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EU-Beurteilungsbericht Thiabendazol
Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen Band D 24

Review Report Thiabendazole
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 24

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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 24. Heft dieser Reihe (Band D 24) 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 Thiabendazol war Spanien 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 24th report belonging to this series (Volume D 24) 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 thiabendazole Spain 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
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Thiabendazole

7603/VI/97-final

22 March 2001

Review report for the active substance **thiabendazole**

Finalised in the Standing Committee on Plant Health at its meeting on 12 December 2000 in view of the inclusion of thiabendazole 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 thiabendazole, 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 1199/97([2]), has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Thiabendazole 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, Merck, Sharp & Dohme (now Syngenta) on 30 July 1993, AgriChem on 15 July 1993, Elf Atochemon 26 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 thiabendazole 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 Spain as rapporteur Member State to carry out the assessment of thiabendazole 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

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

[2] OJ No L 170, 28.06.1997, p.19.

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

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

to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for thiabendazole this deadline was 30 April 1995.

Only Novartis Crop Protection AG (formerly Merck, Sharp & Dohme, now Syngenta) submitted a dossier on 27 April 1995 to the rapporteur Member State which was considered on 4 September 1995 as practically complete and sufficient for a further evaluation. Three of the four notifiers i.e. Elf Atochem – France, Luxan – Netherlands and Agrichem – Netherlands have withdrawn their notification. No further information has been submitted by third parties.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Spain 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 thiabendazole 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 thiabendazole from Novartis Crop Protection AG on 23 October 1996.

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 as well as to Novartis Crop Protection AG (now Syngenta) being the main data submitter, on 29 May 1997.

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 Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from September 1997 to January 1998.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 7 April 1998 for comments and further clarification.

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 19 March 1999 to 14 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 22 September 2000 (SCP/Thiab/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 thiabendazole in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing thiabendazole 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.

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

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 thiabendazole will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each thiabendazole 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, and which are outlined in detail in Background Document C:

- Fungicide for post-harvest use on fruit and potatoes;

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 33 % 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 thiabendazole are given in Appendix I.

The active substance shall comply with the specification submitted by Syngenta AG; the specification is given in Appendix I of this report.

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

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 thiabendazole

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:

- Suitable risk management 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 from post-harvest and potato seed treatments.

- 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.

7. List of studies to be generated

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

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

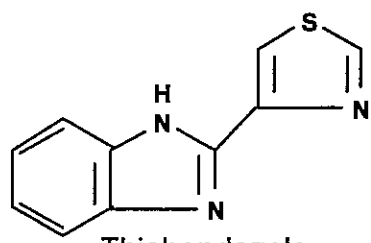
The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing

Committee on Plant Health, in connection with any amendment of the inclusion conditions for thiabendazole in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

THIABENDAZOLE

Common name (ISO)	Thiabendazole
Chemical name (IUPAC)	2-Thiazol-4-yl-1H-benzimidazole
Chemical name (CA)	2-(4-Thiazolyl)-1H-benzimidazole
CIPAC No	323
CAS No	148-79-8
EEC No	205-725-8
FAO SPECIFICATION	-
Minimum purity	985 g / kg
Molecular formula	$C_{10}H_7N_3S$
Molecular mass	201.26
Structural formula	 Thiabendazole

Melting point	297 - 298 °C
Boiling point	Not applicable.
Appearance	Off-white to yellow tan coloured powder
Relative density	D_4^{20} 1.3989
Vapour pressure	5.3×10^{-7} Pa at 25 °C
Henry's law constant	3.7×10^{-6} Pa m^3 mol^{-1}
Solubility in water	pH 4: 0.16 g/l (at 20 ± 0.5 °C) pH 7: 0.03 g/l (at 20 ± 0.5 °C) pH 10: 0.03 g/l (at 20 ± 0.5 °C)
Solubility in organic solvents	at 20 ± 0.5°C — g/l n-heptane: < 0.01 xylene: 0.13 methanol: 8.23 1,2-dichloroethane: 0.8 acetone: 2.43 ethyl acetate: 1.49 n-octanol: 3.91
Partition co-efficient (log P_{ow})	pH 4: $\log_{10} P_{ow}$: 1.62 ± 0.01 (at 20 ± 0.5 °C) pH 7: $\log_{10} P_{ow}$: 2.39 ± 0.14 (at 20 ± 0.5 °C) pH 10: $\log_{10} P_{ow}$: 2.40 ± 0.04 (at 20 ± 0.5 °C)
Hydrolytic stability (DT_{50})	pH 5: DT_{50}: 357 days (at 25°C) pH 7: DT_{50}: 203 days (at 25°C) pH 9: DT_{50}: 271 days (at 25°C)
Dissociation constant	pKa: 4.73 and 12.00
Quantum yield of direct photo-transformation in water at ε >290 nm	Not applicable.
Flammability	Combustion time > 4 minutes (6 min 48 sec) and therefore not considered as highly flammable.
Explosive properties	None. Does not generate heat in the presence of oxygen or undergo exothermic decomposition.
UV/VIS absorption (max.)	UV absorption maxima at 254 nm and 302 nm
Photostability in water (DT_{50})	DT_{50}: 29 hours at pH 5 and 25°C

APPENDIX II

END POINTS AND RELATED INFORMATION

THIABENDAZOLE

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	At least 67 % - 75 % based on urinary excretion within 168 h
Distribution:	Widely.
Potential for accumulation:	Low.
Rate and extent of excretion:	85 % - 92 % within 24 h, mainly via urine
Toxicologically significant compounds:	Parent compound and metabolites
Metabolism in animals:	Extensive, oxidation to 5-hydroxythiabendazole followed by conjugation with glucuronide or sulfate.

