cucumbers (greenhouse), Netherlands Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1115/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.5	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Cucumbers (greenhouse), Netherlands Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1089/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.5	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Cucumbers (greenhouse), Netherlands Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1114/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.6	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Melons, Spain Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1064/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.6	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Melons, Spain Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1063/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.6	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Melons (greenhouse), Spain Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1075/98 GLP/GEP: yes Published: no	1999

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	Date of submission
IIA-6.3.2.6	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Melons (greenhouse), Spain Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1076/98 GLP/GEP: yes Published: no	1999
IIA-6.3.2.6	Tribolet, R.	1999	CGA 215944, WP 25, A-8811 B, Melons (greenhouse), Spain Novartis Crop Protection AG, Basel, Switzerland Study Report No. 1077/98 GLP/GEP: yes Published: no	1999
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A.7 Environmental fate and behaviour

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	Date of submission
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A.8 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	Date of submission
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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	Date of submission
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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 Pymetrozine in Annex 1 to Council Directive 91/414/EEC** (Sanco/1523/2001 rev. 5; Review Report 7455/VI/98 rev. 6).

The Commission presented the Review Report in document 7455/VI/98 rev. 6. The Committee took note of the Review Report.

The following declarations were made:

The Netherlands: The Dutch delegation is of the opinion that the aged residue study of pymethrozine gives rise to different interpretations with regard to the derivation of K_{OC} values for metabolites. Therefore, in the national evaluation The Netherlands have asked for adsorption studies with the individual metabolites for the assessment of the leaching potential.

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 insecticide.

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/PYMET/002-Final-r1
31 January 2001

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE EVALUATION OF PYMETROZINE IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

(Opinion adopted by the Committee on 26 January 2001)

Subject to final editing changes
MW editing
Syngenta 8-02-01

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1. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE EVALUATION OF PYMETROZINE IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

(Opinion adopted by the Committee on 26 January 2001)

2. TERMS OF REFERENCE

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

1) Can the Committee give its opinion on the significance of the changes in serum sodium levels observed in the long-term and carcinogenicity study in rats and should these be considered as an adverse effect in the context of estimating an ADI (Acceptable Daily Intake)?

2) Can the Committee give its opinion on the significance of effects seen in the acute neurotoxicity study and should these be considered as an adverse effect in the context of estimating an acute reference dose?

3. BACKGROUND

The draft Commission Directive for inclusion of pymetrozine in Annex I to Directive 91/414/EEC[1] 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 State (Germany) on the basis of dossier submitted by the notifier (Novartis now Syngenta), a review report prepared by the Commission and the Recommendations of the ECCO[2] Peer Review Programme.

Pymetrozine is a systemic insecticide derived from a novel type of chemistry. It acts selectively against a wide range of aphids and whiteflies. It penetrates green leaves and is transported acropetally within plants. It stops feeding activity of sucking insects. Death will occur after 1 – 3 days because of missing food. It is intended for use in a wide range of crops, such as cotton, tobacco, vegetable and fruit crops, in field and in glasshouse where aphids and whiteflies occur as pests. Its intended rate of use ranges from 0.1 kg a.s./ha to 0.45 kg a.s./ha.

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

4. OPINION

4.1 Question 1

"Can the Committee give its opinion on the significance of the changes in serum sodium levels observed in the long-term and carcinogenicity study in rats[3] and should these be considered as an adverse effect in the context of estimating an ADI[4]?"

Opinion of the Committee:

In the long-term toxicity and carcinogenicity study with pymetrozine in rats transient and slight, but statistically significant, decreases in serum sodium and chloride levels were observed. Similar changes were not reported in other studies nor were effects of pymetrozine on the morphology and function of the kidneys ever reported. The Committee concluded that these changes in serum sodium and chloride levels should not be considered adverse in the context of deriving an ADI.

Scientific background on which the opinion is based:

The kidneys play the main role in osmoregulation by which serum sodium and chloride levels are controlled, and small fluctuations within the physiological range are observed due to variation of dietary salt or water intake.

Slight, though statistically significant, changes in the serum sodium and chloride levels were only observed in the early intervals (week 13, 27 and 53) of the long-term toxicity and carcinogenicity study with pymetrozine in rats, at dose levels equivalent to 5 mg/kg body weight or higher. After week 53 no changes in serum sodium and chloride levels were noted in any dose group. These transient changes were not accompanied by any alteration in the function (serum creatinine and urea) or in morphology of the kidneys.

No decreases in serum sodium and chloride levels were observed in the other toxicity studies in mice, rats and dogs.

In conclusion, the transient slight changes in serum sodium and chloride levels only seen at few intervals in the long-term study in rats are not considered relevant for the derivation of an ADI.

4.2 Question 2

"Can the Committee give its opinion on the significance of effects seen in the acute neurotoxicity study[5] and should these be considered as an adverse effect in the context of estimating an acute reference dose?"

Opinion of the Committee:

The Committee considers that the reversible effects, such as, lower body temperature (both sexes), decreased numbers of rearings (males) and reduced responsiveness to tail pinch (females) observed in the acute gavage neurotoxicity study in rats at lower doses were compound related and as such should be considered in the context of estimating an Acute

[3] Reference 1 under section 5.
[4] Acceptable daily intake.
[5] Reference 2 under section 5.

Reference Dose. In this study a clear NOAEL[6] was not observed (LOAEL[7] 125 mg/kg body weight). However, the reversibility of effects, the dose-response curve, the mode of administration and the lack of neurotoxic effects in the 13 week dietary study in rats at doses up to 201 mg/kg body weight per day (3000 ppm) should be taken into account when deriving the Acute Reference Dose.

