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Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen Band D 14

Review Report Diquat
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 14

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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 14. Heft dieser Reihe (Band D 14) 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 Deiquat war das Vereinigte Königreich 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 14th report belonging to this series (Volume D 14) 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 diquat the United Kingdom acted as Rapporteur Member State.

In the series Legal Regulations of the European Union for Plant Protection Products and their Active Substances the following Reports have been published:

Report	**Legal Regulations of the European Union for Plant Protection Products and their Active Substances**
35/97	Volume A: Directive 91/414/EEC and respective Protocols (3rd Edition, date: 1 November 1997)
68/2000	Volume B: Regulations and Protocols regarding the Evaluation of Active Substances (4th Edition, date: 1 July 2000)
	Volume C: *In Progress*

RICHTLINIE 2001/21/EG DER KOMMISSION

vom 5. März 2001

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

DIE KOMMISSION DER EUROPÄISCHEN GEMEINSCHAFTEN —

gestützt auf den Vertrag zur Gründung der Europäischen Gemeinschaft,

gestützt auf die Richtlinie 91/414/EWG des Rates vom 15. Juli 1991 über das Inverkehrbringen von Pflanzenschutzmitteln [1], zuletzt geändert durch die Richtlinie 2000/80/EG der Kommission [2], insbesondere auf Artikel 6 Absatz 1,

in Erwägung nachstehender Gründe:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

Anhang I der Richtlinie 91/414/EWG wird gemäß dem Anhang der vorliegenden Richtlinie geändert.

Artikel 2

(1) Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens 1. Juli 2002 nachzukommen. Sie unterrichten die Kommission unverzüglich davon.

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

[1] Wissenschaftlicher Pflanzenausschuss SCP/PYRID/002-endg.
[2] Wissenschaftlicher Pflanzenausschuss SCP/THIABEN/002-endg.

Bei Erlass dieser Vorschriften nehmen die Mitgliedstaaten in den Vorschriften selbst oder durch einen Hinweis bei der amtlichen Veröffentlichung auf diese Richtlinie Bezug. Die Mitgliedstaaten regeln die Einzelheiten der Bezugnahme.

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

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

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

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

Artikel 3

Diese Richtlinie tritt am 1. Januar 2002 in Kraft.

Artikel 4

Diese Richtlinie ist an die Mitgliedstaaten gerichtet.

Brüssel, den 5. März 2001

Für die Kommission

David BYRNE

Mitglied der Kommission

ANHANG

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

Nr.	Gemeinsamer Name, Kennnummern	IUPAC-Bezeichnung	Reinheit (1)	Inkrafttreten	Befristung der Eintragung	Sonderbestimmungen
„14	Amitrol CAS-Nr. 61-82-5 CIPAC-Nr. 90	H-[1,2,4]-Triazole-3-yl-amine	900 g/kg	1.1.2002	31.12.2011	Nur Anwendungen als Herbizid dürfen zugelassen werden. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 12. Dezember 2000 abgeschlossenen Prüfungsberichts über Amitrol und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten: — der Anwendersicherheit besondere Aufmerksamkeit widmen; — dem Grundwasserschutz in gefährdeten Gebieten, insbesondere im Hinblick auf Anwendungen in Nicht-Kulturland, besondere Aufmerksamkeit widmen; — dem Schutz von Nutzarthropoden besondere Aufmerksamkeit widmen; — dem Schutz von Vögeln und wildlebenden Säugetieren besondere Aufmerksamkeit widmen. Die Anwendung von Amitrol während der Brutzeit sollte nur zugelassen werden, wenn durch eine entsprechende Risikobewertung keine unannehmbaren Auswirkungen nachgewiesen wurden und wenn die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikobegrenzung umfassen.
15	Diquat CAS-Nr. 2764-72-9 (ion), 85-00-7 (Dibromid) CIPAC-Nr. 55	9,10-Dihydro-8a,10a-diazoniaphenanthren-ion (Dibromid)	950 g/kg	1.1.2002	31.12.2011	Auf der Grundlage der vorliegenden Informationen dürfen nur Anwendungen als Bodenherbizid und Sikkations-Mittel zugelassen werden. Anwendungen zur Bekämpfung von Wasserunkräutern dürfen nicht zugelassen werden. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 12. Dezember 2000 abgeschlossenen Prüfungsberichts über Diquat und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten: — besonders auf die potenziellen Auswirkungen auf Wasserorganismen achten und sicherstellen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikominderung umfassen; — der Anwendersicherheit bei nichtprofessioneller Anwendung besondere Aufmerksamkeit widmen und dafür Sorge tragen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikobegrenzung umfassen.
16	Pyridat CAS-Nr. 55512-33.9 CIPAC-Nr. 447	6-Chlor-3-phenylpyridazin-4-yl)S-octyl-thiocarbonat	900 g/kg	1.1.2002	31.12.2011	Nur Anwendungen als Herbizid dürfen zugelassen werden. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 12. Dezember 2000 abgeschlossenen Prüfungsberichts über Pyridat und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten: — dem Grundwasserschutz besondere Aufmerksamkeit widmen; — besonders auf die potenziellen Auswirkungen auf Wasserorganismen achten und sicherstellen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikominderung umfassen.

