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# EU-Beurteilungsbericht Acibenzolar-S-methyl
## Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen Band D 32

Review Report Acibenzolar-s-methyl
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 32

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**Inhalt / Contents**

Bereits erschienene Beurteilungsberichte / Already published Review Reports

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

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

## 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 32. Heft dieser Reihe (Band D 32) 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 Acibenzolar-S-methyl war Frankreich Berichterstatter.

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

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

**Preface**

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

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

The Federal Biological Research Centre makes available review reports as reports from the Federal Biological Research Centre for Agriculture and Forestry, Volume D of the series "Legal Regulations of the European Union for Plant Protection Products and their Active Substances" via Saphir Verlag against reimbursement of expenses. The present 32nd report belonging to this series (Volume D 32) 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 acibenzolar-S-methyl France 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<br>CAS Nr. 135158-54-2<br>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<br>Der Beurteilungsbericht wurde vom Ständigen Ausschuss für Pflanzenschutz am 29. Juni 2001 abgeschlossen |
| 21 | Cyclanilide<br>CAS Nr. 113136-77-9<br>CICAP Nr. 586 | Nicht verfügbar | 960 g/kg | 1. November 2001 | 31. Oktober 2011 | Nur Verwendungen als Wachstumsregler dürfen zugelassen werden<br>Der Höchstgehalt der Verunreinigung 2,4-Dichloroanilin (2,4-DCA) im hergestellten Wirkstoff sollte sich auf 1 g/kg belaufen<br>Der Beurteilungsbericht wurde vom Ständigen Ausschuss für Pflanzenschutz am 29. Juni 2001 abgeschlossen |
| 22 | Eisen(III)-phosphat<br>CAS Nr. 10045-86-0<br>CICAP Nr. 629 | Eisen(III)-phosphat | 990 g/kg | 1. November 2001 | 31. Oktober 2011 | Nur Verwendungen als Molluscizid dürfen zugelassen werden<br>Der Beurteilungsbericht wurde vom Ständigen Ausschuss für Pflanzenschutz am 29. Juni 2001 abgeschlossen |
| 23 | Pymetrozin<br>CAS Nr. 123312-89-0<br>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<br>Bei der Entscheidungsfindung gemäß den einheitlichen Grundsätzen müssen die Mitgliedstaaten dem Schutz von Wasserorganismen besondere Aufmerksamkeit widmen<br>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<br>CAS Nr. 129630-19-9<br>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<br>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<br>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<br>CAS No 135158-54-2<br>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.<br>Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001. |
| 21 | Cyclanilide<br>CAS No 113136-77-9<br>CIPAC No 586 | Not available | 960 g/kg | 1 November 2001 | 31 October 2011 | Only uses as a plant growth regulator may be authorised.<br>The maximum content of the impurity 2,4-dichloroaniline (2,4-DCA) in the active substance as manufactured should be 1 g/kg.<br>Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001. |
| 22 | Ferric phosphate<br>CAS No 10045-86-0<br>CIPAC No 629 | Ferric phosphate | 990 g/kg | 1 November 2001 | 31 October 2011 | Only uses as a molluscicide may be authorised.<br>Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001 |
| 23 | Pymetrozine<br>CAS No 123312-89-0<br>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.<br>In decision-making according to the uniform principles Member States must pay particular attention to the protection of aquatic organisms.<br>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<br>CAS No 129630-19-9<br>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.<br>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.<br>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**

Acibenzolar-s-methyl

6506/VI/99-final

21 May 2002

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

**Review report for the active substance acibenzolar-s-methyl**

Finalised in the Standing Committee on Plant Health at its meeting on 29 June 2001 in view of the inclusion of CGA 245 704 (acibenzolar-s-methyl) 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 acibenzolar-s-methyl, 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 French authorities received on 15 October 1996 an application from Novartis Crop Protection AG (now Syngenta AG), hereafter referred to as the applicant, for the inclusion of the active substance acibenzolar-s-methyl (CGA 245 704) in Annex I to the Directive. French authorities indicated to the Commission on 5 May 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 acibenzolar-s-methyl 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 19 June 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 97/865EC[1] of 5 December 1997 that these requirements were satisfied.