Acute toxicity

Rat LD_{50} oral:	3100 mg/kg bw
Rat LD_{50} dermal:	> 2000 mg/kg bw
Rat LC_{50} inhalation:	> 0.5 mg/l (maximum concentration achieved)
Skin irritation:	No irritation.
Eye irritation:	No irritation.
Skin sensitisation (test method used and result):	No sensitisation (Maximisation test).

Short term toxicity

Target / critical effect:	Red blood cells, liver and thyroid (rat and dog)
Lowest relevant oral NOAEL / NOEL:	10 mg/kg bw/d (90 d, rat)
Lowest relevant dermal NOAEL / NOEL:	> 1000 mg/kg bw/d (23 d, rabbit)
Lowest relevant inhalation NOAEL / NOEL:	Not established.

Genotoxicity

Not genototoxic *in vivo* (induction of aneuploidy *in vitro* at high concentrations).

Long term toxicity and carcinogenicity

Target / critical effect:	Thyroid and liver. Thyroid follicular cell hyperplasia in rats.
Lowest relevant NOAEL:	10 mg/kg bw /d (2 year study, rat)
Carcinogenicity:	Thyroid adenomas and follicular cell hyperplasia due to liver enzyme induction in rats (based on the available data).

Reproductive toxicity

Target / critical effect - Reproduction:	No reproductive toxic effects at parental toxic doses
Lowest relevant reproductive NOAEL / NOEL:	10 mg/kg bw/d (multigeneration rat).
Target / critical effect - Developmental toxicity:	Not teratogenic. Fetotoxic at maternal toxic dose.
Lowest relevant developmental NOAEL / NOEL:	10 mg/kg bw/d (teratogenicity rat)

Delayed neurotoxicity

No indication of neurotoxicity in standard short and long term toxicity studies.

Other toxicological studies

Mechanistic studies indicate effects on thyroid hormones due to liver enzyme induction in rats..

Medical data

A NOAEL of 3 - 4 mg/kg bw /d was proposed by WHO for human beings.

Adverse reactions have been reported at therapeutic dose of 50 mg/kg bw/d over 2 d.

Summary

	Value	Study	Safety factor
ADI:	0,1 mg/kg bw/d	24 week human two year rat	25 100
AOEL systemic:	0,1 mg/kg bw/d	24 week human two year rat	25 100
AOEL inhalation:	Not defined.	-	-
AOEL dermal:	Not defined.		
ARfD (acute reference dose):	Not required due to low acute toxicity.		

Dermal absorption

10 % (default value)

Based on following considerations, the use of the default value of 10% dermal absorption is considered already a conservative assumption, as this value probably represents an overestimation of the real situation:

- NOAEL 3 week dermal toxicity in rabbits is >1000 mg/kg bw/d; NOAEL of a rabbit teratogenicity study is 24 mg/kg bw/d. This leads to a theoretical dermal absorption of less than 2.4%.
- For a medical preparation of thiabendazole (MENTAZOL) containing lipophilic inerts for facilitation of dermal permeability the achieved dermal absorption is assumed to be 5%.

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	• < 4 % after 120 d
Non-extractable residues after 100 days:	• 20 % after 120 d
Relevant metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	None.

Supplemental studies

Anaerobic:	Stable to anaerobic degradation.
Soil photolysis:	Stable.
Remarks:	None.

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	• > 1 y (25 °C); 1.100 days
DT_{90}lab (20 °C, aerobic):	• Not calculable from older studies.
DT_{50}lab (10 °C, aerobic):	Not calculable.
DT_{50}lab (20 °C, anaerobic):	> 1 y (25 °C)

Field studies (country or region)

DT_{50f} from soil dissipation studies:	DT_{50f}: USA > 2 y
DT_{90f} from soil dissipation studies:	DT_{90f}: Not calculable (extrapolation too vague)
Soil accumulation studies:	Up to approx. 6 times the initial single-application concentration after 20 years of annual applications. Assuming a worst-case dissipation half-life of 1100 days and first-order kinetics (as used in the ECCO 42 report for PEC_{soil} calculations), a maximum soil accumulation in a 5 cm soil layer up to 0.78 mg ai/kg soil is to be expected following the potato seed treatment use at 120 g ai/ha over consecutive 38 years (soil bulk density: 1.5 kg/dm^3). Ploughing of the field down to 20 cm depth would reduce this concentration 4fold to ca 0.2 mg ai/kg in the top 20 cm soil layer. A next seed potato planting at 120 g ai/ha would increase this soil concentration to a maximum value of 0.2 + 0.16 = 0.36 mg ai/kg soil in a 5 cm soil layer.

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

Adsorption/desorption

K_f / K_{oc}:	$K_{OC,ads}$/ $K_{OC,des}$ = 1812/1336 silt loam 22467/18325 clay 3992/4865 sandy loam 1104/3260 sand
K_d	21.8 (silt loam, pH 7.1), 270 (clay, pH 6.7) 16 (sandy loam, pH 6.5), 2.8 (sand, pH 7.4)
pH dependence:	possible, but not strictly evident from study data

Mobility

Laboratory studies:

Column leaching:	Immobile.
Aged residue leaching:	Immobile (> 98 % remained in the top 2.5 cm layer).

Field studies:

Lysimeter/Field leaching studies:	No data. Not indicated since substance immobile (see also ECCO 42 report, specific comments).