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

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

COMMISSION DIRECTIVE 2001/21/EC

of 5 March 2001

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include amitrole, diquat, pyridate and thiabendazole as active substances

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], as last amended by Commission Directive 2000/80/EC [2], and in particular Article 6(1) thereof,

Whereas:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

Article 2

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

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

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

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. With regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto, the deadline for amending or withdrawing authorisations for plant protection products containing amitrole, diquat, pyridate or thiabendazole as the only active substance shall be 1 January 2006.

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

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

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 5 March 2001.

For the Commission

David BYRNE

Member of the Commission

ANNEX

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

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

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

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

EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH & CONSUMER PROTECTION

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

Diquat
1688/VI/97-final
22.03.2001

Review report for the active substance **diquat**

Finalised in the Standing Committee on Plant Health at its meeting on 12 December 2000 in view of the inclusion of diquat 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 diquat, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92([1]) laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1972/99([2]), has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Diquat 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, Zeneca Agrochemicals on 27 July 1993 and Barclay Chemicals on 27 June 1993 notified to the Commission of their wish to secure the inclusion of the active substance diquat 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 the United Kingdom as rapporteur Member State to carry out the assessment of diquat on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for diquat this deadline was 30 April 1995.

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

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

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

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

Both Zeneca Agrochemicals and Barclay Chemicals submitted each a dossier to the rapporteur Member State. Zeneca Agrochemicals was the main data submitter, with a dossier which did not contain substantial data gaps, taking into account the supported uses. The dossier from Barclay Chemicals was limited to data identifying the substance and to published general information on the substance. Information has furthermore been submitted by third parties, in particular a general analysis document prepared by the European Environmental Bureau.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, the United Kingdom submitted on 2 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 diquat 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 diquat from Zeneca Agrochemicals, on 29 July 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 Zeneca Agrochemicals being the main data submitter, on 24 June 1996.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from September to December 1996.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 16 January 1997 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 April 1997 to October 2000, and was finalised in the meeting of the Standing Committee on 12 December 2000.

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

These documents were also submitted to the Scientific Committee for Plants for separate consultation. The report of this Committee was formally adopted on 17 March 2000 (SCP/DIQUAT/Final-002 dated 5 April 2000[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 diquat in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing diquat they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to all operators having notified for this active substance under Article 4(1) of this Regulation.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing diquat 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 diquat 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:

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

- crop desiccation in potatoes;
- terrestrial weed control.

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. Based on the FAO/WHO Standard European Diet (August 1994), excluding water and products of animal origin, total dietary intake does not exceed 35 % of the Acceptable Daily Intake (ADI). 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 diquat are given in Appendix I.

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

The review has established that for the active substance notified by the main data submitter Zeneca Agrochemicals, 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 diquat

(1) 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:

– For the protection of aquatic organisms, risk mitigation measures must be applied where appropriate.

- For the protection of operators risk mitigation measures must be applied where appropriate.

(2) In addition, for the following uses, which have been evaluated, insufficient information has been submitted at this stage to demonstrate that the requirements of Article 4 (1) of the Directive are fulfilled. Therefore, the following 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, for the following uses, as appropriate:

For uses of pre-harvest desiccation of small grain crops Member States must ensure that dietary exposure arising from this use is acceptable.

(3) Finally, on the basis of the information available, it was concluded that aquatic weed control uses do not fulfil the requirements of Article 4 (1) of the Directive. Authorisations for these uses must therefore be withdrawn.

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 diquat in Annex I under the current inclusion conditions.

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

- For non-professional uses Member States shall ensure that sufficient information is submitted (such as specific field studies on amateur use for diquat containing products) to demonstrate that operator exposure is acceptable

- For use of pre-harvest desiccation of small grain crops Member States shall ensure that sufficient information is submitted to demonstrate that dietary exposure arising from this use is acceptable.

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

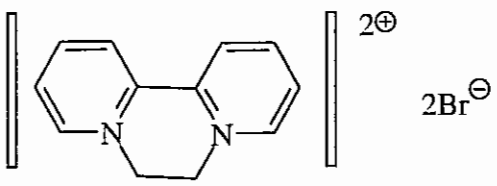
The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on Plant Health, in connection with any amendment of the inclusion conditions for diquat in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

DIQUAT

Common name (ISO)	Diquat (dibromide)
Chemical name (IUPAC)	9,10-dihydro-8a,10a-diazoniaphenanthrene ion (dibromide)
Chemical name (CA)	6,7-dihydrodipyrido[1,2-a:2'1'-c]pyrazinediium(8 & 9 Cl) (dibromide)
CIPAC No	55
CAS No	2764-72-9 (ion), 85-00-7 (dibromide)
EEC No	220-433-0 (ion), 201-579-4 (dibromide)
FAO SPECIFICATION	The material shall consist essentially of an aqueous solution of technical diquat dibromide together with related manufacturing impurities, and may contain small amounts of suspended matter, immiscible solvents and sediment, as specified. The diquat dibromide content shall be declared (not less than 467 g/l at 20 °C, and, when determined, the content obtained shall not differ from that declared by more than ± 25 g/kg. Impurities: For Ethylene Dibromide maximum of 10 mg/kg).
Minimum purity	95 % w/w
Molecular formula	$C_{12}H_{12}N_2$, $C_{12}H_{12}Br_2N_2$ (dibromide)
Molecular mass	184.2, 344 (dibromide)
Structural formula	