[1] OJ No L 351, 23.12.97, p.67.

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 France 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.

The France submitted to the Commission on 17 December 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 acibenzolar-s-methyl 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 Novartis Crop Protection AG being the sole applicant on 11 January 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, analytical methods;
- 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 March to October 1999.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States on 17 March 2000 and the sole applicant on 21 March 2000.

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 in January 2000, and was finalised in the meeting of the Standing Committee on 27 June 2001.

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

These documents were also submitted to the Scientific Committee for Plants. 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 Directive[2]. 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/EC[3] concerning the inclusion of acibenzolar-s-methyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing acibenzolar-s-methyl 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 acibenzolar-s-methyl 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 acibenzolar-s-methyl containing plant protection product for which Member States will grant or review the authorisation.

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[2] Minutes of the plenary of the Scientific Committee on Plants from March 7, 2001

[3] OJ L 276, 19.10.2001, p.17

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

- Plant Activator on wheat, spring barley 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 acibenzolar-s-methyl 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 1,25% of the Acceptable Daily Intake (ADI) (for smokers and 0,4 % for non smokers), based on the FAO/WHO European Diet (August 1994). This low intake value reflects the current limited use pattern for this active substance.

The Theoretical Maximum Daily Intake (TMDI) for a 8.7 kg infant and a 43,6 kg child are respectively 1,5% and 0,5% of the Acceptable Daily Intake (ADI) based on the UK model.

### 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 Environment

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 main identity and the physical/chemical properties of acibenzolar-s-methyl are given in Appendix I.

The active substance shall have a minimum purity of 970 g/kg technical product.

The review has established that for the active substance notified by the applicant (Novartis Crop Protection AG), 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 acibenzolar-s-methyl

On the basis of the proposed and supported uses, the following particular issue has been identified which would require short term attention from Member States, in the framework of authorisations granted, varied or withdrawn, as appropriate.

The acid metabolite (designated as CGA 210007) has a potential for leaching, which might require particular attention in vulnerable areas to ensure protection of groundwater.

## 8. List of studies to be generated

No further studies were identified which were considered at this stage, and under the current inclusion conditions necessary in relation to the inclusion of **acibenzolar-s-methyl** 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 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.

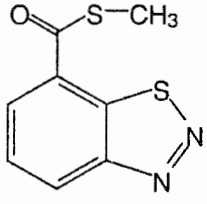
## 10. Updating of this review report

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 acibenzolar-s-methyl in Annex I of the Directive.

# APPENDIX I

## Identity, physical and chemical properties

## ACIBENZOLAR-S-METHYL

| | |
|---|---|
| **Common name (ISO)** | Acibenzolar-s-methyl |
| **Chemical name (IUPAC)** | Methyl benzo[1,2,3]thiadiazole-7-carbothioate |
| **Chemical name (CA)** | 1,2,3-Benzothiadiazole-7-carbothioic acid S-methyl ester |
| **CIPAC No** | 597 |
| **CAS No** | 135158-54-2 |
| **EEC No** | Not allocated. |
| **FAO SPECIFICATION** | Not allocated. |
| **Minimum purity** | 970g/kg |
| **Molecular formula** | $C_8H_6N_2OS_2$ |
| **Molecular mass** | 210.3 |
| **Structural formula** |  |

