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Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen Band D 13

Review Report Amitrole
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 13

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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 13. Heft dieser Reihe (Band D 13) 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 Amitrol 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)
68/2000	Band B: Verordnungen und Protokolle zur Wirkstoffprüfung (4. Auflage, Stand 01. Juli 2000)
	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 13th report belonging to this series (Volume D 13) 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 amitrole 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)
68/2000	Volume B: Regulations and Protocols regarding the Evaluation of Active Substances (4th Edition, date: 1 July 2000)
	Volume C: *In Progress*

RICHTLINIE 2001/21/EG DER KOMMISSION

vom 5. März 2001

zur Änderung von Anhang I der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufnahme der Wirkstoffe Amitrol, Diquat, Pyridat und Thiabendazol

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 2000/80/EG der Kommission [2], insbesondere auf Artikel 6 Absatz 1,

in Erwägung nachstehender Gründe:

(1) Mit der Verordnung (EWG) Nr. 3600/92 der Kommission vom 11. Dezember 1992 [3], zuletzt geändert durch die Verordnung (EG) Nr. 2266/2000 [4], wurden die Durchführungsbestimmungen für die erste Stufe des Arbeitsprogramms gemäß Artikel 8 Absatz 2 der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln (im Folgenden „die Richtlinie" genannt) erlassen. Gemäß vorgenannter Verordnung wurde mit der Verordnung (EG) Nr. 933/94 der Kommission vom 27. April 1994 über die Festsetzung der Wirkstoffe von Pflanzenschutzmitteln und die Bestimmung der berichterstattenden Mitgliedstaaten zur Durchführung der Verordnung (EWG) Nr. 3600/92 [5], zuletzt geändert durch die Verordnung (EG) Nr. 2230/95 [6], die Liste der Wirkstoffe in Pflanzenschutzmitteln festgelegt, die im Hinblick auf ihre mögliche Aufnahme in Anhang I der Richtlinie zu bewerten sind.

(2) Gemäß Artikel 5 Absatz 1 der Richtlinie ist ein Wirkstoff für einen Zeitraum von höchstens zehn Jahren in Anhang I aufzunehmen, wenn angenommen werden kann, dass weder die Anwendung von Pflanzenschutzmitteln, die diesen Wirkstoff enthalten, noch deren Rückstände schädliche Auswirkungen auf die Gesundheit von Mensch und Tier oder auf das Grundwasser bzw. unannehmbare Auswirkungen auf die Umwelt haben werden.

(3) Die Auswirkungen von Amitrol, Diquat, Pyridat und Thiabendazol auf die menschliche Gesundheit und auf die Umwelt wurden gemäß den Bestimmungen der Verordnung (EWG) Nr. 3600/92 für eine Reihe von durch die Antragsteller vorgeschlagenen Anwendungen geprüft. Gemäß der Verordnung (EG) Nr. 933/94 wurde Frankreich zum berichterstattenden Mitgliedstaat für Amitrol, das Vereinigte Königreich zum berichterstattenden Mitgliedstaat für Diquat und Spanien zum berichterstattenden Mitgliedstaat für Thiabendazol benannt. Österreich wurde gemäß der Verordnung (EG) Nr. 491/95 der Kommission zur Änderung der Verordnung (EWG) Nr. 3600/92 und der Verordnung (EG) Nr. 933/94, insbesondere hinsichtlich der Berücksichtigung der benannten Behörden und der Hersteller in Österreich, Finnland und Schweden bei der Durchführung der ersten Stufe des Arbeitsprogramms gemäß Artikel 8 Absatz 2 der Richtlinie [7] zum berichterstattenden Mitgliedstaat für Pyridat ernannt. Die berichterstattenden Mitgliedstaaten haben der Kommission ihre Bewertungsberichte und Empfehlungen am 30. April 1996 (Amitrol), am 2. April 1996 (Diquat), am 18. November 1996 (Pyridat) und am 30. April 1996 (Thiabendazol) gemäß Artikel 7 Absatz 1 Buchstabe c) der Verordnung (EWG) Nr. 3600/92 übermittelt.

(4) Diese Bewertungsberichte wurden von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses für Pflanzenschutz geprüft. Diese Prüfungen wurden am 12. Dezember 2000 in Form der jeweiligen Prüfungsberichte der Kommission für Amitrol, Diquat, Pyridat und Thiabendazol abgeschlossen. Sollten die Prüfungsberichte unter Berücksichtigung technischer und wissenschaftlicher Entwicklungen aktualisiert werden müssen, so sind auch die Bedingungen für die Aufnahme der betreffenden Wirkstoffe in Anhang I der Richtlinie gemäß der Richtlinie zu ändern.

(5) Die Unterlagen und die aus der Prüfung hervorgegangenen Informationen zu Amitrol wurden auch dem Wissenschaftlichen Pflanzenausschuss zur Stellungnahme vorgelegt. Der Ausschuss hat in seiner Stellungnahme vom 6. Juni 2000 [8] die festgesetzte annehmbare Anwenderexposition (AOEL — acceptable Operator exposure level) bestätigt und Hinweise zur Interpretation von Langzeitstudien bei Nagern gegeben. Diesen Empfehlungen wurde bei der Erarbeitung dieser Richtlinie und des entsprechenden Prüfungsberichts Rechnung getragen.

(6) Die Unterlagen und die aus der Prüfung hervorgegangenen Informationen zu Diquat wurden ebenfalls dem Wissenschaftlichen Pflanzenausschuss zur Stellungnahme vorgelegt. Der Ausschuss hat in seiner Stellungnahme vom 5. April 2000 [9] Hinweise zur Interpretation der vorliegenden Studien über die Reproduktion von Vögeln, über potentielle Langzeiteffekte von an Bodenpartikel gebundenen Rückständen, über die potenziellen Auswirkungen der Bekämpfung von Wasserunkräutern und über bestimmte Aspekte der Anwender- und Verbraucherexposition gegeben. In seiner Interpretation der verfügbaren Studien über die Reproduktion von Vögeln kam der Ausschuss zu dem Schluss, dass keine Anhaltspunkte dafür vorliegen, dass Rückstände im Boden unannehmbare Auswirkungen haben werden. Der Ausschuss stellte außerdem fest, dass Anwendungen von

[1] ABl. L 230 vom 19.8.1991, S. 1.
[2] ABl. L 309 vom 9.12.2000, S. 14.
[3] ABl. L 366 vom 15.12.1992, S. 10.
[4] ABl. L 259 vom 13.10.2000, S. 27.
[5] ABl. L 107 vom 28.4.1994, S. 8.
[6] ABl. L 225 vom 22.9.1995, S. 1.
[7] ABl. L 49 vom 4.3.1995, S. 50.
[8] Wissenschaftlicher Pflanzenausschuss SCP/AMITR/002-endg.
[9] Wissenschaftlicher Pflanzenausschuss SCP/DIQUAT/002-endg.

Diquat in der Bekämpfung von Wasserunkräutern möglicherweise mit einem hohen Risiko für nicht zu den Zielgruppen gehörende Wasserorganismen einhergehen können und unzureichende Daten über die wirksame Anwendung von Risikominimierungsmaßnahmen vorliegen. Was die Anwenderexposition betrifft, so empfahl der Ausschuss, Maßnahmen zur Begrenzung der Exposition von nichtprofessionellen Anwendern in Erwägung zu ziehen. Abschließend stellte der Ausschuss fest, dass nicht genügend Informationen vorliegen, um die Exposition von Verbrauchern durch die Aufnahme des Wirkstoffs mit der Nahrung bei Anwendungen als Sikkations-Mittel in kleinkörnigen Getreidearten umfassend zu bewerten. Dieser Stellungnahme wurde bei der Erarbeitung dieser Richtlinie und des entsprechenden Prüfungsberichts Rechnung getragen.

(7) Die Unterlagen und die aus der Prüfung hervorgegangenen Informationen zu Pyridat wurden ebenfalls dem Wissenschaftlichen Pflanzenausschuss zur Stellungnahme vorgelegt. Der Ausschuss hat in seiner Stellungnahme vom 6. Juni 2000 (1) die Gültigkeit der vom Ständigen Ausschuss für Pflanzenschutz festgesetzten annehmbaren Anwenderexposition bestätigt.

(8) Auch die Unterlagen und die aus der Prüfung hervorgegangenen Informationen zu Thiabendazol wurden dem Wissenschaftlichen Pflanzenausschuss zur Stellungnahme vorgelegt. Der Ausschuss hat in seiner Stellungnahme vom 22. September 2000 (2) bestätigt, dass die vorgesehenen Anwendungen von Thiabendazol bei Obst und Kartoffeln nach der Ernte kein unannehmbares Risiko für Wasserorganismen darstellen, vorausgesetzt, dass geeignete Risikominimierungsmaßnahmen getroffen werden. Dieser Empfehlung wurde bei der Erarbeitung dieser Richtlinie und des entsprechenden Prüfungsberichts Rechnung getragen.

(9) Die Untersuchungen haben ergeben, dass davon ausgegangen werden kann, dass die betreffenden Wirkstoffe enthaltende Pflanzenschutzmittel, insbesondere hinsichtlich der geprüften und im Prüfungsbericht der Kommission behandelten Anwendungen, im Allgemeinen die Anforderungen gemäß Artikel 5 Absatz 1 Buchstaben a) und b) der Richtlinie erfüllen. Daher sollten die betreffenden Wirkstoffe in Anhang I aufgenommen werden, damit in allen Mitgliedstaaten die Zulassung von Pflanzenschutzmitteln, die diese Wirkstoffe enthalten, gemäß den Bestimmungen der genannten Richtlinie erfolgen kann.