$C_{12}H_{12}Br_2N_2$ (diquat dibromide)

Melting point	Decomposes at approximately 325 °C
Boiling point	Decomposes
Appearance	Yellow crystalline solid
Relative density	1.61 $g \cdot cm^{-3}$
Vapour pressure	$< 10^{-8}$ kPa at 25 °C
Henry's law constant	$< 5 \cdot 10^{-12}$ $Pa \cdot m^3 \cdot mol^{-1}$
Solubility in water	pH 5.2: 712 g/l at 20 °C pH 7.2: 718 g/l at 20 °C pH 9.2: 713 g/l at 20 °C
Solubility in organic solvents	All at approximately 20 °C: - methanol : 25 g/l - acetone, dichlormethane, toluene, ethyl acetate, hexane : < 0.1 g/l,
Partition co-efficient (log P_{OW})	-4.6 at 20 °C
Hydrolytic stability (DT_{50})	pH 5: stable pH 7: stable pH 9: 8.3 % degradation after 30 d at 25 °C
Dissociation constant	--
Quantum yield of direct photo-transformation in water at ε >290 nm	3.84×10^{-4} at 302-303 nm
Flammability	Diquat dibromide technical is an aqueous solution containing approximately 20% w/w (minimum) diquat, it does not evolve flammable gases and the determination of the flammability of diquat dibromide as manufactured is therefore inappropriate
Explosive properties	The chemical structure of diquat does not include bond groupings which confer explosive properties.
UV/VIS absorption (max.)	204 nm, 272 nm, 310 nm
Photostability (DT_{50})	74 d at pH 7 (sunlight Florida) in water

APPENDIX II

END POINTS AND RELATED INFORMATION

DIQUAT

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Oral, < 10% in 96 h, rat
Distribution:	Highest levels in kidneys, gastro-intestinal tract, lung and liver, certain affinities to eye lens
Potential for accumulation:	Half live in blood 4 h, much longer in eye lens
Rate and extent of excretion:	Absorbed dose extensively excreted in urine and bile within 96 h.
Toxicologically significant compounds:	Diquat ion
Metabolism in animals:	Metabolism was limited, with <20% of the urinary residues (<1% of the administered dose) consisting of metabolites.

Acute toxicity

Rat LD_{50} oral:	LD_{50} (ion) = 214 - 222 mg/kg bw
Rat LD_{50} dermal:	LD_{50} (ion) > 424 mg/kg bw
Rat LC_{50} inhalation:	LC_{50} (ion) = 0.121 - 0.132 mg/l
Skin irritation:	Irritant (dibromide)
Eye irritation:	Irritant (dibromide) - classified on human data
Sensitisation (test method used and result):	Magnusson and Kligman - Positive (dibromide)

Short term toxicity

Target / critical effect:	Cataract (rat), kidney lesions (mouse) - (diquat ion)
Lowest relevant oral NOAEL / NOEL:	0.5 mg/kg bw/d, cataract 1 y dog - (diquat ion)
Lowest relevant dermal NOAEL / NOEL:	No repeat dose study by this route.
Lowest relevant inhalation NOAEL / NOEL:	No repeat dose study by this route.

Genotoxicity

No genotoxicity *in vivo*

Long term toxicity and carcinogenicity

Target / critical effect:	Cataract (rat), kidney lesions (mouse)
Lowest relevant NOAEL:	0.2 mg/kg bw/d, 2 y rat - (diquat ion)
Carcinogenicity:	Negative

Reproductive toxicity

Target / critical effect - Reproduction:	Negative
Lowest relevant reproductive NOAEL / NOEL:	1.4 mg/kg bw/d - general toxicity - rat (NOAEL)
Target / critical effect - Developmental toxicity:	Negative
Lowest relevant developmental NOAEL / NOEL:	1 mg/kg bw/d - NOAEL for maternal toxicity - rabbit

Delayed neurotoxicity

Not relevant

Other toxicological studies

None

Medical data

Published literature and company records report fatalities in cases of oral ingestion of concentrate i.e. not as a consequence of occupational exposure. A few cases of skin irritation and nosebleeds in manufacturing workers.

Summary

	Value	Study	Safety factor
ADI:	0.002 mg/kg bw (diquat ion),	2 y rat	100
AOEL systemic:	0.001 mg/kg bw/d (diquat ion), Corrected for oral absorption.	2 y rat (90 day end point)	100
AOEL inhalation:	not relevant		
AOEL dermal:	not relevant		
ARfD (acute reference dose):	not relevant		

Dermal absorption

About 1 %, human *in vivo*

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	Microbial degradation has been demonstrated only in isolation due to strong adsorption to soil.
Non-extractable residues after 100 days:	Not relevant. See comment above.
Relevant metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	Not relevant. See comment above.