| | |
|---|---|
| **Melting point** | 133 °C |
| **Boiling point** | Approx. 267 °C |
| **Appearance** | White, fine cristalline powder |
| **Relative density** | 1.54 g/cm$^3$ at 22 °C as density |
| **Vapour pressure** | 4.6 x10$^{-4}$ Pa at 25 °C |
| **Henry's law constant** | 1.3 x 10$^{-2}$ Pa x m$^3$ x mol$^{-1}$ |
| **Solubility in water** | 7.7 mg/l at 25°C in pure water |
| **Solubility in organic solvents** | Acetone : 28.0 g/l<br>Toluene : 36.0 g/l<br>Dichloromethane : 160.0 g/l<br>Hexane : 1.3 g/l<br>Methanol : 4.2 g/l<br>Ethyl Acetate : 25.0 g/l<br>Octanol : 5.4 g/l |
| **Partition co-efficient (log $P_{ow}$)** | Log Pow : 3.1 at 25°C |
| **Hydrolytic stability ($DT_{50}$)** | $DT_{50}$ : 3.8 years at pH5<br>$DT_{50}$ : 23.1 weeks at pH7<br>$DT_{50}$ : 19.4 hours at pH9 |
| **Dissociation constant** | No dissociation in the range of pH 1.0 to 9.0 |
| **Quantum yield of direct photo-transformation in water at ε >290 nm** | 2-3 x 10$^{-2}$ mol x einstein $^{-1}$ |
| **Flammability** | Not flammable. |
| **Explosive properties** | Not explosive. |
| **UV/VIS absorption (max.)** | 253 nm ε : 14.7 10$^3$ l mol$^{-1}$ cm$^{-1}$<br>288 nm ε : 5.4 10$^3$<br>324 nm ε : 7.2 10$^3$ |
| **Photostability in water ($DT_{50}$)** | $DT_{50}$ : 0.9 h |

# APPENDIX II

# END POINTS AND RELATED INFORMATION

## ACIBENZOLAR--METHYL

# 1 Toxicology and metabolism

## Absorption, distribution, excretion and metabolism in mammals

| | |
|---|---|
| Rate and extent of absorption: | Oral > 90%. Tmax = 0.25 h (low dose level) – 8 h (high dose level) |
| Distribution: | Widely distributed at 100mg/kg dose level. Highest residues in liver and kidney. |
| Potential for accumulation: | None. |
| Rate and extent of excretion: | Total almost eliminated within 24 hours via urine (≈ 90%) in form of the acid metabolite CGA 210007. |
| Toxicologically significant compounds: | Acid metabolite CGA 210007. Plant metabolites 324041 and 323060 – not of toxicological significance. |
| Metabolism in animals: | >90% metabolised to acid, mainly in liver. Metabolism independent from sex, dose, pre-treatment and species (rat, goat, hen). |
| *Mechanistic studies*<br>Hydrolysis of CGA 245704 *in vitro* (rat and human tissue samples) | Hydrolysis rates of the thioester CGA 245704 to its corresponding acid CGA 210007 : human liver (409) >> rat liver (11) > rat plasma (0.5) > human plasma (0.04) |

## Acute toxicity

| | |
|---|---|
| Rat $LD_{50}$ oral: | > 2000 mg/kg bw |
| Rat $LD_{50}$ dermal: | > 2000 mg/kg bw |
| Rat $LC_{50}$ inhalation: | > 5 mg/l |
| Skin irritation: | Non irritating (rabbit) |
| Eye irritation: | Non irritating |
| Skin sensitization (test method used and result): | Sensitizing (M & K) |

## Short term toxicity

| | |
|---|---|
| Target / critical effect: | Haemolytic anaemia in all species tested. |
| Lowest relevant oral NOAEL / NOEL: | 10 mg/kg bw/d (dog 90 day in capsules) |
| Lowest relevant dermal NOAEL / NOEL: | 1000 mg/kg bw /d (28 day dermal in rat) |
| Lowest relevant inhalation NOAEL / NOEL: | Not required. |

## Genotoxicity

| |
|---|
| Weak evidence of clastogenicity *in vitro*, no significance for carcinogenicity. |

## Long term toxicity and carcinogenicity

| | |
|---|---|
| Target / critical effect: | Anaemia (mouse, rat and dog). Target organs: spleen, kidney (rat),liver, spleen, bone marrow (mouse, dog) |
| Lowest relevant NOAEL: | 8 mg/kg bw/d (2 year rat study) |
| Carcinogenicity: | Not oncogenic in rats and mice. |

## Reproductive toxicity

| | |
|---|---|
| Target / critical effect - Reproduction: | No specific effects on reproduction, reduced body weight gain in offspring at parental toxic doses. |
| Lowest relevant reproductive NOAEL / NOEL: | 25 mg/kg bw/day (200 ppm 2-generation feeding study). |
| Target / critical effect - Developmental toxicity: | Malformations at maternally toxic doses in 3 out of 4 rat studies. |
| Lowest relevant developmental NOAEL / NOEL: | 50 mg/kg bw /day ( dams and foetuses) rat oral teratogenicity study. |