Scientific background on which the opinion is based:

Pymetrozine is rapidly and almost completely absorbed after oral administration. It is extensively and rapidly metabolised with no indication of accumulation. Its acute toxicity is low (oral rat LD_{50}[8] 5820 mg/kg body weight), it is not a skin sensitiser, and is not genotoxic. It is not teratogenic but caused skeletal variations and anomalies at maternally toxic doses (NOAEL 30 and 10 mg/kg body weight in rats and rabbits, respectively). Pymetrozine causes increased incidence of liver tumours in both rats and mice at very high doses but this effect is not considered to be relevant in human risk assessment. The lowest dose target organ for toxicity in all tested animals is the liver with anemia (possibly haemolytic) and decreased spermatogenesis occurring at higher doses. The Acute Refence Dose of 0.1 mg/kg body weight derived by the Rapporteur Member State is based on the NOAEL of 10 mg/kg body weight in the rabbit developmental study.

Neurotoxicity studies:

Groups of CD rats (10/sex) received pymetrozine at 0, 125, 500 or 2000 mg/kg body weight by gavage in water[9]. Animals were subjected to a functional observation battery (FOB) and assessments of locomotor activity at 4 to 5 hours and at 7 and 14 days post dosing. The FOB included open field, reflex, neuromuscular and physiological assessments. At sacrifice, a full post-mortem was performed. Three top dose males died or were sacrificed by day 3. Body weight gain was reduced at 2000 mg/kg body weight in both sexes (<10%). Dose-related reductions in locomotor activity (figure of 8 maze activity counts) were seen in all treated groups at 4 - 5 hours but not at later intervals. Variations in a number of FOB parameters were seen at 4 - 5 hours, occasionally persisting until day 8 in the top dose group (note the general toxicity of this dose). In the low dose animals only lower body temperature (both sexes), decreased numbers of rearings (males) and reduced responsiveness to tail pinch (females) were observed at 4-5 hours. There were no abnormal findings in the nerve or muscular tissue samples examined histologically.

Groups of CD rats (10/sex) received pymetrozine at 0, 500, 1000 or 3000 ppm in the diet for 13 weeks[10]. Animals were subjected to a functional observation battery and assessments of locomotor activity at 4, 8 and 13 weeks. At sacrifice a post-mortem was performed focusing on nervous and muscular tissue. There were no deaths and no substance related clinical observations during the study. Body weight gain was reduced (15 - 25%) in both sexes at 3000 ppm while food consumption was reduced by 10%. There were no adverse findings in the microscopic examination of nervous and muscular tissue. Some behavioural changes were seen but were considered not treatment related. Motor activity, hind limb foot splay and body temperature were also not affected by pymetrozine in this study. It is concluded that administration of pymetrozine

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[6] No observed adverse effect level.
[7] Lowest observable adverse effect level.
[8] Lethal dose, median.
[9] Reference 2 under section 5.
[10] Reference 3 under section 5.

for 13 weeks in the diet to rats did not shown any signs of neurotoxicity at doses up to 3000 ppm (equal to 201 mg/kg body weight per day) (highest dose tested).

In conclusion, some reversible neurotoxic effects were observed in the acute gavage study in rats without a clear NOAEL, the LOAEL being 125 mg/kg body weight. These effects are probably related to the peak tissue concentration reached after gavage, since these were not observed in the 13-week dietary study up to 3000 ppm (equal to 201 mg/kg body weight per day) where the intake is more gradual leading to a lower peak concentration. These effects should be considered when deriving the Acute Reference Dose, taking also into account their reversibility, the shape of the dose-response curve, the mode of administration and the lack of neurotoxic effects in the 13-week rat study.

5. REFERENCES

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6. DOCUMENTS MADE AVAILABLE TO THE COMMITTEE

1. Evaluation of pymetrozine in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market: Terms of reference (Doc. SCP/PYMET/001).

2. Pymetrozine – Evaluation table – Doc. 7454/VI/98-rev.7 (Doc. SCP/PYMET/003).

3. Pymetrozine – Appendices [Appendix I Identity, physical and chemical properties – Appendix II End points and related information – Appendix III List of studies which were submitted during the evaluation process and were not cited in the draft assessment report] (Doc. SCP/PYMET/004).

4. Pymetrozine: Addendum 3 to the Monograph – prepared by Rapporteur Member State: Germany, 3 March 2000 (Doc. SCP/PYMET/005).

5. German comments to UK concerns regarding the proposed ADI and ARfD for Pymetrozine, 19 November 1999, submitted by DG Health and Consumer Protection (Doc. SCP/PYMET/006).

6. Pymetrozine (Monograph) Report of the evaluation of a dossier submitted by Novartis, prepared by Germany made to the European Commission under Article 8(1) of Council Directive 91/414/EEC Volume 1, April 1998.

7. Pymetrozine (Monograph) Report on the evaluation of a dossier submitted by Novartis, prepared by Germany made to the European Commission under Article 8(1) of Council Directive 91/414/EEC Volume 1 *Addendum,* May 1998.

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9. Pymetrozine (Monograph) Report on the evaluation of a dossier submitted by Novartis, prepared by Germany made to the European Commission under Article 8(1) of Council Directive 91/414/EEC Volume 3 Annex B, Summary, scientific evaluation and assessment, April 1998.

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7 ACKNOWLEDGEMENTS

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

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, invited experts: Dr. Fait, Dr. McGregor.

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