(10) Gemäß Artikel 5 Absatz 5 der Richtlinie kann die Aufnahme eines Wirkstoffes in Anhang I jederzeit überprüft werden, wenn es Anzeichen dafür gibt, dass die Kriterien für die Aufnahme nicht mehr erfüllt sind. Die Kommission wird daher die Aufnahme von Amitrol in Anhang I erneut prüfen, wenn die geforderten zusätzlichen Informationen gemäß Punkt 7 des Prüfungsberichts nicht vorgelegt werden.

(11) Gemäß der Richtlinie stellen die Mitgliedstaaten nach Aufnahme eines Wirkstoffs in Anhang I sicher, dass die Zulassungen von Pflanzenschutzmitteln, die diesen Wirkstoff enthalten, innerhalb eines vorgeschriebenen Zeitraums erteilt, widerrufen bzw. geändert werden. Pflanzenschutzmittel dürfen nur zugelassen werden, wenn die Bedingungen in Zusammenhang mit der Aufnahme des betreffenden Wirkstoffs in Anhang I sowie die einheitlichen Grundsätze gemäß der Richtlinie auf der Grundlage von Unterlagen, die den Datenanforderungen entsprechen, erfüllt sind.

(12) Vor der Aufnahme eines Wirkstoffs in Anhang I ist eine angemessene Frist vorzusehen, um es den Mitgliedstaaten und Interessierten zu ermöglichen, sich auf die sich daraus ergebenden neuen Anforderungen vorzubereiten. Nach der Aufnahme ist den Mitgliedstaaten außerdem eine angemessene Frist einzuräumen, um die Bestimmungen der Richtlinie über Pflanzenschutzmittel, die Amitrol, Diquat, Pyridat oder Thiabendazol enthalten, umsetzen zu können. Die Mitgliedstaaten müssen innerhalb dieser Frist gemäß den Bestimmungen der Richtlinie insbesondere bestehende Zulassungen überprüfen und gegebenenfalls neue Zulassungen erteilen. Für die Einreichung und Bewertung der für jedes Pflanzenschutzmittel vollständigen Unterlagen gemäß den in der Richtlinie festgelegten einheitlichen Grundsätzen ist ein längerer Zeitraum vorzusehen. Pflanzenschutzmittel, die mehrere Wirkstoffe enthalten, können jedoch auf der Grundlage der einheitlichen Grundsätze erst vollständig bewertet werden, wenn alle enthaltenen Wirkstoffe in Anhang I der Richtlinie aufgenommen sind.

(13) Es ist vorzuschreiben, dass die Mitgliedstaaten die endgültigen Prüfungsberichte (mit Ausnahme von vertraulichen Informationen) allen Interessierten zur Einsicht zur Verfügung stellen oder zugänglich machen.

(14) Die Prüfungsberichte sind erforderlich für die ordnungsgemäße Umsetzung bestimmter Teile der in der Richtlinie festgelegten einheitlichen Grundsätze durch die Mitgliedstaaten, soweit sich diese Grundsätze auf die Bewertung der Angaben beziehen, die zwecks Aufnahme der Wirkstoffe in Anhang I der Richtlinie vorgelegt wurden.

(15) Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz vom 12. Dezember 2000 —

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

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 1. Juli 2002 nachzukommen. Sie unterrichten die Kommission unverzüglich davon.

Gemäß der Richtlinie 91/414/EWG ändern oder widerrufen sie innerhalb dieses Zeitraums erforderlichenfalls insbesondere bestehende Zulassungen für Pflanzenschutzmittel, die Amitrol, Diquat, Pyridat oder Thiabendazol als Wirkstoff enthalten.

(1) Wissenschaftlicher Pflanzenausschuss SCP/PYRID/002-endg.
(2) Wissenschaftlicher Pflanzenausschuss SCP/THIABEN/002-endg.

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 Bewertung und der Entscheidungsfindung gemäß den einheitlichen Grundsätzen des Anhangs VI der Richtlinie 91/414/EWG auf der Grundlage von Unterlagen, die die Anforderungen des Anhangs III der genannten Richtlinie erfüllen, läuft die Frist für die Änderung oder den Widerruf von Zulassungen von Pflanzenschutzmitteln, die Amitrol, Diquat, Pyridat oder Thiabendazol als einzigen Wirkstoff enthalten, bis zum 1. Januar 2006.

(3) Bei Pflanzenschutzmitteln, die Amitrol, Diquat, Pyridat oder Thiabendazol zusammen mit einem anderen noch nicht in Anhang I der Richtlinie 91/414/EWG aufgenommenen Wirkstoff enthalten, läuft die Frist für die Änderung oder den Widerruf von Zulassungen vier Jahre nach dem Inkrafttreten der Richtlinie zur Änderung des Anhangs I mit der Aufnahme des letzten dieser Wirkstoffe ab.

(4) Die Mitgliedstaaten stellen die Prüfungsberichte (mit Ausnahme von vertraulichen Informationen im Sinne des Artikels 14 der Richtlinie 91/414/EWG) allen Interessierten zur Einsicht zur Verfügung oder machen sie gegebenenfalls auf besonderen Antrag zugänglich.

(5) Die Mitgliedstaaten teilen der Kommission mit, falls die erforderlichen zusätzlichen Informationen gemäß Punkt 7 des Prüfungsberichts für Amitrol bis zum 1. Januar 2002 nicht übermittelt wurden. In diesem Fall wird die Kommission die Aufnahme von Amitrol in Anhang I der Richtlinie 91/414/EWG erneut überprüfen.

Artikel 3

Diese Richtlinie tritt am 1. Januar 2002 in Kraft.

Artikel 4

Diese Richtlinie ist an die Mitgliedstaaten gerichtet.

Brüssel, den 5. März 2001

Für die Kommission

David BYRNE

Mitglied der Kommission

ANHANG

Die folgenden Einträge (Nummern 14 bis 17) werden an die Tabelle in Anhang I der Richtlinie 91/414/EWG angefügt:

Nr.	Gemeinsamer Name, Kennnummern	IUPAC-Bezeichnung	Reinheit (1)	Inkrafttreten	Befristung der Eintragung	Sonderbestimmungen
„14	Amitrol CAS-Nr. 61-82-5 CIPAC-Nr. 90	H-[1,2,4]-Triazole-3-yl-amine	900 g/kg	1.1.2002	31.12.2011	Nur Anwendungen als Herbizid dürfen zugelassen werden. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 12. Dezember 2000 abgeschlossenen Prüfungsberichts über Amitrol und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten: — der Anwendersicherheit besondere Aufmerksamkeit widmen; — dem Grundwasserschutz in gefährdeten Gebieten, insbesondere im Hinblick auf Anwendungen in Nicht-Kulturland, besondere Aufmerksamkeit widmen; — dem Schutz von Nutzarthropoden besondere Aufmerksamkeit widmen; — dem Schutz von Vögeln und wildlebenden Säugetieren besondere Aufmerksamkeit widmen. Die Anwendung von Amitrol während der Brutzeit sollte nur zugelassen werden, wenn durch eine entsprechende Risikobewertung keine unannehmbaren Auswirkungen nachgewiesen wurden und wenn die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikobegrenzung umfassen.
15	Diquat CAS-Nr. 2764-72-9 (ion), 85-00-7 (Dibromid) CIPAC-Nr. 55	9,10-Dihydro-8a,10a-diazoniaphenanthren-ion (Dibromid)	950 g/kg	1.1.2002	31.12.2011	Auf der Grundlage der vorliegenden Informationen dürfen nur Anwendungen als Bodenherbizid und Sikkations-Mittel zugelassen werden. Anwendungen zur Bekämpfung von Wasserunkräutern dürfen nicht zugelassen werden. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 12. Dezember 2000 abgeschlossenen Prüfungsberichts über Diquat und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten: — besonders auf die potenziellen Auswirkungen auf Wasserorganismen achten und sicherstellen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikominderung umfassen; — der Anwendersicherheit bei nichtprofessioneller Anwendung besondere Aufmerksamkeit widmen und dafür Sorge tragen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikobegrenzung umfassen.
16	Pyridat CAS-Nr. 55512-33-9 CIPAC-Nr. 447	6-Chlor-3-phenylpyridazin-4-yl)S-octyl-thiocarbonat	900 g/kg	1.1.2002	31.12.2011	Nur Anwendungen als Herbizid dürfen zugelassen werden. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 12. Dezember 2000 abgeschlossenen Prüfungsberichts über Pyridat und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten: — dem Grundwasserschutz besondere Aufmerksamkeit widmen; — besonders auf die potenziellen Auswirkungen auf Wasserorganismen achten und sicherstellen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikominderung umfassen.

Nr.	Gemeinsamer Name, Kennnummern	IUPAC-Bezeichnung	Reinheit (1)	Inkrafttreten	Befristung der Eintragung	Sonderbestimmungen
17	Thiabendazol CAS-Nr. 148-79-8 CIPAC-Nr. 323	2-Thiazol-4-yl-1H-benzimidazol	985 g/kg	1.1.2002	31.12.2011	Nur Anwendungen als Fungizid dürfen zugelassen werden. Blattspritzungen dürfen nicht zugelassen werden. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 12. Dezember 2000 abgeschlossenen Prüfungsberichts über Thiabendazol und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten: — dem Schutz von Wasserorganismen und Sedimentlebewesen besondere Aufmerksamkeit widmen und sicherstellen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikominderung umfassen. Es müssen geeignete Maßnahmen zur Risikobegrenzung (z. B. Klärung mit Kieselgur oder Aktivkohle) durchgeführt werden, um Oberflächengewässer vor übermäßiger Kontamination durch Abwasser zu schützen.