## Delayed neurotoxicity

| |
|---|
| No evidence of neurotoxicity. |

## Other toxicological studies

| | Studies on plant metabolite CGA 210007 |
|---|---|
| **Acute toxicity** | |
| Rat oral $LD_{50}$ | >2000 mg/kg |
| Rat dermal $LD_{50}$ | >2000 mg/kg |
| Skin irritation | Non irritant (rabbit). |
| **Short term toxicity** (28 day rat) | Anaemia. Increased liver weight and decreased thymus weight. NOEL = 100 mg/kg bw/day |
| **Genotoxicity** | |
| Reverse gene mutation (*E coli – S typhimurium*) | 95.1% purity : +S9 : positive (TA 98)<br>-S9 : positive (TA 98) |
| Gene mutation mammalian cells (V79/HPGRT) | 99.4% purity : S9 : Negative (± S9) |
| Chromosomal aberrations mammalian cells (CHO-CCl61) | Negative |
| UDS rat hepatocytes | Negative |
| Micronucleus mouse | Negative |
| Study on possible immunotoxicity | Anaemia not related to the formation of antibodies against CGA 245704 (serum from rat). |
| *In vitro* study on the mechanism leading to hemolytic anaemia | CGA 245704 and methane thiol induce erythrocytes glutathion depletion, altered haemoglobin and increased lipid peroxidation.<br>Anaemia not related to antibodies. |

## Medical data

| |
|---|
| Occasional irritation (skin, eyes and respiratory tract) seen in exposed workers. |

## Summary

| | Value | Study | Safety factor |
|---|---|---|---|
| ADI: | 0.1 mg/kg bw/day | 90 day and 12 month dog studies | 100 |
| AOEL systemic: | 0.1mg/kgbw/d | 90 day dog study | 100 |
| AOEL inhalation: | not allocated | | |
| AOEL dermal: | not allocated | | |
| ARfD (acute reference dose): | Not allocated (not necessary). | | |

## Dermal absorption

| |
|---|
| Spray application: 81% |
| Mix/load: 16% |

# 2 Fate and behaviour in the environment

## 2.1 Fate and behaviour in soil

### Route of degradation

**Aerobic:**

| | |
|---|---|
| Mineralization after 100 days: | Phenyl label : 7.5 *- 44.1 % (90 d) at 20° C (5 soils)<br>*soil with a low microbial biomass |
| Non-extractable residues after 100 days: | Phenyl label : 27.7 - 59.8 % (90 d) at 20° C (5 soils) |
| Relevant metabolites above 10 % of applied active substance: name and/or code<br>% of applied rate (range and maximum) | CGA 210007 : max. 82.6 - 96.1 % (1 - 7 d) |

**Supplemental studies**

| | |
|---|---|
| **Anaerobic:** | Not determined for a.s., not required (spring application, rapid aerobic degradation).<br>CGA 210007 not degraded. |
| **Soil photolysis:** | Light enhances the slow degradation of acibenzolar-S-methyl on dry soil and the degradation of CGA 210007 rapidly formed on wet soil.<br>Bound residues (irradiation, wet soil): 61 % |
| **Remarks:** | None. |

# Rate of degradation

## Laboratory studies

$DT_{50}$lab (20 °C, aerobic):

$DT_{50lab}$ (20°C, aerobic, 60-75% FC): days (initial concentration ~1mg/ kg)

| Soil type | pH | OC | a.s. | CGA 210007 |
|---|---|---|---|---|
| Silt loam | 7.0 | 2.7 | 0.2 | 16.5 |
| Loamy sand | 7.4 | 1.7 | 0.2 | 23.1 |
| Sand | 8.2 | 0.6 | 0.5 | 106.0* |
| Sandy loam | 7.6 | 1.3 | 0.4 | 19.3 |
| Silty loam | 7.2 | 2.1 | 0.3 | 26.7** |