Supplemental studies

Anaerobic:	Relatively stable, withstands degradation
Soil photolysis:	No significant degradation in 32 d
Remarks:	Standard requirements are not applicable due to strong adsorption to soil.

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	No measurable degradation in soil under laboratory conditions after one year.
DT_{90}lab (20 °C, aerobic):	Not relevant. See comment above.
DT_{50}lab (10 °C, aerobic):	Not relevant. See comment above.
DT_{50}lab (20 °C, anaerobic):	Not relevant. See comment above.

Field studies (country or region)

DT_{50f} from soil dissipation studies:	DT_{50} = 10 - 20 y (UK), 1.2 - 3.6 y (US)
DT_{90f} from soil dissipation studies:	DT_{90} values were never reached
Soil accumulation studies:	Performed as part of US soil dissipation study - refer to detailed results. (16% of diquat applied remained in the soil after 11 years of annual application to the soil at 1 kg diquat/ha/yr)
Soil residue studies:	< 0.05 - 2.3 mg/kg (Denmark 32 sites) 0.11 mg/kg (maximum), 0.03 mg/kg (average) for various Western European Countries

Remarks	
e.g. effect of soil pH on degradation rate	The strong adsorption of diquat to soil precludes diquat degradation in soil being studied effectively by standard guideline methods. The strong adsorption also greatly reduces the rate of formation of degradation products to amounts that would not be detectable using standard methods. Soil microbial studies fulfil the scientific intent of demonstrating the intrinsic degradability of diquat.

Adsorption/desorption

	Following end points based on the results obtained from a soil residue study performed at 32 sites in Denmark. (Bewick *et al*, 1984)
K_f / K_{OC}	Koc values (32 soils in study) ranged from 32,000 to 7,900,000 (very strong adsorption in all the soils tested - with 31 of the soils having Koc values at least one order of magnitude greater than 5,000). Mean Koc value = 2,184,750 Median Koc value = 1,600,000
K_d	Kd values (32 soils in study) ranged from 1,200 to 92,000 (very strong adsorption in all the soils tested) Mean Kd value = 27,100 Median Kd value = 23,500
ph dependence	Not relevant

Mobility

Laboratory studies:

Column leaching:	Not relevant as all studies indicate that diquat is immobile.
Aged residue leaching:	Not relevant as all studies indicate that diquat is immobile.

Field studies:

Lysimeter/Field leaching studies:	Not relevant as all studies indicate that diquat is immobile.

Remarks:	Adsorption is correlated to clay content.

Adsorption capacity is quantified by wheat bioasssay (SAC-WB). Most soils have a large excess in adsorption capacity. For very sandy soil exceedance may be a possibility following repeated high application rates.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	No sterile hydrolysis at environmental pHs.
Relevant metabolites:	None
Photolytic degradation:	DT_{50} < 7 d (UK summer conditions)
Relevant metabolites:	None

Biological degradation

Ready biological degradability:	No, due to rapid adsorption by sediment or suspended solids.
Water/sediment study: DT_{50} water: DT_{90} water: DT_{50} whole system: DT_{90} whole system: Distribution in water / sediment systems (active substance) Distribution in water / sediment systems (metabolites)	DT_{50} = 12 - 24 hours. Aquatic biodegradation studies, (two water/sediment studies performed in the laboratory under aerobic or anaerobic conditions, and a field study performed in natural ponds in the US) show similar results. The primary route of dissipation of diquat from natural water is through very rapid adsorption onto sediment, or by adsorption onto plant material and/or suspended particulate matter which ultimately settle to the bottom of the pond or water course. The field study in natural ponds shows that diquat dispersion within and dissipation from water are both extremely rapid with difficulties in measuring these accurately. Substantial dissipation occurs after a few hours, with estimates of the DT50 for the partition to sediment ranging from <8 to 34 hours, with a mean of 12 to 24 hours. Diquat was stable withstanding degradation under the conditions of the aerobic and anerobic studies conducted in pond water and sand sediment.
Accumulation in water and/or sediment:	Not relevant as diquat dissipates very rapidly by adsorption onto sediment; plant material and/or suspended particulate matter which settle to the bottom of the pond or water course. There is no evidence of desorption of diquat back into the water in the relevant studies.

Degradation in the saturated zone	See above remarks.
Remarks:	None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	$< 10^{-8}$ kPa at 25 °C
Henry's law constant:	$5 \cdot 10^{-12}$ Pa·m^3·mol^{-1}

Photolytic degradation

Direct photolysis in air:	Not relevant, due to low vapour pressure.
Photochemical oxidative degradation in air	Not relevant, due to low vapour pressure.
DT_{50}:	
Volatilisation:	Not relevant, due to low vapour pressure.
Remarks:	None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD_{50} (diquat ion - rat)= 214 - 222 mg/kg bw
Short term oral toxicity to mammals:	NOAEL 8.9mg /kg bw/d, 90 day rat (diquat ion) NOAEL 0.5 mg/kg bw/d, 1 y dog - (diquat ion)
Acute toxicity to birds:	LD_{50} = 83 mg /kg bw (diquat ion) *Anas platyrhynchos*
Dietary toxicity to birds:	LC_{50} = 721 ppm, 5 d study (diquat ion) *Coturnix japonica*
Reproductive toxicity to birds:	NOEC = 5 mg/kg (diquat ion)