(1) Nähere Angaben zur Identität und Spezifikation der Wirkstoffe sind in den betreffenden Prüfungsberichten enthalten."

COMMISSION DIRECTIVE 2001/21/EC

of 5 March 2001

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include amitrole, diquat, pyridate and thiabendazole 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 2000/80/EC [2], and in particular Article 6(1) thereof,

Whereas:

(1) Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market [3], as last amended by Regulation (EC) No 2266/2000 [4], laid down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC (hereinafter referred to as 'the Directive'). Pursuant to that Regulation, Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member State for the implementation of Regulation (EEC) No 3600/92 [5], as last amended by Regulation (EC) No 2230/95 [6], laid down the list of active substances of plant protection products to be assessed, with a view to their possible inclusion in Annex I to the Directive.

(2) In accordance with Article 5(1) of the Directive, an active substance should be included in Annex I for a period not exceeding 10 years if it may be expected that neither the use of, nor residues from, plant protection products containing the active substance will have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment.

(3) For amitrole, diquat, pyridate and thiabendazole the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the respective notifiers. Under Regulation (EC) No 933/94, France was designated as rapporteur Member State for amitrole, the United Kingdom for diquat, and Spain for thiabendazole. Austria was designated as rapporteur Member State for pyridate under Regulation (EC) No 491/95 [7] amending Regulation (EEC) No 3600/92 and Regulation (EC) No 933/94, in particular with regard to the integration of the designated public authorities and the producers in Austria, Finland and Sweden in the implementation of the first stage of the programme of work referred to in Article 8(2) of the Directive. The rapporteur Member States submitted the relevant assessment report and recommendation to the Commission on 30 April 1996 (amitrole), on 2 April 1996 (diquat), on 18 November 1996 (pyridate) and 30 April 1996 (thiabendazole) in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(4) These assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. The reviews were finalised on 12 December 2000 in the format of the respective Commission review reports for amitrole, diquat, pyridate and thiabendazole. If the review reports have to be updated to take account of technical and scientific developments, the conditions for the inclusion of the substances concerned in Annex I to the Directive will also need to be amended in accordance with the Directive.

(5) The dossier and the information from the review of amitrole were submitted to the Scientific Committee for Plants for consultation. In its opinion of 6 June 2000 [8], the Committee confirmed the acceptable operator exposure level selected and offered advice on the interpretation of the long-term studies in rodents. The recommendations were taken into consideration in this Directive and in the relevant review report.

(6) The dossier and the information from the review of diquat were also submitted to the Scientific Committee for Plants for consultation. In its opinion of 5 April 2000 [9], the Committee offered advice on the interpretation of the available studies on bird reproduction, on potential long-term effects of residues bound to soil particles, on the potential environmental impact of aquatic weed control, and on certain aspects of operator and consumer exposure. The Committee offered its interpretation of the bird reproduction studies available. It concluded that there are no indications that residues in soil will have unacceptable effects. Further, the Committee noted that aquatic weed control uses of diquat may pose a high risk to non-target aquatic organisms and insufficient data is available to demonstrate that efficient risk mitigation measures can be applied.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 309, 9.12.2000, p. 14.
[3] OJ L 366, 15.12.1992, p. 10.
[4] OJ L 259, 13.10.2000, p. 27.
[5] OJ L 107, 28.4.1994, p. 8.
[6] OJ L 225, 22.9.1995, p. 1.
[7] OJ L 49, 4.3.1995, p. 50.

[8] Scientific Committee on Plants SCP/AMITR/002 final.
[9] Scientific Committee on Plants SCP/DIQUAT/002 final.

With regard to operator exposure, the Committee advised that measures should be considered to limit exposure of non-professional users. Finally, the Committee noted that insufficient information is available to fully assess the dietary exposure of consumers related to uses as desiccant in small grain cereals. Those opinions were taken into consideration in this Directive and in the relevant review report.

(7) For pyridate also, the dossier and the information from the review were submitted to the Scientific Committee for Plants for consultation. In its opinion of 6 June 2000 [1], the Committee confirmed the validity of the acceptable operator exposure level selected within the Standing Committee on Plant Health.

(8) For thiabendazole as well, the dossier and the information from the review were submitted to the Scientific Committee for Plants for consultation. In its opinion of 22 September 2000 [2], the Committee confirmed that the intended post-harvest uses of thiabendazole for fruit and potatoes will not pose an unacceptable risk to aquatic organisms, provided that adequate risk mitigation measures are applied. This recommendation was taken into consideration in this Directive and in the relevant review report.

(9) It has appeared from the various examinations made that plant protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of the Directive, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include the active substances concerned in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing the active substances concerned can be granted in accordance with the provisions of the said Directive.

(10) Article 5(5) of the Directive provides that the inclusion of an active substance in Annex I can be reviewed at any time if there are indications that the criteria for inclusion are no longer satisfied. Therefore, the Commission will reconsider the inclusion in Annex I of amitrole if the requested additional information as outlined in point 7 of the review report were not submitted.

(11) The Directive provides that after inclusion of an active substance in Annex I, Member States must, within a prescribed period, grant, vary or withdraw, as appropriate, the authorisations of the plant protection products containing the active substance. In particular, plant protection products should not be authorised unless account is taken of the conditions associated with the inclusion of the active substance in Annex I and the uniform principles laid down in the Directive on the basis of a dossier satisfying the prescribed data requirements.

(12) A reasonable period must be provided for before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion. Moreover, after inclusion, a reasonable period is necessary to permit Member States to implement the provisions of the Directive on plant protection products containing amitrole, diquat, pyridate or thiabendazole. In particular, Member States must, within that period, review existing authorisations and, where appropriate, grant new authorisations in accordance with the provisions of the Directive. A longer period should be provided for the submission and assessment of the complete dossier of each plant protection product in accordance with the uniform principles laid down in the Directive. For plant protection products containing several active substances, the complete evaluation on the basis of the uniform principles can only be carried out when all the active substances concerned have been included in Annex I to the Directive.

(13) It is appropriate to provide that the finalised review reports (except for confidential information) are kept available or made available by the Member States for consultation by any interested parties.

(14) The review reports are required for the proper implementation by the Member States, of several sections of the uniform principles laid down in the Directive, where those principles refer to the evaluation of the data which were submitted for the purpose of the inclusion of the active substances in Annex I to the Directive.

(15) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health delivered on 12 December 2000,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

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

In particular they shall, in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing amitrole, diquat, pyridate or thiabendazole as active substances by that date.

[1] Scientific Committee on Plants SCP/PYRID/002 final.
[2] Scientific Committee on Plants SCP/THIABEN/002-final.

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. 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 deadline for amending or withdrawing authorisations for plant protection products containing amitrole, diquat, pyridate or thiabendazole as the only active substance shall be 1 January 2006.

3. For plant protection products containing amitrole, diquat, pyridate or thiabendazole together with another active substance which is in Annex I to Directive 91/414/EEC, the period for amending or withdrawing authorisations shall expire four years after the entry into force of the Directive which amended Annex I so as to add the last of those substances to it.

4. Member States shall keep available the review reports for amitrole, diquat, pyridate and thiabendazole (except for confidential information within the meaning of Article 14 of Directive 91/414/EEC) for consultation by any interested parties or shall make it available to them on specific request.

5. Member States shall inform the Commission if the requested additional information outlined in point 7 of the Review Report for amitrole is not submitted by 1 January 2002. In such case the Commission will reconsider the inclusion of amitrole in Annex I to Directive 91/414/EEC.

Article 3

This Directive shall enter into force on 1 January, 2002.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 5 March 2001.

For the Commission

David BYRNE

Member of the Commission

ANNEX

The following entries (numbered 14 to 17) shall be added at the end of the table in Annex I to Directive 91/414/EC:

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'14	Amitrole CAS No 61-82-5 CIPAC No 90	H-[1,2,4]-triazole-3-ylamine	900 g/kg	1.1.2002	31.12.2011	Only uses as herbicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on amitrole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 December 2000 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of operators — must pay particular attention to the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses — must pay particular attention to the protection of beneficial arthropods — must pay particular attention to the protection of birds and wild mammals. Use of amitrole during the breeding season may only be authorised when an appropriate risk assessment has demonstrated that there is no unacceptable impact and when the conditions of authorisation include, where appropriate, risk mitigation measures
15	Diquat CAS No 2764-72-9 (ion), 85-00-7 (dibromide) CIPAC No 55	9,10-Dihydro-8a,10a-diazoniaphenanthrene ion (dibromide)	950 g/kg	1.1.2002	31.12.2011	On the basis of currently available information, only uses as terrestrial herbicide and desiccant may be authorised. Uses in aquatic weed control shall not be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on diquat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 December 2000 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures — must pay particular attention to operator safety as related to non-professional use and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures
16	Pyridate CAS No 55512-33.9 CIPAC No 447	6-Chloro-3-phenylpyridazin-4-yl S-octyl thiocarbonate	900 g/kg	1.1.2002	31.12.2011	Only uses as herbicide may be authorised For the implementation of the uniform priciples of Annex VI, the conclusions of the review report on pyridate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 December 2000 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of groundwater — must pay particular attention to the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
17	Thiabendazole CAS No 148-79-8 CIPAC No 323	2-Thiazol-4-yl-1H-benzimidazole	985 g/kg	1.1.2002	31.12.2011	Only uses as fungicide may be authorised. Foliar spray applications shall not be authorised For the implementation of the uniform priciples of Annex VI, the conclusions of the review report on thiabendazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 December 2000 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of aquatic and sediment-dwelling organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Suitable risk mitigation measures (e.g. depuration with diatom earth or activated carbon) have to be implemented to protect surface waters from unacceptable levels of contamination via wastewater

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

EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH & CONSUMER PROTECTION

Directorate E - Public, animal and plant health
Unit E1 Legislation relating to crop products and animal nutrition

Amitrole

6839/VI/97-final

22 March 2001

Review report for the active substance **amitrole**

Finalised in the Standing Committee on Plant Health at its meeting on **12 December 2000 in view of the inclusion of amitrole in Annex I of Directive 91/414/EEC**

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of amitrole, made in the context of the work programme for review of existing active substances provided for in Article 8(2) 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.