*soil with a low microbial biomass

** 13.2 d (initial concentration 0.1 mg/kg)

$DT_{50lab}$ (silty loam, 20°C, 30% F.C, pH 7.2, 2.1 % OC.):
0.5 d (a.s.); 88.3 d (CGA 210007)

$DT_{90}$lab (20 °C, aerobic):

$DT_{90lab}$ (20°C, aerobic, 60-75% FC): days (initial concentration~~1mg/kg)

| Soil type | pH | OC | a.s. | CGA 210007 |
|---|---|---|---|---|
| Silt loam | 7.0 | 2.7 | 0.7 | 54.8 |
| Loamy sand | 7.4 | 1.7 | 0.7 | 76.8 |
| Sand | 8.2 | 0.6 | 1.7 | 354.0* |
| Sandy loam | 7.6 | 1.3 | 1.2 | 64.0 |
| Silty loam | 7.2 | 2.1 | 0.9 | 88.7** |

*soil with a low microbial biomass

** 43.9 d at low concentration (0.1 vs. 1 mg/kg)

$DT_{90lab}$ (silty loam, 20°C, 30% FC,pH 7.2, 2.1 % O
1.8 d (a.s.), 293 d (CGA 210007)

$DT_{50}$lab (10 °C, aerobic):

$DT_{50lab}$ (10°C, aerobic, 60% FC, silty loam, pH 7.2, 2.1 % OC):
1 d (a.s.); 70.4 d (CGA 210007)

$DT_{90}$lab (10 °C, aerobic):

$DT_{90lab}$ (10°C, aerobic, 60% FC, same soil):
3.3 d (a.s.), 234 d (CGA 210007)

$DT_{50}$lab (20 °C, anaerobic):

$DT_{50lab}$ (20°C, anaerobic):
a.s. not determined, not required
CGA 210007: stable

**Field studies (country or region)**

| | |
|---|---|
| $DT_{50f}$ from soil dissipation studies: | $DT_{50f}$:<br>Switzerland : (2 sites, 50 g a.s./ha):<br>site 1 silty clay (pH 6.6), crops, LOD 1 µg/kg<br>$DT_{50f}$ : 0.1 d for a.s. (sqrt 1.5st order)<br>$DT_{50f}$ < 14 d for CGA 210007<br>site 2 loamy sand (pH 7.5), bare soil, LOD 4 µg/kg<br>$DT_{50f}$ : 5 d for total residues (sqrt 1st order)<br><br>France : (2 sites, 100 g a.s./ha, LOD 4 µg/kg):<br>sandy loam (pH 7.3) and clay loam (pH 7.8), bare soil<br>$DT_{50f}$ < 14 d for total residues<br><br>North Carolina : (4 x 115 g./ha, 7 d apart, LOQ 10 µg/kg):<br>sand (pH 6.2), bare soil<br>$DT_{50f}$ 2 d for a.s. ($R^2$ 0.52)<br>$DT_{50f}$ 7 d for CGA 210007 ($R^2$ 0.67)<br><br>California (same conditions):<br>loamy sand (pH 7.8), tomatoes and bare soil<br><br>$DT_{50f}$ a.s.:27 d (bare soil) and 16 d (tomatoes)<br><br>$DT_{50f}$ CGA 210007: 59 d (bare soil) and 45 d (tomatoes) ($R^2$ > 0.77) |
| $DT_{90f}$ from soil dissipation studies: | Not required. |
| Soil accumulation studies: | Switzerland 50 g a.s./ha for 3 years, LOD 4 µg/kg<br>loamy sand (pH 7.8), cereals<br>100 d after each treatment total residues < LOD |
| Soil residue studies: | Not required |

| | |
|---|---|
| **Remarks:**<br>e.g. effect of soil pH on degradation rate | None. |

## Adsorption/desorption

$K_f$ / $K_{oc}$:

Acibenzolar

| Soil type | pH | OC | Kf | 1/n | Koc |
|---|---|---|---|---|---|
| Loamy sand | 7.3 | 0.8 | 8.3 | 0.79 | 1041 |
| Loam | 5.5 | 1.4 | 13.7 | 0.79 | 981 |
| Sand | 6.8 | 0.3 | 5.7 | 0.78 | 1885 |
| Silt loam | 7.2 | 4.7 | 58.0 | 0.75 | 1235 |
| mean | | | | | 1285 |

CGA 210007

| Soil type | pH | OC | Kf | 1/n | Koc |
|---|---|---|---|---|---|
| Silt loam | 6.6 | 1.4 | 0.9 | 0.86 | 65 |
| Sand | 5.4 | 0.35 | 0.6 | 0.84 | 174 |
| Loam | 7.3 | 1.5 | 2.3 | 0.82 | 150 |
| Loamy sand | 6.2 | 0.46 | 1.4 | 0.83 | 312 |
| Clay loam | 8.0 | 0.58 | 0.5 | 0.76 | 89 |
| Sandy loam | 7.3 | 0.75 | 0.3 | 0.87 | 40 |
| mean | | | | | 138 |

$K_d$

see Kf above

pH dependence:

For both compounds no evidence for pH dependence.

## Mobility

**Laboratory studies**:

Column leaching:

4 soil types (sand, loamy sand, loam, silt loam; pH 5.5 - 7.3 , OC 0.4 - 4.7 %)

Radioactivity in leachates : 0.15-2.73 %

Radioactivity in the 0-6 cm soil layer : 63.5-88.5 %

Aged residue leaching:

2 soil types (silt loam pH 7.2 , OC 2.4 %; loamy sand pH 7.6, OC 2 %)

After 5 h incubation, a.s.: 13.9 -22.7 %,
CGA 210007 : 70.2-63.8 %

200 mm / 2 d : 0.17 and 0.23 % RA in leachates

508 mm / 40 d. : 0.28 and 14.9 % RA in leachates

(mainly as CGA 210007)

**Field studies**:

Lysimeter/Field leaching studies:

Not required

**Remarks:**

| |
|---|
| Modelling using PELMO 3.00 for 10 years, single app to wheat and the German scenario, multiple appl. to tobacco and 2 Italian scenarios ( Southern Europe), multiple appl. to tomatoes and 3 Italian, French and Spanish scenarios (Southern Europe). DT50 1d (acibenzolar) and 27 d (CGA 210007). Koc 492 (acibenzolar) and 65 d (CGA 210007). PECgw<0.00 (acibenzolar-S-methyl) and <0.048µg/l (CGA 210007 |

# 2.2 Fate and behaviour in water

## Abiotic degradation

| | |
|---|---|
| Hydrolytic degradation: | pH 5; $DT_{50}$ : stable<br>pH 7 ; $DT_{50}$ : 162 d (value at 20° C extrapolated from experiments at 24, 50 and 70°C)<br>pH 9 ; $DT_{50}$ : 19 h (value at 20° C extrapolated from experiments at 24, 50 and 70°C) |
| Relevant metabolites: | CGA 210007 : pH 9, 41.3 % at 24°C (stable at all pH) |
| Photolytic degradation: | pH 5.1, 25°C; $DT_{50}$ 0.75 h<br>volatiles up to 19 % (mainly $CO_2$) |
| Relevant metabolites: | numerous metabolites, all < 10 % |