Remarks:	None.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	pH 5: Stable. pH 7: Stable. pH 9: Stable. Also stable under processing hydrolysis conditions (pH 4, 5, 6 at 90° C, 100° C, 120° C).
Relevant metabolites:	None.
Photolytic degradation:	DT_{50}: 29 hours at pH 5 and 25°C
Relevant metabolites:	Several minor metabolites < 10%; and one Metabolite at 10.22% at one timepoint (benzimidazole-2-carboxamide).

Biological degradation

Readily biodegradable:	Not ready biodegradable.
Water/sediment study: DT_{50} water: DT_{90} water: DT_{50} whole system: DT_{90} whole system:	$DT_{50\ water}$: 1.6 – 2.3 days $DT_{90\ water}$: 5.3 – 7.8 days $DT_{50\ whole\ system}$: 1.6 – 4.3 days (1^{st} compartment) 375 – 4332 days (2^{nd} compartment) $DT_{90\ whole\ system}$: 825 – 12465 days
Distribution in water / sediment systems (active substance)	Water: ca 94% at day 0 to < 10% at day 14 sediment: 20 –40 % at day 1 to ca 30 - 71% at day 181
Distribution in water / sediment systems (metabolites)	Water and sediment with degradates < 2% at all time points Mineralization: 0.5-1.8% at day 180. Non-extractables accounting for at maximum ca 32 to ca 65%
Accumulation in water and/or sediment:	Rapid and almost complete partitioning of the a.s. within 14 days to the organic matter of suspended particles and sediments.

Degradation in the saturated zone

Not indicated (immobile substance).

Remarks:

None.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	5.3×10^{-7} Pa at 25 °C
Henry's law constant:	3.7×10^{-6} Pa m^3 mol^{-1}

Photolytic degradation

Direct photolysis in air:	Not relevant (no foliar use).
Photochemical oxidative degradation in air	Not relevant (no foliar use).
DT_{50}:	Estimation acc. to Atkinson calculation: 2 – 3.5 hd
Volatilisation:	From plant surfaces: not volatile. From soil: not volatile.

Remarks:	None.

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	Rat LD50 3100 mg/kg bw
Acute toxicity to birds:	Quail LD50 >2250 mg/kg bw
Dietary toxicity to birds:	Quail or duck LC50 >5620 mg /kg diet
Reproductive toxicity to birds:	Quail or duck NOEC >400 mg /kg diet
Short term oral toxicity to mammals:	NOEL (90 d, rat) 10 mg /kg bw/ d
Long term oral toxicity to mammals	NOAEL (2y, rat) 10 mg/kg bw/d

Aquatic Organisms

Acute toxicity fish:	LC50 (rainbow trout, 96h): 0.55 mg/l ()
Long term toxicity fish:	NOEC 0.11 mg/l early life, fathead minnow 0.012 mg/l embryo/ larvae, 30d, rainbow trout
Bioaccumulation fish:	BCF 96.5
Acute toxicity invertebrate:	LC50 (Daphnia, 48h) 0.81 mg/l
Chronic toxicity invertebrate:	NOEC (Daphnia, 21d) 0.042 mg/l
Acute toxicity algae:	EC50 (96h) 9.0 mg/l NOEC 3.2 mg/l
Chronic toxicity sediment dwelling organism:	$NOEC_{nominal\ system\ (added\ to\ water}$ 2.0 mg/l $NOEC_{sediment}$: 3 mg/kg LOEC > 2.0 mg/l

Honeybees

Acute oral toxicity:	Not applicable (no foliar use).
Acute contact toxicity:	Not applicable (no foliar use).

Other arthropod species

Test species	Effect % (1x = 0.9 kg/ai/ha; 2x = 1.8 kg ai/ha)	
Aleochara bilineata	Mortality: No effect Fecundity: 27%	harmless
Aphidius rhopalosiphi	Mortality: No effect Fecundity: 62% (2x)	slightly harmful
Chrysoperla carnea	Mortality: 4 % (2x) Fecundity: 27%	harmless

Typlodromus pyri	Mortality:	3 %	
	Fecundity:	5% (2x)	harmless

Earthworms

Acute toxicity:	LC50	> 1000 mg / kg soil
Reproductive toxicity:	NOEC	4.2 mg / kg soil

Soil micro-organisms

Nitrogen mineralization:	No effects up to 9 mg/kg soil.
Carbon mineralization:	No effects up to 9 mg/kg soil.

APPENDIX III

THIABENDAZOLE

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.3 Data on application and further information
B.4 Proposals for classification and labelling,
None.

B.2 Physical and chemical properties

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[2] on previous use in granting national authorizations
IIA 1.11 IIA 2.1.1 IIA 2.2 IIA 2.6 IIA 2.7 IIA 2.8 IIA 2.11.1	Meeus, Ir.P.	1997	Physical and Chemical Properties of Thiabendazole Technical Station de Phytopharmacie de l'etat GLP/GEP: yes unpublished	

[1] List based on a detailed analysis from Spain in its submission of 18/05/2000 (background document C).

[2] Based on information received from notifier at the date of finalisation of the present review report. Neither the Commission nor the Member States are responsible for the completeness or validity of the information provided..