Commission Regulation (EEC) No 3600/92([1]) laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1972/99([2]), has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. amitrole is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, Bayer AG on 21 July 1993, CFPI on 28 July 1993, Helm AG on 23 July 1993, SA John & Stephen B. on 29 July 1993 and B.V. Luxan on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance amitrole in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94([3]), as last amended by Regulation (EC) No 2230/95([4]), designated France as rapporteur Member State to carry out the assessment of amitrole on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC)

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[1] OJ No L 366, 15.12.1992, p.10.

[2] OJ No L 244, 16.09.1999, p.41.

[3] OJ No L 107, 28.04.1994, p.8.

[4] OJ No L 225, 22.09.1995, p.1.

No 3600/92, as well as for other parties with regard to further technical and scientific information; for amitrole this deadline was 30 April 1995.

Bayer AG and CFPI jointly submitted a dossier to the rapporteur Member State. CFPI was the main data submitter, with a dossier which did not contain substantial data gaps, taking into account the supported uses. The dossier was considered as complete. No information has further been submitted by third parties.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, France submitted on 30 April 1996 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of amitrole in Annex I to the Directive. Moreover, in accordance with the same provisions, the Commission and the Member States received also the summary dossier on amitrole from CFPI, on 6 January 1997.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 25 October 1996 as well as to CFPI being the main data submitter, on 6 November 1996.

The Commission organised an intensive consultation of technical experts from a certain 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 January to April 1997.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 10 April 1997 for comments and further clarification.

In accordance with the provisions of Article 6(4) of Directive 91/414/EEC concerning consultation in the light of a possible unfavourable decision for the active substance the Commission organised a tripartite meeting with the main data submitter and the rapporteur Member State for this active substance on 17 November 1997.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review 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 February 1998 to October 2000, and was finalised in the meeting of the Standing Committee on 12 December 2000.

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

These documents were also submitted to the Scientific Committee for Plants for separate consultation. The report of this Committee was formally adopted on 6 June 2000 (SCP/AMITR/002-Final [5]).

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 2001/21/EC concerning the inclusion of amitrole in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing amitrole 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 accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, 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 all operators having notified for this active substance under Article 4(1) of this Regulation.

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 to have 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 amitrole 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

[5] Opinion of the scientific Committee on Plants regarding the inclusion of amitrole in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market

of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each amitrole 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 main data submitter:

- Herbicide for non-selective control of annual and perennial monocotyledonous and dicotyledonous weeds in vineyards, orchards, for intercropping and minimum tillage, and non-crop uses like railroads, roadsides or industrial settings.

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.

With particular regard to residues, 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; excluding water and products of animal origin) for a 60 kg adult is < 3 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

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

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 6 of this report.

4. Identity and Physical/chemical properties

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

The active substance shall comply with the FAO specification and there seem not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report.

The review has established that for the active substance notified by the main data submitter CFPI none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, France is also satisfied, on the basis of the information currently available, that the substances notified by Bayer AG does not, in the meaning of Article 13(2) and (5) of the Directive, differ significantly in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main data submitter.

5. 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 re-evaluation process are set out under point 1 above. These endpoints are listed in Appendix II.

6. 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 amitrole

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

- Operator exposure: Member states must pay particular attention to the protection of operators.

- Protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses.

- Protection of beneficial arthropods.

- To ensure the protection of birds and wild mammals use of amitrole during the breeding season may only be authorised when an appropriate risk assessment has demonstrated that there is no unacceptable impact and when the conditions of authorisation include, where appropriate, risk mitigation measures.

7. List of studies to be generated

The main data submitter undertakes to identify two impurities of the active substance as manufactured (impurities "D" and "F")[6]. This data has to be provided to the Member States by 1 January 2002, as outlined in Article 2 of the inclusion Directive.

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

- Field studies related to the exposure of operators to permit a better estimate of the exposure.
- Further testing of the effects on non-target arthropods under semi-field or field conditions.

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[6] See background document C

8. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. 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.

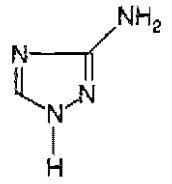
9. Updating of this review report

The technical information in this report may require to be updated from time to time in order 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 amitrole in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

AMITROLE

Common name (ISO)	Amitrole
Chemical name (IUPAC)	1-*H*-1,2,4-triazol-3-ylamine
Chemical name (CA)	1-*H*-1,2,4-triazol-3-amine
CIPAC No	90
CAS No	61-82-5
EEC No	613-011-00-6
FAO SPECIFICATION	1998 (≥ 900g/kg)
Minimum purity	The active substance as manufactured shall have a specified minimum purity of at least 900 g/kg
Molecular formula	$C_2H_4N_4$
Molecular mass	84.08
Structural formula	

Melting point	157 - 159 °C
Boiling point	Not applicable
Appearance	Colourless crystals
Relative density	1.138 at 20°C
Vapour pressure	3.3 ·x 10^{-5} Pa at 20 °C *
Henry's law constant	1.7610^{-8} x Pa x m^3 x mol^{-1} at 20°C
Solubility in water	280 g/l at 23 °C; pH not specified 264 g/l at pH 7, 261 g/l at pH 10
Solubility in organic solvents	isopropanol : 27g/l at 20°C toluene : 0.02 g/l at 20°C dichloromethane : 0.10 g/l at 20°C n-hexane : < 0.01 g/l at 20°C
Partition co-efficient (log P_{ow})	- 0.969 at pH 7 at 23 °C
Hydrolytic stability (DT_{50})	Insignificant hydrolytic degradation at pH 5, 7 and 9
Dissociation constant	pK_1 4.14 at 20°C, pK_2 10.7 at 20°C
Quantum yield of direct photo-transformation in water at λ >290 nm	Photostable No absorption at λ>290nm
Flammability	Brief ignition and rapid extinction
Explosive properties	Lower explosion limit = Ca.500 g/m^3 No sensitive to impact
UV/VIS absorption (max.)	UV_{max} 198 nm ; ε 4947 L.mol^{-1}.cm^{-1}
Photostability in water (DT_{50})	Stable in water.

APPENDIX II

END POINTS AND RELATED INFORMATION

AMITROLE

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Almost completely absorbed; oral; rat <1d (70 - 95%)
Distribution:	Rapid to all tissues; liver highest level
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	Eliminated within 2 days; urine (70 - 95%)
Toxicologically significant compounds:	Parent (50 - 60%); + triazolylalanine
Metabolism in animals:	3 minor metabolites. Presence of mercapturic acid metabolite.

Acute toxicity

Rat LD_{50} oral:	> 5000 mg/kg bw; no effects iv 5000 mg/kg
Rat LD_{50} dermal:	> 2500 mg/kg bw; no effects >10000; rabbit
Rat LC_{50} inhalation:	0.439 mg/l
Skin irritation:	Not irritant.
Eye irritation:	Not classified.
Skin sensitization (test method used and result):	Not a sensitizer (M and K)

Short term toxicity

Target / critical effect:	Thyroid inhibition/secondary liver; several species.
Lowest relevant oral NOAEL / NOEL:	0.1 mg/kg bw/d; 90 d rat 0.3 mg/kg bw/d; 1 y dog
Lowest relevant dermal NOAEL / NOEL:	100 mg/kg/d, 28d rat
Lowest relevant inhalation NOAEL / NOEL:	Not toxic by inhalation

Genotoxicity

Possible weak effect *in-vitro*, negative *in-vivo*.

Long term toxicity and carcinogenicity

Target / critical effect:	Thyroid inhibition; rat
Lowest relevant NOAEL:	0.5 mg/kg bw/d; (effects on thyroid only)
Carcinogenicity:	Thyroid tumours/threshold .

Reproductive toxicity

Target / critical effect - Reproduction:	Thyroid : increase weight
Lowest relevant reproductive NOAEL / NOEL:	0,9 mg/kg/d, two generation rat
Target / critical effect - Developmental toxicity:	Rabbit, decrease fetal weight, visceral and skeletal variants
Lowest relevant developmental NOAEL / NOEL:	5 mg/kg/d rabbit maternal toxicity

Delayed neurotoxicity

Not relevant

Other toxicological studies

Medical data

Indicative data 10 mg in human - 'slight inhibition' of iodine uptake.

Summary

	Value	Study	Safety factor
ADI:	0.001 mg/kg bw/d;	rat 90d	100
AOEL systemic:	0.001 mg/kg bw/d	rat 90 d	100
AOEL inhalation:	0.25 mg/kg bw/d	4 week inhalation; rat	100
AOEL dermal:	1 mg/kg bw/d	3 week dermal; rabbit/rat	100
ARfD (acute reference dose):	Not relevant in view of the hazard profile of the substance.		