Aquatic Organisms

Acute toxicity fish:	LC_{50} = 21 mg /l, 96 h static study (diquat ion) *Oncorhynchus mykiss* LC_{50} = 6.1 mg /l, 96 h flow through study (diquat ion) *Oncorhynchus mykiss*
Long term toxicity fish:	*Pimephales promelas* 34 day study on embryos/larvae - NOEC (larval weight) considered to be 0.12 mg diquat/litre based on mean measured concentration
Bioaccumulation fish:	Low risk of bioaccumulation
Acute toxicity invertebrate:	EC_{50} = 1.2 mg/l, 48 h study *Daphnia magna* (diquat ion)
Chronic toxicity invertebrate:	21-day LC50 was 0.16 mg/l based on nominal concentration *Daphnia magna* (diquat ion). 21-day NOEC = 0.125 mg/l based on nominal concentration.
Acute toxicity algae:	EC_{50} = 0.011 - 1.0 mg/l, 96 h study (diquat ion) *Psuedokirchneriella subcapitata (syn. Rhapidocellis subcapitata and Selenastrum capricornutum)*
Acute toxicity algae - study in presence of sediment	NOEC biomass = 320 µg/l with EbC50 of >320 µg/l. 72 hours (diquat ion).. NOEC growth rate = 320 µg/l with ErC50 of >320 µg/l. 72 hours (diquat ion). *Psuedokirchneriella subcapitata (syn. Rhapidocellis subcapitata and Selenastrum capricornutum)*

Chronic toxicity sediment dwelling organism:	NOEC > 100 mg diquat ion/kg^{-1} sediment (diquat ion). *Chironomus riparius*
Acute toxicity aquatic plants:	No data requirement set at time of review.

Honeybees

Acute oral toxicity:	LD_{50} = 13 µg /bee (diquat ion)
Acute contact toxicity:	LD_{50} = 60 µg /bee (diquat ion)

Other arthropod species

Test species	% Effect
Aphidius rhopalosiphi	An extended laboratory study. At full field rate (i.e. 5 l/ha) there was significant mortality of wasps in the treatment compared to the control. No adverse effects were noted on either fecundity or behaviour.
Coccinella septumpunctata.	Extended laboratory study. Bean plants treated with 'Reglone' at 5 l/ha (1000 g /ha) - equivalent to the maximum field rate. Larvae of *Coccinella septumpunctata* exposed to residues of the test substance. Corrected pre-imaginal mortality of *Coccinella septumpunctata* was 58%, mortality for the positive control was 78.9%. The reproduction rate was: • 640.9 eggs/female in the treatment • 255.3 eggs/female in the control. R value 151.0%. Results within the range of historical control variability. IOBC classification : slightly harmful
Trichogramma cacocecie	Laboratory study: exposed to 'Reglone' at 1000 g diquat ion/ha - equivalent to maximum field rate. Parisitisation capacity reduced by 58 %. Exposed adults reduced by 98%.
Chrysoperla carnea	Laboratory study: exposed to 'Reglone' at 1600 g diquat ion/ha. 96% mortality recorded in exposed larvae.

Pterosticus melanarius	Exposed to 'Reglone' at 1600g diquat ion/ha on loamy sand. No lethal or sublethal effects.
Pardosa spp.	Exposed to 'Reglone' at 1600g diquat ion/ha on loamy sand. No lethal or sublethal effects.

Earthworms

Acute toxicity:	LC_{50} = 130 mg as/kg soil 14 day (diquat ion) NOEC > 18 mg as/kg soil 14 day (diquat ion)

Soil micro-organisms

Nitrogen mineralization:	No significant effects up to 50.0 kg diquat/ha
Carbon mineralization:	No significant effects up to 720 kg as/ha

APPENDIX III

DIQUAT

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[6].

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[2] on previous use in granting national authorizations
IIA 2, 7.2.1.1	Hendley P Upton BP Skidmore MW	1985	Diquat : Hydrolytic stability in water at pH 5, 7 and 9. RJ0452B 5C.1/15 GLP or GEP: yes Published: no	Germany 1994
IIA 2, 7.2.1.2	Moffatt F	1993	Diquat : Environmental half-life and quantum yield for direct photo-transformation in aqueous solution. RJ1545B 5C.1/17 GLP or GEP: yes Published: no	Germany 1994
IIA 2, 7.2.1.2	Tegala B Skidmore MW	1987	Diquat: an aqueous photolysis study. ICI Jealott's Hill Research Station Report No. RJ0613B 5C 1/16. GLP or GEP: yes Published: no	Germany 1994

[6] List based on a detailed analysis from the United Kingdom.

[2] Entries are based on information received from the Notifier. Neither the Commission nor the Member States are responsible for the completeness or validity of this information provided.