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 on previous use in granting national authorizations
IIA 6.0	Johnson, N.A.	1995	Effect of Freezer Storage on the Magnitude of the Residue Thiabendazole and Benzimidazole in Whole Potatoes and Potato Peel. Merck Research Laboratories, Rahway, NJ. Project 618-380-92851 GLP/GEP: yes unpublished	
IIA 6.0	Johnson, N.A.	1995	Effect of Freezer Storage on the Magnitude of the Residue Thiabemdazole and Benzimidazole in Whole Mushrooms Merck Research Laboratories, Rahway, NJ. Project 618-380-R/111611 GLP/GEP: yes unpublished	
IIA 6.0	Johnson, N.A.	1992	Effect of Freezer Storage on the Magnitude of the Residue (Thiabemdazole) on Whole Grapefruit and Grapefruit By-Products Merck Research Laboratories GLP/GEP: yes unpublished	
IIA 6.0	Johnson, N.A.	1992	Effect of Freezer Storage on the Magnitude of the Residue (Thiabemdazole) on Whole Apple and Apple By-Products Merck Research Laboratories GLP/GEP: yes unpublished	
IIA 6.0	Johnson, N.A.	1995	Effect of Freezer Storage on the Magnitude of the Residues of Thiabendazole and Benzimidazole in Whole Potatoes and Potato Peel Merck Research Laboratories GLP/GEP: yes unpublished	

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
II A 5.1.1	Craine, E.M.	1990	Thiabendazole: A Metabolism Study in Rats with ^{14}C-Thiabendazole. WIL Report No.: WIL-146002 Source: WIL Research Laboratories, Inc., Ashland, Ohio, USA GLP/GEP: yes unpublished	
II A 5.1.1	Sved, D.V.	1995	Isolation of a Metabolite of Thiabendazole from Rat Urine. WIL Report No.: WIL-146003 Source: WIL Research Labs., Ashland, Ohio, USA GLP/GEP: yes unpublished	
II A 5.3.2	Batham, P. and Lankas, G.R.	1990	A Fourteen Week Oral Toxicity Study in the Beagle Dog. MSD Report No.: 89-9010 GLP/GEP: yes unpublished	
II A 5.3.2	Lankas, G.R.	1993b	Fifty-Three-Week Oral Toxicity Study in Dogs. MSD Report No.: 91-068-0 GLP/GEP: yes unpublished	
II A 5.3.2	Myers, B.A. and Lankas, G.R.	1990	Thiabendazole: A 14-Week Dietary Toxicity Study in Rats. MSD Report No.: 90-9002 GLP/GEP: yes unpublished	
II A 5.4	Galloway, S.M. and Lankas, G.R.	1994	Thiabendazole: Assay for Chromosomal Aberrations in Mouse Bone Marrow. MSD Report No.: 94-8603 GLP/GEP: yes unpublished	

[2] Reports received from Member States at the date of finalisation of the present review report (not exhaustive).