Dermal absorption

1%

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	20 - 60 % after 7 d (25 °C)
Non-extractable residues after 100 days:	max of 20 - 50 % after 7 d 17 - 19 % after 100 d
Relevant metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	None, all detectable metabolites < 2.5 %

Supplemental studies

Anaerobic:	Amitrole degraded more slowly than in aerobic conditions (< 50 % remaining after 56 d at 25 °C) and high levels of unextractable residues are formed.
Soil photolysis:	Stable in dry soil in the dark (91 % on day 0 to 66 % on day 30) Slowly degraded in light with DT_{50} of 73 d
Remarks:	None.

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	5 d max. (22 °C)
DT_{90}lab (20 °C, aerobic):	22 d max. (22 °C)
DT_{50}lab (10 °C, aerobic):	No data available and data not required
DT_{50}lab (20 °C, anaerobic):	< 50 % amitrole after 56 d

Field studies (country or region)

DT_{50f} from soil dissipation studies:	1 UK site (loam soil), 20 kg/ha radiolabelled amitrole (April) DT_{50f} : 21 d (3-56 d period, 39 mm rainfall), 15 d (3-112 d period) RA below 30 cm < 0.3 %
DT_{90f} from soil dissipation studies:	50 d (3-112 d period)

Soil accumulation studies:	Not relevant
Soil residue studies:	Not relevant

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

None.

Adsorption/desorption

K_f / K_{oc}:	Kf : 0.15 - 3.79, 8 soils OC 0.5-3.4 % pH 5.3-7.4 K_{OC} = 20 - 202 (mean 91) same soils as above
K_d	
pH dependence:	Within normal agricultural conditions - no effect of soil parameters.

Mobility

Laboratory studies:

Column leaching:	Standard soil 2.1 (worst case agricultural soil) 6.8 % silt+clay, 0.6 % OC, pH 6: 24 - 31 % in leachate (mainly amitrole) Agricultural soil 32.4 % silt+clay, 2.9 % OC, pH 5.5: 0.8 % max. in leachate
Aged residue leaching:	Incubation time was too long (30 d) therefore so much has degraded the data are not reliable.

Field studies:

Lysimeter/Field leaching studies:	No reliable data available (detection limit too high, µg/l)

Remarks:

Soil TLC shows amitrole to be intermediate to very mobile.

Available monitoring data to assess risk from crop uses
- ground water : no contamination (7 French sites, appl. To vineyard and non crop areas, 1998)
except at one site (point source contamination
- drinking water : no contamination of drinking water coming from 5 French rivers.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	DT_{50} stable at pH 4/5, 7 and 9 (at 25 °C for 30 d)
Relevant metabolites:	None
Photolytic degradation:	Stable (at 25 °C for 30 d, pH 5 - 9).
Relevant metabolites:	None

Biological degradation

Readily biodegradable:	Not readily biodegradable
Water/sediment study:	
DT_{50} water: DT_{90} water: DT_{50} whole system: DT_{90} whole system:	DT_{50} water: 47 and 94 d DT_{90} water: 156 and 312 d DT_{50} whole system: 91 and 95 d DT_{90} whole system: 302 and 316 d
Distribution in water / sediment systems (active substance)	max. 10.3 % (30 d)
Distribution in water / sediment systems (metabolites)	metabolites < 3 % each in water or sediment
Accumulation in water and/or sediment:	Amitrole is much more persistent in the sediment than in the soil.

Degradation in the saturated zone	No data, not required
Remarks:	None.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	$3.3 \cdot 10^{-5}$ Pa at 20 °C
Henry's law constant:	$1.76 \cdot 10^{-8}$ Pa·m^3·mol^{-1} at 20 °C

Photolytic degradation

Direct photolysis in air:	Stable
Photochemical oxidative degradation in air	4.8 hours
DT_{50}:	
Volatilisation:	from soil: negligible from plants: about 11 %

Remarks: Low volatilisation under practical use conditions.

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 > 5 000 mg/kg (rat)
Acute toxicity to birds:	LD50 (quail) > 2 150 mg/kg
Dietary toxicity to birds:	LC50 (quail, duck) > 5 000 ppm
Reproductive toxicity to birds:	NOEC (quail, duck) = 100 ppm
long term oral toxicity to mammals::	NOEL (two generation rat) = 0,9 mg/kg/d

Aquatic Organisms

Acute toxicity fish:	LC50 (trout, 96 h) > 1 000 mg/l LC50 (golden orfe, 96 h) > 6 000 mg/l
Long term toxicity fish:	NOEC (trout, 21 d) = 100 mg/l
Bioaccumulation fish:	BCF= 2.38 (whole fish) in 7 days
Acute toxicity invertebrate:	EC50 (daphnids, 48 h) = 6.1 mg as/l (test substance: SG 86%)
Chronic toxicity invertebrate:	NOEC (daphnids, 21 d) = 0.32 mg/l
Acute toxicity algae:	EC50 (*Sc. subspicatus*, 72 h) = 2.3 mg/l EC50 (*A. flos-aquae*, 72 h) = 2.5 mg/l
Chronic toxicity sediment dwelling organism:	not relevant
Acute toxicity aquatic plants:	EC50 (*L. gibba*, 14 d) = 2.5 mg/l

Honeybees

Acute oral toxicity:	> 152 microg/bee
Acute contact toxicity:	> 100 microg/bee

Other arthropod species

Aphidius colemani (adults; lab. test)	Effect (mortality): 80 % (4.72 kg as/ha; test substance: SL 236 g as/l)
Typhlodromus pyri (protonymphs; lab. test)	Effect (mortality): 100 % (4.72 kg as/ha; test substance SL 236 g as/l)
Orius insidiosus (nymphs, 2nd stage; lab. test)	Effect (mortality): 100 % (4.72 kg as/ha; test substance SL 236 g as/l)
Poecilus cupreus (adults; lab. test)	Effect (mortality): 3.7 % (4.72 kg as/ha; test substance SL 236 g as/l)
Poecilus cupreus (adults; lab. test)	Effect (mortality): 0 % Effect (food consumption) = 1.18 * (14.6 kg as/ha; test substance WP 50 % w/w as)
Pardosa armentata (adults)	Effect (mortality): 100 % (4.9 kg as/ha; test substance WP 50 % w/w as)
Aleochara bilineata (adults; lab. test)	Effect (mortality): 0 % Effect (reproduction) = 0.01 * (5.0 kg as/ha; test substance WP 50 % w/w as)
Aleochara bilineata (adults; lab. test)	Effect (mortality): 11.7 % Effect (fecundity) = 1.0 * (5.0 kg as/ha; test substance WP 50 % w/w as)

* ratio treated/control

Earthworms

Acute toxicity:	LC50 > 448 mg as/kg
Reproductive toxicity:	not relevant

Soil micro-organisms

Nitrogen mineralization:	transient retardation of nitrification processes, recovery after 42 d (dose: 4 x PECs).
Carbon mineralization:	no effect (dose: 4 x PECs)

APPENDIX III

AMITROLE

List of studies for which the main submitter has claimed data protection and which during the re-evaluation process were considered as essential for the evaluation with a view to Annex I inclusion[1].

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[2] on previous use in granting national authorizations
IIA4.2.1	McGuire C.H.	1997	Validation of an analytical method for the determination of amitrole in grapes and analysis of amitrole in grapes Source : HUNTINGTON LIFE SC. (UK) Owner : CFPI Report Nr. : 96/CPF020/0540 GLP Unpublished	
IIA4.2.5	Weber H.	1997	Validation of the Bayer method 00125 for the determination of the residues of Amitrole in products of animal origin. Source : Dr. SPECHT & PARTNER Owner : CFPI Report Nr. : CFP-9501V GLP Unpublished	

[1] List based on a detailed analysis from Rapporteur Member State.
[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive).

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[2] on previous use in granting national authorizations
IIA5.1	Iatropoulous M.J., Murray K., Wang C.X. and Williams G.M.	1995	Effects of amitrole on hydrogen peroxide degrading enzymes in rat and mouse liver Source : AMERICAN HEALTH FOUNDATION (USA) Owner : CFPI Report Nr. : RM-1510 GLP Unpublished	
IIA5.1	Anderson C. and Brauner A.	1995	[5-^{14}C]-amitrole : investigation of the biokinetic behaviour and the metabolism in the rat Source : BAYER AG (D) Owner : CFPI Report Nr. : RM-508/95 GLP Unpublished	
IIA5.1	Marty M. and Vincent C.M.	1999	Amitrole (3-amino-1,2,4-triazole) - *In vitro* cutaneous absorption through human skin Source : Faculté de Pharmacie (F) Owner : CFPI Report Nr. : --- Non GLP Unpublished	
IIA5.2.1	Jouffrey S. de	1996	Acute oral toxicity in rats – Technical Amitrole Source : CIT (F) Owner : CFPI Report Nr. : 12897 TAR GLP Unpublished	
IIA5.2.6	Manciaux X.	1997	Amitrole - Skin sensitization test in Guinea pigs Source : CIT (F) Owner : CFPI Report Nr. : 14945 TSG GLP Unpublished	