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 2	Wollerton C	1987 a	Pure diquat dibromide: Physico-chemical data file. RJ0582B 2B.2/7 GLP or GEP: yes Published: no	Finland 1994
IIA 2	Wollerton C	1987 b	Diquat manufacturing use product : Physico-chemical data file. RJ0534B 2B 2/6 GLP or GEP: yes Published: no	Finland 1994
IIA 4.2.3	Anderson L Earl M	1990	Diquat : Determination of residues in water at 0.1 ug/litre. ME/JAP/DLTL GLP or GEP: no Published: no	
IIA 4.2.4	Anderson L	1994	Paraquat and diquat. Validation of model to determine residues in air. RJ1659B GLP or GEP: yes Published: no	
IIA 4.2.1, IIA 4.2.2	Anderson L	1994	The determination of residues of paraquat and diquat in crops : A second derivative spectrophotometric method. RAM 252/01 GLP or GEP: yes Published: no	
IIA 4.2.2	Anderson L	1994	The determination of residues of paraquat and diquat in soil: a second derivative spectrophotometric method RAM 253/01 GLP : yesPublished: no	

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 4.2.3	Anderson L	1994	The determination of residues of paraquat and diquat in water, milk, oils and other liquids : A second derivative spectrophotometric method with confirmatory method for water residues by HPLC. RAM 254/01 GLP: yes Published: no	
4.2.1, 4.2.2	Anderson L and Boseley A D:	1997	The determination of paraquat and diquat in crops and soil - a high performance liquid chromatography method (RAM 272/02) GLP or GEP: yes Published: no	
IIA 4.2.1	Coombe NB	1994	Validation of Zeneca Agrochemicals standard operating procedures for the analysis of diquat and paraquat residues in crops, soil and water containing both compounds. CEMR - 322 GLP or GEP: yes Published: no	
IIA 4.2.5	Earl M	1992 a	Diquat : Method validation data - determination of residues in milk. ME/JAP/DLTL1 GLP or GEP: yes Published: no	
IIA 4.2.5	Earl M	1992 b	Diquat : Method validation data. Determination of residues in animal tissues. ME/JAP/DLTL2 GLP : yes Published: no	

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 4.2.5	Earl M	1993	Diquat : Determination of residues of diquat in animal tissues - a spectrophotometric method. RAM 008/01 GLP or GEP: no Published: no	
4.2.1, 4.2.2	James W	1996	Paraquat and diquat: validation of a method for the determination of residues in crops and soil: ZEN 0396 GLP or GEP: yes Published: no	
IIA 4.2.5	Thomas D Woollen BH	1994	Rapid methods for the semi-quantitative determination of paraquat and diquat in urine. CTL/R/1191 (tox series) GLP or GEP: yes Published: no	
IIA 4.2.5	Thomas D	1995	The determination of paraquat and diquat in biological fluids by reversed phase HPLC with UV detection. CT05-287 GLP or GEP: yes Published: no	
IIA 4.1	Thorndycraft MD	1992	The determination of diquat in aqueous concentrates and formulated materials by spectrophotometry. PAM 146 GLP : yes Published: no	

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[2] on previous use in granting national authorizations
IIA 5.3.2	Hodge MCE	1989 a	Diquat : 90 day feeding study in rats. CTL/P/1832 (revised) 4B.1/1 GLP or GEP: yes Published: no	Italy 1992 Germany 1994
IIA 5.5	Harling RJ Buist DP Gopinath C	1997	Diquat dibromide: Evaluation of potential carcinogenicity and chronic toxicity by prolonged dietary administration to rats. ICI 406/83763 (CTL/c/1327), Addendum report 2 (2 year data) GLP or GEP: no Published: no	
IIA 5.6.2	Hodge MCE	1989 b	Diquat : Teratogenicity study in the rabbit. CTL/P/2379 4B.4/10 GLP or GEP: yes Published: no	Finland 1994
IIA 5.6.2	Hodge MCE	1989 c	First amendment to Diquat : Teratogenicity study in the rabbit. CTL/P/2379 4B.4/10 GLP or GEP: yes Published: no	
IIA 5.6.2	Hodge MCE	1989 d	Second amendment to Diquat : Teratogenicity study in the rabbit. CTL/P/2379 4B.4/10 GLP or GEP: yes Published: no	Italy 1992
IIA 5.6.1	Hodge MCE	1990	Diquat : Multigeneration study in the rat. CTL/P/2462 4B.4/13 GLP or GEP: yes Published: no	Finland 1994
IIA 5.5	Hodge MCE	1992 a	Diquat : Two year feeding study in mice. CTL/P/3409 4B.2/7 GLP or GEP: yes Published: no	