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
II A 5.4	Lankas, G.R. and Storer, R.D.	1989	Thiabendazole *In Vitro* DNA Alkaline Elution/Rat Hepatocyte Assay. MSD Report No.: 89-8312 GLP/GEP: yes unpublished	
II A 5.4.1.1, II A 5.4.1.2	Lankas, G.R. and Sina, J.F.	1993a	Microbial Mutagenicity Assay in *Salmonella typhimurium* and *Escherichia coli.* MSD ReportS No.: 92-8074 and 92-8079 GLP/GEP: yes unpublished	
II A 5.5	Lankas, G.R.	1995	Thiabendazole: Fourteen-Week Dietary Thyroxine Clearance Study in Rats with a 14-Week Recovery Period. MSD Report No.: 94-024-0 GLP/GEP: yes unpublished	
II A 5.5	Lankas, G.R. and Wolfe, G.W.	1993c	Thiabendazole: One-Hundred-Six-Week Dietary Toxicity/Carcinogenicity Study in Rats. MSD Report No.: 90-9009 GLP/GEP: yes unpublished	
II A 5.6.1	Wise, L.D. and Lankas, G.R.	1992	Thiabendazole: Two-Generation Dietary Reproduction Study in Rats. MSD Report No.: 90-733-0 GLP/GEP: yes unpublished	
II A 5.6.2	Lankas, G.R. and Wise, L.D.	1991	Thiabendazole: Oral Developmental Toxicity Study in Rabbits. MSD Report No.: 90-734-0 GLP/GEP: yes 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
II A 5.6.2	Nakatsuka, T, Matsumoto, H. and Ikemoto, F.	1995a	Thiabendazole: Oral Range-Finding Study in Pregnant Mice. MSD Report No.: 94-9909 Source: Development Research Laboratories, Banyu Pharmaceutical Co. Ltd., 810 Nishijo, Memumamachi, Osato-gun, Saitama-ken, 360.02, Japan. GLP/GEP: no unpublished	
II A 5.6.2	Nakatsuka, T., Matsumoto, H. and Fumihiko, I.	1995b	Thiabendazole: Oral Developmental Toxicity Study in Mice. MSD Report No.: 94-9818 Source: Development Research Laboratories, Banyu Pharmaceutical Co. Ltd., 810 Nishijo, Memumamachi, Osato-gun, Saitama-ken, 360.02, Japan. GLP/GEP: yes unpublished	
II A 5.6.2	Wise, L.D.	1990	Thiabendazole: Oral Developmental Toxicity Study in Rats. MSD Report No.: 90-713-0 GLP/GEP: yes unpublished	
IIA 5.2.6	Cantoreggi, S.	1998	MK 360 B - Skin sensitization in the Guinea pig (Maximization test). Novartis Crop Protection AG, Switzerland Final report No. 973077 GLP/GEP: yes unpublished	
IIA 5.4	Deparade, E.	1998	Thiabendazole - Micronucleus test, mouse. Novartis Crop Protection AG, Switzerland Final report No. 973095 GLP/GEP: yes 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 on previous use in granting national authorizations
II A 6.1	Halls, T.D.J. and Sanson, D.R.	1991a	The Metabolic Fate of Thiabendazole (TBZ) in Wheat. MSD Report No.: 37724 Source: Analytical Biochemistry Labs., Inc., Columbia, MO, USA GLP/GEP: yes unpublished	
II A 6.1	Halls, T.D.J. and Sanson, D.R.	1991b	The Metabolic Fate of Thiabendazole (TBZ) in Soybeans. MSD Report No.: 37725 Source: Analytical Biochemistry Labs., Inc., Columbia, MO, USA GLP/GEP: yes unpublished	
II A 6.1	Halls, T.D.J. and Sanson, D.R.	1991c	The Metabolic Fate of Thiabendazole (TBZ) in Sugar Beets. MSD Report No.: 37726 Source: Analytical Biochemistry Labs., Inc., Columbia, MO, USA GLP/GEP: yes unpublished	
II A 6.2	Halls, T.D.J. and Sanson, D.R.	1992	14 C-Thiabendazole Confined Accumulation on Rotational Crops. MSD Report No.: 37727 Source: Analytical Biochemistry Labs., Inc., Columbia, MO, USA GLP/GEP: yes unpublished	
II A 6.3.1	McKenzie, J.	1991	The Determination of Concentrations of Thiabendazole in Potatoes (Source: United Kingdom). Source: Restec Laboratories Ltd., Birlingham, Worcestershire, U.K. Restec Report No.: MAV 0191 GLP/GEP: yes 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
II A 6.3.1	MSD AgVet, Spain	1991 - 1992	Summary of Trial Results in Determination of the Level of Thiabendazole Residues in or on some Horticultural Products made with Ground Equipment in Spain. MSD Report GLP/GEP: no unpublished	
II A 6.3.1	Norton, J.A.	1993a	Determination of the Magnitude of Residues of the Fungicide Thiabendazole in Green and Ripened Banana Fruit Imported from Honduras. MSD Report No.: 93768 Source: Research Designed for Agriculture (RDA), 2345 East 16th Street, Yuma, AZ 85365 and Merck Research Labs., 12 East Lincoln Av., Rahway, NJ, USA GLP/GEP: yes unpublished	
II A 6.3.1	Norton, J.A.	1993b	The Determination of the Presence and Magnitude of Residues of the Fungicide Thiabendazole in Sweet Potatoes Grown from Seed Roots Treated with MERTECT 340-F. MSD Report No.: 92851 GLP/GEP: yes unpublished	
II A 6.3.1	Norton, J.A.	1995a	Determination of the Magnitude of Residue of the Fungicide Thiabendazole (TBZ) in Green Banana Fruit by Post Harvest Dip Application. MSD Report No.: 618-360-94346 GLP/GEP: yes 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
II A 6.3.1	Norton' J.A.	1995b	Determination of the Magnitude of Residues of the Fungicide Thiabendazole in/on Citrus Treated with an Aqueous Dip and Wax Treatment. MSD Report No.: 618-360-94168 GLP/GEP: yes unpublished	
II A 6.3.1	Norton, J.A. and Armstrong, T.F.	1992a	Determination of the Magnitude of the Residues of the Fungicide Thiabendazole in Citrus Treated with a Dip and Wax Treatments. MSD Report No.: 93064 Source: Stewart Agricultural Research Services Inc., Missouri and Merck Research Labs., Three Bridges, NJ, USA GLP/GEP: yes unpublished	
II A 6.3.1	Norton, J.A. and Armstrong, T.F.	1992b	Determination of the Magnitude of the Residues of the Fungicide Thiabendazole in Pome Fruit (Pears) Treated with a Dip and Wax Treatments. MSD Report No.: 93104 / 93109 GLP/GEP: yes unpublished	
II A 6.3.1	Norton, J.A. and Nelson, R.	1992c	Determination of the Presence and Magnitude of the Residues of the Fungicide Thiabendazole in Mushrooms Treated with MERTECT 340-F in Irrigation Water and by Direct Application. MSD Report No.: 93041 GLP/GEP: yes 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
II A 6.3.1	Tecnidex	1992a	Industrial Trials for Assessing the Effectiveness and Phytotoxicity of the Formulation TECTO 20-S (ARBOTECT) in the Control of Post-Harvest Diseases in Citrus Fruits. MSD Report No.: none Source: Tecnidex, Paterna (Valencia), Spain. GLP/GEP: no unpublished	
II A 6.3.1	Tecnidex	1992b	Report on the Pre-Registration Trial of the Post-Harvest use of the Fungicidal Formulation TECTO 20S (ARBOTECT) in Pomes. MSD Report GLP/GEP: no unpublished	
II A 6.3.2	Norton, J.A. and Armstrong, T.F.	1993c	Determination of the Magnitude of the Residues of the Fungicide Thiabendazole in Potatoes Treated with MERTECT 340-F by Mist Application. MSD Report No.: 93036 Source: Laboratoire Agriculteurs de France, Paris, France GLP/GEP: yes unpublished	
IIA 6.3	Norton, J.A.	1995	Determination of the Magnitude of Residues of the Fungicide Thiabendazole in/on Citrus Treated with an Aqueous Dip and Wax Treatment: MSD Report No. 618-360-94168. GLP/GEP: yes 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
IIA 6.3	Partington, K.	1997	To determine the magnitude of thiabendazole residues in the raw agricultural commodity apples and pears resulting from a single treatment with PN 64661 or PN 64668 applied as dips or sprays in Northern France Agrisearch UK Limited, Melbourne, Engalnd, UK and ADME Bioanalyses, Mougins, France (2.12.1997) GLP/GEP: yes unpublished	