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	Reports[2] on previous use in granting national authorizations
IIA5.3.2	Fabreguettes C.	1998	Amitrole : Ten-week toxicity study by oral administration (gavage) in rats Source : CIT (F) Owner : CFPI Report Nr. : 15513 TSR GLP Unpublished	
IIA5.3.2	Fabreguettes C.	1998	Amitrole : Fourteen-week toxicity study by oral administration (gavage) in Cynomolgus monkeys Source : CIT (F) Owner : CFPI Report Nr. : 15512 TSP GLP Unpublished	
IIA5.3.3	Roger R.	1999	Amitrole - Four-week toxicity study by cutaneous route in rats Source : CIT (F) Owner : CFPI Report Nr. : 16998 TSR GLP Unpublished	
IIA5.5/02	Jones, R.D., Lake, S.G.	1994	Technical grade Amitrole, a chronic toxicity feeding in the beagle dog. Source : MILES Inc. Owner : CFPI Report Nr. : 92-276-RX GLP Unpublished	
IIA5.6.1	Richard J.	1994	Amitrole – Two generation study by oral route (dietary mixture) in rats Source : CIT (F) Owner : CFPI Report Nr. : 95214 RSR GLP Unpublished	
IIA5.6.2/06	Kolb, J.	1994	Developmental toxicity study in rabbits after oral administration. Source : Bayer (D) Owner : CFPI Report Nr. : 23486 GLP Unpublished	

B.7 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	Reports[2] on previous use in granting national authorizations
IIA6.1	Schanne C.	1998	[^{14}C]-AMITROLE - Isolation and characterisation of an unknown major radioactive fraction on olives Source : SPRINGBORN Laboratories (CH) Owner : CFPI Report Nr. : 97-044-1002 GLP Unpublished	
IIA6.6.1.1/ 03	Placke, F.	1993	Determination of residues of Aminotriazol 50 WP in/on **apples** under actual conditions in Germany. Source : Bayer AG (D) Owner : CFPI Report Nr. : RA-2003 (includes following studies : 0514-91, 0515-91, 0516-91) GLP Unpublished	
IIA6.6.1.1	Anonymous (Residue form)	1991	Residues trials with Aminotriazol in **apples** in Germany. Source : Bayer AG (D) Owner : CFPI Report Nr. : 0514-91, 0515-91, 0516-91 GLP Unpublished	
IIA6.6.1.1	Anonymous (Residue form)	1991	Residues trials with Ustinex KR in **apples** conducted in Portugal. Source : Bayer AG (D) Owner : CFPI Report Nr. : 0229-92, 0230-92 GLP Unpublished	

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	Reports[2] on previous use in granting national authorizations
IIA6.6.1.1/ 05	Placke, F.	1994	Determination of residues of Ustinex KR 70 WP in/on **apples and pear** under actual use conditions in Portugal. Source : Bayer AG (D) Owner : CFPI Report Nr. : RA-2004 (includes following studies :0229-92, 0230-92, 0231-92) GLP Unpublished	
IIA6.6.1.2/ 03	Anonymous (Residue form)	1991	Residues trials with Ustinex KR in **pear** conducted in Portugal. Source : Bayer AG (D) Owner : CFPI Report Nr. : 0231-92 GLP Unpublished	
IIA6.6.2/0 1	Placke, F.	1994	Determination of residues of Ustinex KR 70 WP in/on **peaches** under actual use conditions in Spain. Source : Bayer AG (D) Owner : CFPI Report Nr. : RA-2005 (includes following studies : 0225-92, 0226-92, 0227-92, 0228-92) GLP Unpublished	
IIA6.6.2/0 2	Anonymous (Residue form)	1992	Residues trials with Ustinex KR in **peaches** conducted in Spain. Source : Bayer AG (D) Owner ; CFPI Report Nr. : 0225-92, 0226-92, 0227-92, 0228-92 GLP Unpublished	

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	Reports[2] on previous use in granting national authorizations
IIA6.6.3/01	Toussaint, G.	1992	Determination of amitrole residues in **grapes**. Source : Hazleton (F) Owner : CFPI Report Nr. : 911101 GLP Unpublished	
IIA6.6.3/02	Clemson, A.D.		Determination of amitrole residues in **grapes** : validation of the analytical method and analysis of **grapes** treated with Weedazol TL. Source : Huntingdon Life Sciences Ltd (UK) Owner : CFPI Report Nr. : 94/CFP017/0450 GLP Unpublished	
IIA6.6.3/03	Anonymous (Residues form)	1990	Residue trials with Ustinex KR in **grapes** in Germany. Source : Bayer AG (D) Owner : CFPI Report Nr. : 0724-90, 0725-90 GLP Unpublished	
IIA6.6.3/04	Placke, F.	1993	Determination of residues of Ustinex KR 80 WP in **grapes** under actual use condtions in Germany. Source : Bayer (AG) Owner : CFPI Report Nr. : RA-2127 (inludes following studies : 0252-91, 0253-91, 0254-91) GLP Unpublished	
IIA6.6.3/05	Anonymous (Residues form)	1991	Residue trials with Ustinex KR in **grapes** in Germany. Source : Bayer AG (D) Owner : CFPI Report Nr. : 0252-91, 0253-91, 0254-91 GLP Unpublished	

B.8 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	Reports on previous use in granting national authorizations
IIA7.2.1	Scholz K.	1995	Aerobic metabolism of amitrole in an aquatic model ecosystem Source : BAYER AG (D) Report Nr. : MR 570/95 Owner : CFPI GLP Unpublished	

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA8.1.3	Gallagher S.P.	1999	Amitrole : A reproduction study with the Mallard (*Anas platyrhynchos*) Source : WILDLIFE INTERNATIONAL Ltd (USA) Owner : CFPI Report Nr. : 461-108 GLP Unpublished	
IIA8.1.3	Gallagher S.P.	1998	Amitrole : A reproduction study with the Northern bobwhite (*Colinus virginianus*) Source : WILDLIFE INTERNATIONAL Ltd (USA) Owner : CFPI Report Nr. : 461-107 GLP Unpublished	
IIA8.2.6	Palmer J.S. and Krueger H.O.	1998	Amitrole : A 5-day toxicity test with the freshwater alga (*Anabaena flosaquae*) Source : WILDLIFE INTERNATIONAL Ltd (USA) Owner : CFPI Report Nr. : 461A-104 GLP Unpublished	
IIA8.2.6	Naudin S.	1997	CA1678 : Static acute toxicity test with daphnids (*Daphnia magna*) Source : SPRINGBORN Laboratories (CH) Owner : CFPI Report Nr : 97-042-1002 GLP Unpublished	

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	Reports on previous use in granting national authorizations
IIA8.2.8	Palmer J.S. and Krueger H.O.	1998	Amitrole : A 14-day toxicity test with duckweed (*Lemna gibba*) Source : WILDLIFE INTERNATIONAL Ltd (USA) Owner : CFPI Report Nr. : 461A-105 GLP Unpublished	
IIA8.3.1.1	Candolfi M.P.	1996	Laboratory oral and contact test with the honeybee, Apis mellifera, based on the Eppo guideline 170 (1992) with Weedazol TL. Source : SPRINGBORN Lab. (Europe) AG (CH) Owner : CFPI Report Nr. : 95-033-1002 GLP Unpublished	
IIA8.3.1.1	Schmitzer S.	1998	Laboratory testing for toxicity (acute contact and oral LD50) of technical Amitrole to honey bees (Apis mellifera L.) (Hymenoptera, Apidae). Source : IBACON (D) Owner : CFPI Report Nr. : 288036 GLP Unpublished	
IIA8.3.2	Candolfi M.P.	1995	Laboratory acute toxicity with the parasitic wasp, Aphidius colemani, based on Polgar (1988) with Weedazol TL. **Source :** SPRINGBORN Lab. (Europe) AG (CH) Owner : CFPI Report Nr. : 94-017-1002 GLP Unpublished	

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	Reports on previous use in granting national authorizations
IIA8.3.2	Candolfi M.P.	1995	Acute toxicity with the ground beetle, Poecilus cupreus, based on Heimbach, IOBC guidelines (1992) with Weedazol TL. Source : SPRINGBORN Lab. (Europe) AG (CH) Owner : CFPI Report Nr. : 94-019-1002 GLP Unpublished	
IIA8.3.2	Candolfi M.P.	1995	Laboratory contact toxicity test on the predator Orius insidiosus (Heteroptera : Anthocoridae) based on Stäubli and pasquier (1988) with Weedazol TL. Source : SPRINGBORN Lab. (Europe) AG (CH) Owner : CFPI Report Nr. : 94-020-1002 GLP Unpublished	
IIA8.3.2	Candolfi M.P.	1995	Laboratory contact toxicity test with the predacious mite, Typhlodromus pyri, following the method of Overmeer (1988) with Weedazol TL. Source : SPRINGBORN Lab. (Europe) AG (CH) Owner : CFPI Report Nr. : 94-018-1002 GLP Unpublished	
IIA8.3.2	Gossman A. and Luhrs U.	1999	Effects of CA1678 on the Predatory Mite *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) - Extended Laboratory study Source : IBACON (D) Owner : CFPI Report Nr. : 3662062 GLP Unpublished	

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	Reports on previous use in granting national authorizations
IIA8.3.2	Moll M.	1999	Effects of CA1678 on the Parasitoid Aphidius rhopalosiphi (Hymenoptera, Aphidiidae) - Extended Laboratory study Source : IBACON (D) Owner : CFPI Report Nr. : 3661002 GLP Unpublished	
IIA8.7	Armstrong K.	1999	Amitrole : Activated sludge, respiration inhibition test Source : INVERESK RESEARCH (UK) Owner : CFPI Report Nr. : 16952 GLP Unpublished	
IIIA10.6.1.1	Candolfi M.P.	1995	Weedazol TL : 14-day toxicity test with earthworm, Eisinia foetida, based on OECD guideline # 207. Source : Springborn Lab.(Europe) AG (CH) Owner : CFPI Report Nr. : 95-027-1002 GLP Unpublished	

SUMMARY REPORT
OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH HELD ON 12 DECEMBER 2000 IN BRUSSELS

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

1 **Examination and possible vote on a Draft Commission Decision making it possible for Member States to extend provisional authorisations granted for the new active substances IKI 11454, TO 1145 (fosthiazate), CGA 329351 (metalaxyl-m), MON 37500 (sulfosulfuron) and Spodoptera nuclear polyhedrosis virus** (Sanco/4000/2000 rev. 3).