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 5.5	Hodge MCE	1992 b	First supplement to Diquat : Two year feeding study in mice. CTL/P/3409 4B.2/7 GLP or GEP: yes Published: no	
IIA 5.6.2	Hodge MCE	1994	Third amendment to Diquat : Teratogenicity study in the rabbit. CTL/P/2379 4B.4/10 GLP or GEP: yes Published: no	
IIA 5.3.2	Hopkins MN	1990	Diquat : 1 year feeding study in dogs. CTL/P/2596 4B.2/6 GLP or GEP: yes Published: no	Italy 1992 Finland 1994 Germany 1994
IIA 5.1.1	Johnston AM Jones C McCallum J Scott G	1991 a	The elimination of [^{14}C]-diquat in the rat following single oral administration (high dose level). IRI 7504 (CTL/C/2555) 4B.6/21 GLP or GEP: yes Published: no	
IIA 5.1.1	Johnston AM Mutch PJ Scott G	1991 b	The elimination of [^{14}C]-diquat in the rat following single oral administration (low dose level). IRI 7417 (CTL/C/2554) 4B.6/22 GLP or GEP: yes Published: no	
IIA 5.1.1	Johnston AM Jones C McCallum J Scott G	1991 c	The disposition of [^{14}C]-diquat in the rat. IRI 7480 (CTL/C/2553) 4B.6/23 GLP or GEP: yes Published: no	
IIA 5.2.1	McCall JC Robinson P	1990 a	Diquat dibromide : Acute oral toxicity to the rat. CTL/P/2999 3B.1/25 GLP or GEP: yes Published: no	Finland 1994 Germany 1994

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 5.2.2	McCall JC Robinson P	1990 b	Diquat dibromide : Acute dermal toxicity to the rat. CTL/P/2982 3B.1/26 GLP or GEP: yes Published: no	Finland 1994 Germany 1994
IIA 5.2.6	Rattray N Robinson P	1990	Diquat : Skin sensitisation to the guinea pig. CTL/P/2773 3B.1/24 GLP or GEP: yes Published: no	Finland 1994
IIA 5.2.2	Scott RC Walker M Mawdsley SJ	1991	First revision to diquat : *In vitro* absorption from technical concentrate ('Reglone 40') and spray strength solution through human skin. CTL/P/970 3E.2/9 GLP or GEP: yes Published: no	Italy 1992 Germany 1994
IIA 5.6.2	Wickramaratne GA	1989	Diquat : Teratogenicity study in the rat. CTL/P/2331 4B.4/9 GLP or GEP: yes Published: no	
IIA 5.6.2	Wickramaratne GA	1989	First supplement to diquat : Teratogenicity study in the rat. CTL/P/ GLP or GEP: yes Published: no	
IIA 5.6.2	Wickramaratne GA	1989	First amendment to diquat : Teratogenicity study in the rat. CTL/P/2331 4B.4/9 GLP or GEP: yes Published: no	
IIA 5.1.2	Williams SGP Cameron BD McGuire GM	1991	Identification of the major radioactive components in urine and faeces from rats following single oral administration of [^{14}C]-diquat. 7563 (CTL/C/2523) 4B.6/24 GLP or GEP: yes Published: no	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[2] on previous use in granting national authorizations
6	Anderson L	1996	Diquat: storage stability of the residues in frozen carrot, cabbage, wheat grain and soil (final report) TMJ3575B GLP or GEP: yes Published: no	
6.5	Anderson L	1999	Diquat: residue levels in wheat and processed fractions generated during bread production from trials carried out in the United Kingdom during 1998. 98JH073 GLP or GEP: yes Published: no	
IIA 6.3.2i, IIA 6.3.2ii, IIA 6.3.2v	Anderson L Lant MS	1994 a	Diquat: Residue levels in carrots, lettuces and onions from trials carried out in Italy in 1993. RJ1730B GLP or GEP: yes Published: no	
IIA 6.3.1	Anderson L Lant MS Compagnon JM	1994 b	Diquat: Residue levels in grapes from trials carried out in France during 1993. RJ1681B GLP or GEP: yes Published: no	
IIA 6.3.4	Anderson L Elsworth S	1994 e	Diquat: Residue levels in linseed from trials carried out in the United Kingdom during 1993. RJ1727B GLP or GEP: yes Published: no	

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 6.3.4	Anderson L Lant MS Renard C	1995 a	Diquat: Residue levels in sunflowers from trials carried out in France during 1993. RJ1734B GLP or GEP: yes Published: no	
IIA 6.3.1	Dick JP Taylor PS Bonfanti F	1995 a	Diquat: Residue levels in grapes from trials carried out in Italy during 1993. RJ 1800B GLP or GEP: yes Published: no	
IIA 6.3.1	Dick JP Taylor PS Bonfanti F	1995 b	Paraquat and diquat: Residue levels in olive fruit and oil from trials carried out in Italy during 1993. RJ1810B GLP or GEP: yes Published: no	
IIA 6.3.4	Earl M Anderson L	1989 b	Diquat: Residues in flax from trials carried out in Denmark in 1988. M4911B GLP or GEP: yes Published: no	
IIA 6.3.3	Earl M	1991 b	Diquat: Residues in peas from trials carried out in the United Kingdom during 1990. M5373B GLP or GEP: yes Published: no	
IIA 6.3.1	Earl M	1993 b	Diquat: Residue levels in bananas from trials carried out in Ecuador during 1992/1993. RJ1487B GLP or GEP: yes Published: no	