IIA, 6.31/001	Kissling, M.	1999a	MK 360, SC 500, A-10466 C, Apples, France (North) Novartis Crop Protection AG, Basel, Switzerland Final report No. 2243/98, 04.03.1999 GLP/GEP: yes unpublished	
IIA, 6.31/002	Kissling, M.	1999b	MK 360, SC 500, A-10466 C, Apples, France (North) Novartis Crop Protection AG, Basel, Switzerland Final report No. 2244/98, 04.03.1999 GLP/GEP: yes unpublished	
IIA, 6.31/003	Kissling, M.	1999c	MK 360, SC 500, A-10466 C, Apples, France (North) Novartis Crop Protection AG, Basel, Switzerland Final report No. 2245/98, 04.03.1999 GLP/GEP: yes unpublished	
IIA, 6.31/004	Kissling, M.	1999d	MK 360, SC 500, A-10466 C, Apples, France (North) Novartis Crop Protection AG, Basel, Switzerland Final report No. 2246/98, 04.03.1999 GLP/GEP: yes 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
IIA, 6.31/005	Kissling, M.	1999e	MK 360, SC 500, A-10466 C, Apples, France (North) Novartis Crop Protection AG, Basel, Switzerland Final report No. 2247/98, 04.03.1999 GLP/GEP: yes unpublished	
IIA, 6.31/006	Kissling, M.	1999f	MK 360, SC 500, A-10466 C, Apples, France (North) Novartis Crop Protection AG, Basel, Switzerland Final report No. 2248/98, 04.03.1999 GLP/GEP: yes unpublished	
IIA, 6.31/007	Kissling, M.	1999g	MK 360, SC 500, A-10466 C, Apples, France (North) Novartis Crop Protection AG, Basel, Switzerland Final report No. 2249/98, 26.03.1999 GLP/GEP: yes unpublished	
IIA, 6.31/008	Kissling, M.	1999h	MK 360, SC 500, A-10466 C, Apples, France (North) Novartis Crop Protection AG, Basel, Switzerland Final report No. 2250/98, 30.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/001	Kissling, M.	1999a	MK 360, SC 500, A-10466 C, Mandarins, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2276/98, 25.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/002	Kissling, M.	1999b	MK 360, SC 500, A-10466 C, Mandarins, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2277/98, 25.03.1999 GLP/GEP: yes 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
IIA, 6.32/003	Kissling, M.	1999c	MK 360, SC 500, A-10466 C, Mandarins, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2278/98, 25.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/004	Kissling, M.	1999d	MK 360, SC 500, A-10466 C, Mandarins, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2279/98, 25.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/005	Kissling, M.	1999e	MK 360, SC 500, A-10466 C, Mandarins, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2284/98, 26.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/006	Kissling, M.	1999f	MK 360, SC 500, A-10466 C, Mandarins, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2285/98, 26.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/007	Kissling, M.	1999g	MK 360, SC 500, A-10466 C, Mandarins, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2286/98, 26.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/008	Kissling, M.	1999h	MK 360, SC 500, A-10466 C, Mandarins, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2287/98, 26.03.1999 GLP/GEP: yes 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
IIA, 6.32/009	Kissling, M.	1999i	MK 360, SC 500, A-10466 C, Mandarins, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2292/98, 26.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/010	Kissling, M.	1999j	MK 360, SC 500, A-10466 C, Mandarins, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2293/98, 26.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/011	Kissling, M.	1999k	MK 360, SC 500, A-10466 C, Mandarins, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2294/98, 26.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/012	Kissling, M.	1999l	MK 360, SC 500, A-10466 C, Mandarins, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2295/98, 26.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/013	Kissling, M.	1999m	MK 360, SC 500, A-10466 C, Oranges, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2281/98, 25.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/014	Kissling, M.	1999n	MK 360, SC 500, A-10466 C, Oranges, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2282/98, 25.03.1999 GLP/GEP: yes 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
IIA, 6.32/015	Kissling, M.	1999o	MK 360, SC 500, A-10466 C, Oranges, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2283/98, 25.03.1999 GLP/GEP: yes unpublished	
IIA, 6.32/016	Kissling, M.	1999p	MK 360, SC 500, A-10466 C, Oranges, Spain Novartis Crop Protection AG, Basel, Switzerland Final report No. 2289/98, 26.03.1999 GLP/GEP: yes unpublished	
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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
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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
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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
II A 8.2.1	Holmes, C.M., Swigert, J.P. and Smith, G.J.	1992	Thiabendazole: A 96-Hour Static Acute Toxicity Test with the Bluegill Sunfish, *Lepomis macrochirus*. Wildlife International Report No.: 105-118A Source: Wildlife International, Easton, Maryland, USA GLP/GEP: yes unpublished	
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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
II A 8.2.4	Hirsch, M.P.	1991	Bioconcentration of Thiabendazole [2-(4-thiazolyl)-1H-benzimidazole] in Bluegill Sunfish, *Lepomis macrochirus.* Eastman Kodak Report No.: EN-456-GWN009-1 Source: Health and Environment Labs, Eastman Kodak Company, New York, USA GLP/GEP: yes unpublished	
II A 8.2.5	Holmes, C.M., Bellantoni, D.C. and Peters, G.T.	1990	Thiabendazole: A 48-Hour Flow-Through Acute Toxicity Test with the Cladoceran (*Daphnia magna).* Wildlife International Report No.: 105A-101 Source: Wildlife International, Easton, Maryland, USA GLP/GEP: yes unpublished	
II A 8.2.5	Surprenant, D.C.	1989c	Acute Toxicity of Thiabendazole to Mysid Shrimp (*Mysidopsis bahia*) Under Flow-Through Conditions. Springborn Report No.: 89-1-2955 Source: Springborn Life Sciences, Inc., Wareham, MA, USA GLP/GEP: yes unpublished	
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IIA 8.2.7	van der Kolk, J.	1998	MK 360 B (Thiabendazole): chronic effects on Midge Larvae (Chironomus riparius) in a water / sediment system Springborn Lab., Horn, Switzerland Final report No. 98-230-1047, 16.11.1998 GLP/GEP: yes 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
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IIA 8.7	van der Kolk, J.	1998	MK 360 B (Thiabendazole) activated sludge, respiration inhibition test Springborn Lab., Horn, Switzerland Final report No. 98-227-1047, 10.09.1998 GLP/GEP: yes 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.