Vote : favourable opinion by qualified majority (84 in favour, 4 against).

The decision will allow Member States to extend provisional authorisations of products containing these substances until a final decision on Annex I inclusion can be made.

2 **Examination and possible vote on a Draft Commission Directive concerning the inclusion of pyridate in Annex I to Council Directive 91/414/EEC** (Directive Sanco/4043/2000 rev 3 (Pyridate) Review Report 7576/VI/97-rev. 5).

The Commission presented the Review Report. The Committee took note of the Review Report.

The following declarations were made:

The Netherlands: "The Dutch delegation is of the opinion that for national authorisations of pyridate it might be appropriate to use, under national use conditions, a different dermal absorption figure than that indicated in the endpoint lists of the Review Reports. The Dutch delegation is further of the opinion that for national authorisations of pyridate it might be appropriate to use a long-term AOEL instead of the present short-term AOEL in the endpoint list of the review reports."

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

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

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

Vote : unanimous favourable opinion.

3 **Examination and possible vote on a Draft Commission Directive concerning the inclusion of amitrole in Annex I to Council Directive 91/414/EEC** (Directive Sanco/4043/2000 rev 3 (Amitrole); Review Report 6839/VI/97-rev. 4).

The Commission presented the Review Report. The Committee took note of the Review Report.

The following declarations were made:

The Netherlands: Same declaration as for pyridate.

Sweden: In our view it is not possible to include amitrole in Annex I to Directive 91/414/EEC, since it cannot be expected that products containing this substance will fulfil the conditions stated in Article 5 of the Directive, particularly with regard to the protection of operators and environment.

One of our concerns is that amitrole could be regarded as an endocrine disruptor and is listed in group I in the Commission draft document "Establishment of a priority list of substances for further evaluation of their role on endocrine disruption" COM (1999)706. This mechanism may imply that not all relevant endpoints are being covered by the standard toxicity tests. Thus, there is a larger uncertainty for these kinds of substances, which has not been taken into adequate consideration in the present risk assessment.

Commission: Same declaration as for pyridate.

The Commission further declares that Article 5 (5) of Directive 91/414/EEC provides that the inclusion of an active substance in Annex I can be reviewed at any time if there are indications that the criteria for inclusion are no longer satisfied. Therefore, the Commission will reconsider the inclusion of amitrole in Annex I if the additional information as outlined in point 7 of the Review Report would not be submitted within the timelines provided.

Vote : favourable opinion with qualified majority (67 votes in favour, 20 against).

4 **Examination and possible vote on a Draft Commission Directive concerning the inclusion of diquat in Annex I to Council Directive 91/414/EEC** (Directive Sanco/4043/2000 rev 3 (Diquat); Review Report 1688/VI/97-rev.8).

The Commission presented the Review Reports on the four substances. The Committee took note of the Review Reports.

The following declarations were made:

The Netherlands: Same declaration as for pyridate.

Portugal: The portugese delegation considers that the phrase "uses in aquatic weed control shall not be authorised" included in the specific provisions of Annex I of the Directive, is

not clear. Our favourable vote is based on the understanding that this phrase refers to the direct application of the herbicide into the water against aquatic weeds.

This declaration is supported by Spain and Greece.

Ireland: The terms of the proposed inclusion of diquat in Annex I of Directive 91/414/EEC contravenes the provisions of Art. 4 of that Directive to the extend that it pre-empts decisions to be made by Member States in granting authorisations following application of the Uniform Principles (Annex VI) in relation to plant protection products containing diquat.

Germany: Germany votes against the proposed Directive concerning diquat for the sole reason that it contains specific provisions concerning the authorisation and restriction of certain uses, which should be subject to national regulatory decisions. Germany would welcome if this principal question would be clarified soon within the Commission, in view of future decisions and with the aim to speed up decision making.

United Kingdom: The United Kingdom believes that the use of diquat as an aquatic herbicide under carefully controlled conditions is acceptable and should not be restricted in the Annex I decision. It believes that this use should be permitted and regulated by Member States in accordance with the Uniform Principles.

However, the United Kingdom is prepared to support the Commission's proposal in the interest of making progress with the review. This support is on the understanding that the issue of aquatic use will be re-considered before the Directive comes into force. The United Kingdom will prepare a revised risk assessment for consideration by the Scientific Committee on Plants to facilitate this process.

This declaration is supported by Ireland and Greece.

France: France has decided to vote in favour of the inclusion of diquat in Annex I of Council Directive 91/414/EEC. It would like to associate the following declaration to this vote: France considers the restriction introduced into the specific provisions of the Annex as inadequate. The evaluation of non-representative uses and/or uses specific to local conditions must be conducted by the Member States. Further, the phrasing concerning the specific conditions of use is not sufficiently clear. France therefore hopes that the present Directive will be revised, if the acceptability of aquatic uses can be demonstrated.

Commission: Same declaration as for pyridate.

In response to the declarations made by the United Kingdom and France the Commission declares that it will do its part to ensure that further information concerning aquatic weed control with diquat will be evaluated without delay in the working groups of the Standing Committee for Plant Health and the Scientific Committee on Plants.

Vote: favourable opinion with qualified majority (71 votes in favour, 16 against).

5 **Examination and possible vote on a Draft Commission Directive concerning the inclusion of thiabendazole in Annex I to Council Directive 91/414/EEC** (Directive Sanco/4043/2000 rev 3 (Thiabendazole) Review Report 7603/VI/97-rev. 3).

The Commission presented the Review Report. The Committee took note of the Review Report.

The following declarations were made:

The Netherlands: Same declaration as for pyridate.

Sweden: Sweden declares that post harvest disease control on fruit and ware potatoes is not and has never been approved in Sweden. These uses have been considered not to be in line with the national risk reduction policy on pestieides, with regard to consumer safety, and on the principles of integrated pest management. Control of storage diseases has sufficiently been achieved by other means, such as climatic control in warehouses. Our opinion is that even if the MRL's are not exceeded, a national approval for post harvest use will lead to increased dietary exposure for consumers and thereby counteract the national risk reduction policy on pesticides. Sweden intends to continue its line of action to prevent the use of pesticides on edible plant products.

Germany: Germany votes in favour, but confirms that the declaration given on diquat also applies to the specific provisions given for thiabendazole.

Commission: Same declaration as for pyridate.

Vote : favourable opinion with qualified majority (80 votes in favour, 7 against).

6 **Examination of a Commission project concerning the non-inclusion of parathion in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.**

A text for a draft proposal was not tabled. With the exception of Germany, which had not yet defined its position, all delegations expressed their support in principle for the non-inclusion of parathion in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations.

7 **Examination and possible vote on a Draft Commission Decision concerning the possible inclusion of certain active substances into Annex I to Directive 91/414/EEC** (Sanco/4090/2000 rev.2; report from the Working Group Legislation).

In relation to giving its opinion on the Draft Commission Decision concerning the possible inclusion of certain active substances into Annex I to Directive 91/414/EEC, the Standing Committee on Plant Health took note of the following data requirements, established by the Commission, having consulted the Committee for the active substances listed in its Annex.

	Data requirements contained in document :
2,4-DB	Doc. 7602/VI/97 rev. 15 of 15/11/00
Acephate	Doc. SANCO/3056/99 rev. 0-2 of 07/07/00
Amitraz	Doc. 6493/VI/99 rev. 5 of 05/10/00
Chlorpropham	Doc. SANCO/3040/99 rev. 0-3 of 06/09/00
Chlorpyrifos	Doc. SANCO/3058/99 rev. 0-3 of 08/09/00
Chlorpyrifos-methyl	Doc. SANCO/3060/99 rev. 0-3 of 08/09/00
Daminozide	Doc. SANCO/3042/99 rev. 1 of 15/11/00
Deltamethrin	Doc. 6488/VI/99 rev. 3 of 21/12/99
Linuron	Doc. 7596/VI/97 rev. 9 of 20/03/00
Mecoprop	Doc. SANCO/3062/99 rev. 0-2 of 07/07/00
Mecoprop-P	Doc. SANCO/3064/99 rev. 0-2 of 07/07/00
Molinate	Doc. SANCO/3046/99 rev. 0-3 of 06/07/00
Pendimethalin	Doc. 7476/VI/98 rev. 7 of 22/08/00
Propiconazole	Doc. 3048/SANCO/99 rev. 0-3 of 07/07/00
Propyzamide	Doc. 6486/VI/99 rev. 3 of 27/12/99
Thiram	Doc. 6491/VI/99 rev. 6 of 15/11/00
Ziram	Doc. 6492/VI/99 rev. 5 of 15/11/00

The following long term studies have been identified as necessary :

Linuron : Earthworm reproduction study (Annex II, point 8.4.2)

Molinate : Avian reproduction study (Annex II, point 8.1.3)

Vote : unanimous favourable opinion.

The Decision sets timelines for the submission of additional or outstanding information on 17 substances being evaluated under the first review program.

8 **Any other business.**

8.1: Final report of the FOCUS workgroup for groundwater scenarios (SANCO/321/2000 rev. 2).