## Biological degradation

| | |
|---|---|
| Readily biodegradable: | Not readily biodegradable. |
| Water/sediment study: | |
| a.s<br>$DT_{50}$ water:<br>$DT_{90}$ water:<br>$DT_{50}$ whole system:<br>$DT_{90}$ whole system: | <br>$DT_{50w}$ < 1 d<br>$DT_{90w}$ < 3 d<br>$DT_{50ws}$ < 1 d<br>$DT_{90ws}$ 2.1-2.7 d |
| CGA 210007<br>$DT_{50}$ water:<br>$DT_{90}$ water:<br>$DT_{50}$ whole system:<br>$DT_{90}$ whole system: | <br>$DT_{50w}$:164 d (pond)-293 d (river)<br>$DT_{90w}$ : 544 d (pond)-973 d (river)<br>$DT_{50ws}$: 287d (pond)-426 d (river)<br>$DT_{90ws}$ : 953 d (pond)-1414 d (river) |
| Distribution in water / sediment systems (active substance) | max. 39.5/32.2% in water/sediment (0 d; river); 52.4 / 36.2 % in water / sediment (0d; pond). <LOD in both water and sediment after 7d |
| Distribution in water / sediment systems (metabolites) | CGA 210007 max. 75/17.8 % in water/sediment (3 d, river) and 44/38.2 % in water/sediment (59 d, pond)<br>33.4/23.3 %in water/sediment (363 d, river)<br>25.0/23.0 % in water/sediment (363 d, pond) |
| Mineralization | 9.5% within 1 year |
| Non extractable residues | 26-36% after 1 year |
| Accumulation in water and/or sediment: | Accumulation of CGA 210007 in water : higher plate concentration 1.12 µg/l (drift at 1m) and 0.17µg/l (d at 5m) for tobacco (maximum appl. rate) using DT5 300d. |

| | |
|---|---|
| **Degradation in the saturated zone** | not required |
| **Remarks:** | None. |

## 2.3 Fate and behaviour in air

### Volatility

| | |
|---|---|
| Vapour pressure: | $4.6 \times 10^{-4}$ Pa at 25 °C |
| Henry's law constant: | $1.3 \times 10^{-2}$ Pa $m^3$ $mole^{-1}$ |

### Photolytic degradation

| | |
|---|---|
| Direct photolysis in air: | No data, absorption at 288 and 324 nm |
| Photochemical oxidative degradation in air | $DT_{50}$ 19 - 40 h |
| $DT_{50}$: | (Atkinson) |
| Volatilisation: | Volatilization from soil and plant < 10 % in one day.<br>Volatilisation from plant surface : 38% in one day. |
| **Remarks:** | None. |

# 3 Ecotoxicology

## Terrestrial Vertebrates

| | |
|---|---|
| Acute toxicity to mammals: | LD50 (rat, acute oral) > 2 000 mg/kg bw |
| Short term oral toxicity to mammals: | NOEL (rat, reproduction) = 200 ppm |
| Acute toxicity to birds: | LD50 (bobwhite quail) > 2 000 mg/kg bw<br>LD50 (mallard duck) > 2 000 mg/kg bw |
| Dietary toxicity to birds: | LC50 (bobwhite quail) > 5 200 ppm<br>LC50 (mallard duck) > 5 200 ppm |
| Reproductive toxicity to birds: | NOEL (bobwhite quail) = 600 ppm |

## Aquatic Organisms

| | |
|---|---|
| Acute toxicity fish: | LC50 (trout, 96 h): 0.4 mg/l<br>LC50 (trout, 96 h): >100 mg/l (CGA 210007) |
| Long term toxicity fish: | NOEC (trout, 87 d): 0.026 mg/l |
| Bioaccumulation fish: | Log Pow : 3.1 at 25°C<br>BCF at 16 ppb:<br>118 (whole fish), 48 (fillet), 199 (viscera)<br>BCF at 156 ppb:<br>117 (whole fish), 47 (fillet), 194 (viscera)<br>Clearance time $CT_{50}$: 0.35 d (16 ppb), 0.3 d (156 ppb)<br>$CT_{90}$: not determined |
| Acute toxicity invertebrate: | EC50 (daphnid, 48 h): 2.4 mg/l<br>EC50 (daphnid, 48 h): 58 mg/l (CGA 210007) |
| Chronic toxicity invertebrate: | NOEC (daphnid, 22 d): 0.044 mg/l<br>NOEC (daphnid, 21d ): 30 mg/l (CGA 210007) |
| Acute toxicity algae: | EC50 (*Scenedesmus subspicatus*, 72 h): 0.5 mg/l<br>EC50 (*Scenedesmus subspicatus*, 72 h): 90 mg/l (CGA 210007) |
| Chronic toxicity sediment dwelling organism: | Not required |

## Honeybees

| | |
|---|---|
| Acute oral toxicity: | LD 50: > 128 µg /bee |
| Acute contact toxicity: | LD 50: > 100 µg /bee |