Extract

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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 pesticides, with regard to consumer safety, and on the principles of integrated pest management. Control of storage diseases diseases has sufficiently been achieved by other means, such as climatic control in warehouses. Our opinion is that even 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).

...

A CHECCHI LANG
Director

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

SCIENTIFIC COMMITTEE ON PLANTS **SCP/THIABEN/002-Final**
22 September 2000

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

(Opinion adopted by the Scientific Committee on Plants on 22 September 2000)

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1. TITLE

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

2. TERMS OF REFERENCE

The Scientific Committee on Plants (SCP) is requested to consider the following question:

"Can the Committee comment on the potential environmental risk associated with the post-harvest use of thiabendazole and can it confirm that the proposed risk mitigation measures (waste water treatment) are adequate to protect surface waters?"

3. BACKGROUND

The draft Commission Directive for inclusion of thiabendazole in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market was submitted to the Committee for opinion. The Committee had been supplied with documentation comprising an evaluation report (monograph) prepared by the Rapporteur Member State (Spain) of a dossier submitted by the notifier (Novartis), a review report prepared by the Commission and the Recommendations of the ECCO[1] Peer Review Programme.

Thiabendazole is a fungicide of the benzimidazole group. It is mainly used for post-harvest treatment (dipping or drenching) of fruits (bananas, citrus fruits, pome fruits) and potatoes (seed and ware potatoes).

4. OPINION

Question

"Can the Committee comment on the potential environmental risk associated with the post-harvest use of thiabendazole and can it confirm that the proposed risk mitigation measures (waste water treatment) are adequate to protect surface waters?"

[1] European Community Co-ordination.

Opinion

The SCP is of the opinion that a discharge of thiabendazole waste water (from dips and/or drenches) poses a potential risk for the functioning of the sewage treatment plant (STP) and for the receiving surface water.

Based on a risk assessment of untreated thiabendazole contaminated waste water the SCP is of the opinion that the waste water will not pose an unacceptable risk to the micro-organisms in the STP and the algae in the receiving surface water. A more refined risk assessment and/or mitigation measures are necessary for fish, daphnids and sediment dwelling organisms.

Based on the data provided, the SCP is of the opinion that the intended post-harvest uses (dipping and drenching) of thiabendazole for bananas, citrus, bulbs, pome fruits and potatoes in the EU will not pose an unacceptable risk to the aquatic organisms when adequate mitigation measures (depuration with diatom soil and activated carbon) have been carried out.

Scientific background on which the opinion is based

The risk of the use of a PPP[2] for aquatic organisms is normally based on a risk quotient, the TER[3]. The first step in the risk assessment is based on realistic worst case assumptions. When the TERs for the acute situation (based on EC_{50}[4] values) are above 100 for fish and daphnids and above 10 for algae the use of the PPP is considered to be safe. When the TERs are lower than 100 or 10 a refined risk assessment should be carried out or proposed mitigation measures must show that they are adequate to protect surface water.

4.1 Emission scenario

For the risk assessment of post-harvest uses of thiabendazole in dips and drenches an emission scenario depicted by Spain will be used. It is based on a representative citrus treatment (and covers also pome fruit applications[5]). Per day 50 tons of oranges are drenched in a total volume of 1000 litres containing 2.2 grams thiabendazole per litre (2.2 kg a.s.[6] per day). It is assumed that only 10% of this amount is adsorbed by the fruits. Therefore, the daily emission rate to the sewage treatment plant (STP) is 2 kg a.s.

4.2 Model calculations for STP according to USES 3.0

The computer model for the sewage treatment plant in USES 3.0 (RIVM, VROM, VWS 1999) is the same model as described in the Technical guidance document[7] in support of Commission Directive 93/67/EEC laying down the principles for assessment of risks to man and the environment of substances notified in accordance

[2] Plant Protection Product.
[3] The toxicity over exposure ratio.
[4] Median effective concentration.
[5] see document SCP/THIABEN/007.
[6] Active substance.
[7] Reference n° 3 in Section 5.

with Council Directive 67/548/EEC and Commission Regulation (EC) N° 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to human and the environment of existing substances in accordance with Council Regulation (EEC) N° 793/93.

The sewage treatment plant is modelled as an average-size treatment plant based on aerobic degradation by activated sludge, and consisting of 9 (or 6) compartments. This model is a multi-media box model of the 'Mackay-type, level III'. The model calculates steady-state concentrations in a STP consisting of a primary settler (optional), an aeration tank and a solid-liquid separator.