The Committee took note of the report. It is agreed that questions concerning the interpretation and decision making related to the groundwater scenarios will be further discussed in the Working Group "Plant Protection Products - Evaluation " in the context of the review of individual substances.

8.2: Proposal for a symposium concerning the consequences of the review program under Council Directive 91/414/EEC for European agriculture (Point raised by Germany).

The Commission at this stage sees no priority to hold such a symposium. As agreed in the Working Group "Plant Protection Products - Legislation" Member States are asked to report on the expected consequences of Regulation (EC) N° 451/2000 by May 2001 and further steps will be decided thereafter.

8.3: Participation of accession countries in the peer review and the working groups of the Standing Committee for Plant Health (Point raised by Greece).

The Commission notes that accession countries can not, at this stage, participate in the Standing Committee for Plant Health and its working groups. The Commission will consider options of their participation in the peer review meetings.

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 B – Scientific Health Opinions
Unit B2 – Management of scientific committees I

SCIENTIFIC COMMITTEE ON PLANTS

SCP/AMITR/002-Final
13 July 2000

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE INCLUSION OF AMITROLE (AMINOTRIAZOLE) IN ANNEX I TO COUNCIL DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

(Opinion adopted by the Scientific Committee on Plants on 6 June 2000)

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1. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE INCLUSION OF AMITROLE (AMINOTRIAZOLE) IN ANNEX I TO COUNCIL DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

2. TERMS OF REFERENCE

The Scientific Committee on Plants is requested to respond to the following questions in the context of the Commission's work on the implementation of Directive 91/414/EEC[1] concerning the placing of plant protection products on the market.

1) Can the Committee confirm that the appropriate study for the estimation of the AOEL[2] is the dermal 28-day study? If not, which study would the Committee propose?

2) Can the Committee comment on the relevance for man of the thyroid tumors found in rodents?

3. BACKGROUND

Amitrole also known as aminotriazole is an existing active substance in the context of Directive 91/414/EEC concerning the placing of plant protection products on the market and is one of the active substances covered by the first stage of the work programme provided for under the Directive.

In order to prepare its opinion, the Scientific Committee on Plants had access to documentation comprising a monograph prepared by France as Rapporteur Member State (RMS) and the recommendations of the ECCO[3] Peer Review Programme.

Amitrole is a non-selective broad spectrum systemic herbicide mainly acting via the foliage but also with some activity through the roots. It is used on cultivated areas and for total weed control in non-cropping situations, such as, roadsides, railway lines and buildings. Rates of applications vary from 1.2 to 3.6 kg a.s./ha.

4. OPINION

4.1. Question 1

Can the Committee confirm that for amitrole, the appropriate study for the estimation of the AOEL is the dermal 28-day study? If not, which study would the Committee propose?

[1] OJ L 230, 19.08.1991, p.1.
[2] Acceptable Operator Exposure Level
[3] European Community Co-ordination

Opinion

Due to the toxicological properties of amitrole, the NOAEL[4] of 100 mg/kg bw/day observed in the dermal 28-day study in rats can be used for the derivation of AOEL, taking into consideration an estimated skin absorption rate of 0.1-1 %.

Scientific background on which the opinion is based

Amitrole has been subjected to extensive toxicological testing. The main resulting evidence can be summarised as follows:

1. Oral absorption of amitrole in rats is fast, distribution is rapid without evidence of accumulation, metabolism is limited, and excretion is complete mainly through urine as unchanged compound. Blood levels of amitrole in rats are identical after 4 and 21 day administration indicating the absence of accumulation.

2. The critical effect of amitrole in experimental animals consists of an anti-thyroid action due to blockage of thyroid peroxidase, decrease of thyroid hormone levels and the consequent stimulation of the thyroid by the pituitary gland. The fall in the level of thyroid circulating hormones in the dosed animals is considered to be a reliable and early indicator of such an effect.

3. Consistent with its physico-chemical properties, absorption of amitrole through skin is very limited. A study in rats indicated that only 0.1% amitrole penetrates the skin. An *in vitro* study on human skin indicated dermal absorption varying from 0.5 to 3.5 %. A 15-day dermal toxicity study performed in 1984 in rabbits and a more recent 28-day dermal toxicity study in rats, performed according to the OECD Guideline n° 410, indicated a NOAEL of 100 mg/kg bw/day. The comparison of these NOAELs with the NOAEL of 1.5 mg/kg bw/day observed in an oral 28-day study in rats and with the NOAEL of 0.1 mg/kg bw/day observed in an oral 13-week study in male rats confirms that the ratio between skin and oral absorption is of about two to three orders of magnitude.

An overall evaluation of the results of the studies available in several species (rats, rabbits, mice, hamsters, dogs, monkeys and humans) indicates that:

a. oral short-term and long-term NOAELs in rats differ by only one order of magnitude;
b. dermal short-term toxicity, when considering the rate of skin absorption, also provides a similar NOAEL;
c. the NOAELs for the critical effect on thyroid in species other than the rat are either similar or greater;
d. primates, including man, appear to be much less sensitive than rats to the critical thyroid effect.

Conclusion.

In order to derive the AOEL for amitrole, the NOAEL of 100 mg/kg bw/day observed in the dermal 28-day study in rats can be used. Estimating the skin absorption rate at around

[4] No Observed Adverse Effect Level

0.1-1 %, such a NOAEL would provide an estimated no-effect absorption level of 0.1-1 mg/kg bw/day which is comparable to the NOAEL of 1.5 mg/kg bw/day observed in the oral 28-day study in rats and the NOAEL of 0.1 mg/kg bw/day observed in the oral 13-week study in rats (estimated oral absorption rate: 100%).

4.2. Question 2

Can the Committee comment on the relevance for man of the thyroid tumors found in rodents?

Opinion

The thyroid tumours found in rats after long-term amitrole treatment appear to be of little or no relevance for humans. The thyroid carcinogenic effect of amitrole appears to be mediated through thyroid-pituitary disruption to which humans are less sensitive than rodents.

Scientific background on which the opinion is based

Amitrole has been shown to be goitrogenic in several species including mice, rats and hamsters and causes thyroid cancer in rats after prolonged exposure. Antithyroid effect of amitrole appears to be linked to its inhibition of thyroid peroxidase which is thought to catalyse both thyroglobulin iodination and tyrosine (3-monoiodotyrosine and 3,5-diiodotyrosine) coupling, leading to the formation of the thyroid hormones T4 (3,3,3',5'-tetraiodotyronine) and T3 (3,5,3'-triiodotyronine). Consequently, rats treated with amitrole have low serum T4 and T3 levels with a parallel increase in TSH[5] levels. In turn, high TSH levels cause increased thyroid weight and follicular cell number (with associated increased mitotic activity) which might progress towards malignancy. It should be pointed out that progression to malignancy can be, at least partially, halted by administration of thyroid hormones or surgical hypophysectomy, both procedures leading to reduced TSH levels (3, 4, 5).

It should also be noted that adult rats lack the thyroid hormone binding globulin, which is the specific high-affinity serum carrier protein present in humans. The absence of this carrier protein results in a greater proportion of free serum thyroid hormones, which is readily available to metabolism and excretion. Consequently, these hormones have a shorter half-life and the required accelerated production is driven by very high TSH levels. These levels are much higher in rats than in humans (6- to 60-fold) which renders rats more sensitive than humans to chemically induced thyroid-pituitary disruption (1, 2, 3).

Genotoxicity studies with amitrole gave negative results in most tests. Whether a potential genotoxicity might play a role in thyroid cancerogenesis after hypertrophic and hyperplastic stimulation remains to be ascertained. However, tumours in rats have been observed only after thyroid homeostasis disruption[6].

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[5] Thyroid stimulating hormone

[6] The Committee is aware that in view of some positive/equivocal or missing genotoxicity data the significance of tumors at sites other than the thyroid in amitrole-treated mice reported in older published studies will be re-evaluated by the International Agency for Research on Cancer (IARC) in the near future.

Conflicting data have been reported that relate to high TSH levels and thyroid cancer in humans. Pre-existing goitre or thyroid nodules seem related to increased thyroid cancer risk; however, an association between hypothyroidism and thyroid cancer has not been demonstrated. The only known human thyroid carcinogen is x-irradiation and no chemical has been identified as being carcinogenic to the human thyroid (1, 2, 3, 4).

In summary, humans appear to be less sensitive to thyroid disruption than rodents. Furthermore, rats show significant increases in thyroid cancer associated with thyroid – pituitary disruption while humans show little increase, if any.
In conclusion, since

a. the thyroid carcinogenic effect of amitrole appears to be mediated through thyroid-pituitary disruption to which humans are less sensitive
b. there does not seem to be a role for increased TSH in human thyroid carcinogenicity,

the thyroid tumours found in rats after long-term amitrole treatment appear to be of little or no relevance for humans.

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(4) Amitrole: operator exposure – Risk assessment using UK-POEM and German model – summary table. (SCP/AMITR/4)
(5) Amitrole: draft review report for the active substance 6839/VI/97-rev.0 (SCP/AMITR/5/)

7. ACKNOWLEDGEMENTS

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Toxicology: Professor M. Maroni (Chairman), and Committee Members Dr. M.-P. Delcour-Firquet, Dr. O. Meyer, Dr A. Moretto, Prof. K. Savolainen, Prof. A. Silva Fernandes, Dr. G. Speijers, and invited experts Dr. A. Fait; (Question 2) Professors C. L. Galli, J. Parry, R. Schulte-Hermann and Drs. J. Rice and P. Wester

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