## Other arthropod species

| | |
|---|---|
| *Aphidius matricariae* | Mortality and parasitisation (female adult):<br>-4 % Effect (0.03 kg a.s./ha; 50% WG) |
| *Typhlodromus pyri* | Mortality and fecundity (protonymph/adult):<br>15.6 % Effect (0.03 kg a.s./ha; 50% WG) |
| *Orius insidiosus* | Mortality and predation (adult):<br>8 % Effect (0.03 kg a.s./ha; 50% WG) |
| *Poecilus cupreus* | Mortality and fecundity (nymph):<br>7.2 % Effect (0.03 kg a.s./ha; 50% WG) |

## Earthworms

| | |
|---|---|
| Acute toxicity: | LC50 > 1 000 mg /kg soil<br>NOEC<12.3 mg/kg soil |
| Reproductive toxicity: | NOEC = 2.675 mg/kg soil (CGA 210007) |

## Soil micro-organisms

| | |
|---|---|
| Nitrogen mineralization: | deviations < ± 25% *(RMS to check)* |
| Carbon mineralization: | deviations < ± 25%*(RMS to check)* |

# Appendix III

# ACIBENZOLAR-S-METHYL

The following studies were submitted after the peer review examination and were not cited in the monograph:

## Annex II + III Data and Information

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| IIIA 2.7.3 | Kundel, P. | 1998 | Final report on product stability HDPE jar<br>Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland, 26.5.1998<br>GLP, not published<br>Novartis File N° 245704-503 |

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| IIIA 2.7.3 | Kundel, P. | 1997 | Statement of BION 50WG A9180A<br>Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland, 16.5.1997<br>non-GLP, not published |
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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 Acibenzolar in Annex 1 to Council Directive 91/414/EEC** (Sanco/1945/2000 rev. 7; Review Report 6506/VI/99 rev. 8).

The Commission presented the Review Report in document 6506/VI/99 rev. 8. The Committee took note of the Review Report.

The following declarations were made:

The Netherlands: The Dutch delegation is of the opinion that during the process of authorisation the results of the dermal penetration study of acibenzolar-s-methyl should be interpreted in the light of the forthcoming guidance document on dermal absorption.

This declaratin was supported by Denmark.

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 plant activator against fungal diseases.

A CHECCHI LANG
Director

# Auszug

## 5.2 Acibenzolar-S-methyl

This new active substance had been referred to the Committee without any question for response. Following an exchange of views the Committee noted the documentation submitted and decided that there were no issues that it wished to raise regarding the active substance in the context of a possible inclusion in Annex I to Directive 91/414/EEC. It was recognised that national authorisations would involve specific risk management in line with Annex VI (Uniform Principles) of Directive 91/414/EEC.

The Committee reiterated its earlier statements that absence of comments should only be interpreted as an indication of no obvious reasons necessitating comments.

Prof. Maroni raised the question on the expectation of the Commission concerning the dossiers with no precise questions. He pointed out that so far the Committee has been expected to address specific questions by scrutinising the documentation produced by the ECCO process, the monograph prepared by rapporteur member states and where necessary the original studies directly related to the specific issues raised by the question.

The Committee confirmed that there had been no in-depth peer review of the monograph and stressed that it does not have the resources to perform such a work. It was agreed the Chairman of the Committee should write a letter to the Commission services requesting clarification as to the Commission's expectation where dossiers are referred without questions. In addition, Prof. Hardy will raise the matter of referral of unclear and insufficiently focused questions: such questions require the deployment of greater resource from the Committee that would otherwise be necessary, slow the work progress and risk that the Committee does not respond to the precise needs of the Commission.

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

Heft 86, 2001: EU-Beurteilungsbericht Pyrazophos. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 20.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.

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.
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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.

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Bearbeitet von Dr. Martina Erdtmann-Vourliotis, Dr. Axel Wilkening und Susanne Schaper, getr. Zählung.

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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 Wühlmausschäden im ökologischen Landbau. Bearbeitet von Dr. Hans-Joachim Pelz, 109 S.