Input and configuration:

– Local emission to wastewater during episode	2 kg/day.
– Type of local STP	With primary settler (9-box)
– Calculate dilution from river flow rate	No
– Kom[8] (mean of 4 values)	4260

Local PECs[9] [based on Kom value (l/kg)]:

– PEC for micro-organisms in STP	0.539 mg/l
– Local PEC in surface water during emission period	0.0536 mg/l
– Local PEC in sediment during emission period	4.26 mg/kg wet weight

4.3 Available toxicity data

Organisms	Acute (EC_{50})	Chronic (NOEC[10])
Fish	0.55 mg/l	0.12 mg/l
Daphnids	0.81 mg/l	0.48 mg/l
Algae	8.99 mg/l	3.2 mg/l
Sediment dwelling organisms	--	3 mg/kg sediment
Micro-organisms (respiration)	>1000 mg/l[11]	--

4.4 TERs for the acute situation

Organisms	TER based on Kom (EC_{50} / PEC)
Fish	0.55/0.0536 = 10.2
Daphnids	0.81/0.0536 = 15.0
Algae	8.99/0.0536 = 168
Sediment dwelling organisms	3/4.26 = 0.7
Micro-organisms in STP	1000/0.539 = 1855

The TERs for acute exposure for algae and micro-organisms are above 10 and therefore no additional risk assessment is necessary.

[8] Organic matter adsorption coefficient.
[9] Predicted environmental concentrations.
[10] No observed effect concentration.
[11] Reference is summarised in Attachment IX of Report 98-227-1047, J. van der Kolk (1998).

The TERs for fish and daphnids are below 100 and a therefore more refined risk assessment or immediate risk mitigation is necessary.

4.5 Percent reduction necessary to achieve acceptable TER values

TERs based on Kom:
- Fish (TER is below 100): necessary emission reduction of 90 % (2 kg to 0.2 kg/day).
- Daphnids (TER is below 100): necessary emission reduction of 85 % (2 kg to 0.3 kg/day).
- Algae (TER is above 10): no reduction is necessary.
- Sediment dwelling organisms (TER is below 10): necessary emission reduction of 93 % (2 kg to 0.14 kg/day).
- Micro-organisms (TER is above 10): no reduction is necessary.

An overall reduction factor of 20 by sewage treatment would be sufficient to reduce the risk to aquatic organisms to an acceptable level.

4.6 Waste water treatment information

Nine studies (two under GLP), carried out by Tecnidex S.A. from Spain, have been conducted to assess the efficacy of depuration of thiabendazole contaminated waste water. The depuration technique is based on adsorption on granular activated carbon and a pre-treatment filtration of the contaminated waste water through bags of mesh size 1 micrometer filled with a diatom soil for eliminating solids. Starting concentrations of thiabendazole in the waste water ranged between 74 and 3200 mg/l.

After the pre-treatment reductions of 50-70% of the thiabendazole concentrations were obtained. Combined with the adsorption on granular activated carbon a contamination reduction of at least a factor of 7000 could be achieved. The best performance in the test was obtained using three carbon bottles and a retention time of 2 hours (references 110, 113, 117, 118, 119, 120 and 121, numbers refer to the documentation that was send to the RMS[12]).

4.7 Conclusion

Discharging thiabendazole contaminated waste water from dips or drenches into the sewage system poses a potential risk for the sewage treatment plant and for the receiving surface water.

TERs greater than 10 have been calculated for micro-organisms in the STP and the algae in the receiving surface water. TERs smaller than 100 have been calculated for fish and daphnids and smaller than 10 for sediment dwelling organisms (based on Kom values).

The proposed risk mitigation measures (waste water treatment as described above) are adequate to protect surface waters; a reduction by a factor of at least 7000 can be

[12] Rapporteur Member State.

achieved (which is a factor 350 greater than that calculated to be necessary to reduce the risk to an acceptable level in the chosen scenario).

5. REFERENCES

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2. RIVM, VROM, VWS (1999) Uniform System for the Evaluation of Substances 3.0 (USES 3.0). National Institute of Public Health and the Environment (RIVM, Ministry of Housing, Spatial Planning and the Environment (VROM), Ministry of Health, Welfare and Sport (VWS), The Netherlands. RIVM report 601450004.

3. Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances, EC Catalogue Numbers CR-48-96-001, 002, 003, 004-EN-C. Office for Official Publications of the European Community, 2 Rue Mercier, L-2965 Luxembourg.

6. DOCUMENTATION MADE AVAILABLE TO THE COMMITTEE

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

2. Evaluation table, Doc. 7604/VI/97rev. 11 (Doc. SCP/THIABEN/003).

3. Draft review report, Doc. 7603/VI/97-rev 0 (Doc. SCP/THIABEN/004).

4. Appendices to the evaluation of thiabendazole in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Doc. SCP/THIABEN/005).

5. Document D2 List of authorised uses in the EU and actual uses sorted by crops. P. Dieterle /CP 6.62 / April 1999 version 3 (Doc. SCP/THIABEN/006).

6. Report (Monograph) and proposed decision of Spain made to the European Commission under Article 7(1) of Regulation 3600/92 – July 1996 (Volumes 1, 2, 3 and 4).

6. Addendum to the Monograph Environmental, Fate and Behaviour and Ecotoxicology, prepared by Instituto Nacional De investigation y Tecnologia Agraria y Alimentaria (I.N.I.A) Spain – December 1999 (Doc. SCP/THIABEN/007)

7. ACKNOWLEDGEMENTS

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

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

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