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 6.3.1	Earl M	1994 a	Diquat: Residue levels in bananas from trials carried out in Costa Rica and Guatemala during 1992. RJ1534B GLP or GEP: yes Published: no	
IIA 6.3.3	Earl M Hall G	1994 b	Diquat: Residues levels in peas from trials carried out in the United Kingdom during 1992. RJ1502B GLP or GEP: yes Published: no	
IIA 6.2	French DA Leahey JP	1988	Diquat : Quantification and characterisation of radioactive residues in hen tissues and eggs. RJ0622B GLP or GEP: yes Published: no	
IIA 6.1.1	Heath J Leahey JP	1989	Diquat : Degradation on wheat. RJ0731B 4D.1/15 GLP or GEP: yes Published: no	
IIA 6.1.1	Heath J	1992	Diquat : Irradiation in aqueous solutions of glucose. RJ1199B GLP or GEP: yes Published: no	
IIA 6.3.1	Kennedy SH	1987 a	Paraquat/diquat: Residues in olives from trials carried out during 1987 in Spain. M4580B GLP or GEP: yes Published: no	
IIA 6.2	Lappin GJ Platt JA Davies DJ	1993	Diquat wheat chaff residues : Bioavailability study in the rat. CTL/P/4141 4B.6/25 GLP or GEP: yes Published: no	

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 6.1.2	Lee SGK	1989	Diquat confined accumulation study in rotational crops. MEF-0026 GLP or GEP: yes Published: no	
IIA 6.3.2ii	Massey J	1987 a	Paraquat/diquat : Residues in onions from trials carried out in West Germany during 1984. M4415B GLP or GEP: yes Published: no	Germany 1994
IIA 6.3.2v	Massey J	1987 b	Paraquat/diquat: Residues in lettuce from trials carried out in West Germany during 1984. M4416B GLP or GEP: yes Published: no	Germany 1994
IIA 6.3.2i	Massey J	1987 c	Paraquat/diquat: Residues in carrots from trials carried out in West Germany during 1984. M4417B GLP or GEP: yes Published: no	Germany 1994
IIA 6.3.3	Massey JA	1987 d	Diquat: Residues in peas from trials carried out in Denmark during 1986. M4459B GLP or GEP: yes Published: no	Germany 1994

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[2] on previous use in granting national authorizations

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 7.2.1.3.2	Cranor W Daly D	1988	Aerobic aquatic metabolism of ^{14}C-diquat. 36556 GLP or GEP: yes Published: no	
IIA 7.1.1.2.2	Anderson L Earl M	1990	Diquat: Residues in soil following desiccation of crops with 'Reglone' (interim). RJ0862B 5B.2/13 GLP : yes Published: no	
IIA 7.1.1.2.2	Dyson JS Kirsch O Stevens JEB	1995	Diquat: Long-term, soil trial at Goldsboro USA 1979-1991. 1. Trial description and crop measurements. TMJ3330B 5B.2/14 GLP or GEP: no Published: no	
IIA 7.1.1.2.2	Dyson JS Chapman P Farmer K	1995	Diquat: Long-term soil trial at Goldsboro USA 1979-1991 2. Fate of soil residues. TMJ3331B 5B.2/15 GLP or GEP: no Published: no	
IIA 7.1.1.2.2	Dyson JS Chapman P	1995	Diquat: Long-term high-rate trial, Frensham UK. TMJ3431B 5B.1/16 GLP or GEP: no Published: no	
IIA 7.1.2	Fergsuon RE Dyson JS Lane MCG	1994	Diquat: Adsorption and desorption properties in temperate soils. TMJ3310B 5B.1/36 GLP or GEP: no Published: no	
IIA 7.2.1.3.2	Johnston JJ	1988	Anaerobic aquatic metabolism of diquat. MEF-0072 GLP or GEP: yes Published: no	

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 7.1.1.1.2	Joseph RSI Sidmore MW	1989	Diquat : Photolytic stability on soil surfaces. RJ0573B 5B.1/29 GLP or GEP: yes Published: no	
IIA 7.1.1.1	Rickets D	1997	Diquat - Microbial degradation Technical letter GLP : yes Published: no	

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[2] on previous use in granting national authorizations
8.2.7	Ashwell J A	1999	Diquat: Sediment toxicity test with *Chironomus riparius.* 98JH195 GLP or GEP: yes Published: no	
IIA 8.3.5	Edwards PJ Earl M Anderson L McIndoe E	1991	Diquat : Effect on plant cover and estimation of dietary exposure of birds following aerial desiccation of lentils. RJ1011B 5E.1(b)/1 GLP or GEP: yes Published: no	
IIA 8.3.3.1	Edwards PJ Coulson JM	1993	Diquat: Toxicity to the earthworm *Eisenia foetida* of a 200 g litre soluble concentrate. TMJ3048B GLP or GEP: no Published: no	

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 8.3.2, IIA 8.3.5	Gough HJ McMullin LC Jackson D White JS	1991	Diquat : Laboratory toxicity to the Carabid beetle *Pterostichus melanarius*, a Lycosid spider *Pardosa spp.* and larvae of the Green Lacewing *Chrysopa carnea* of residues of a 200 g/l aqueous formulation. RJ0922B 5E3(a)/1 GLP or GEP: yes Published: no	
8.3.2	Kuhner C	1997	Reglone - acute toxicity to the ladybird *Coccinella septempunctata* (Coleoptera, Coccinellidae) - extended laboratory test - 97030/01-NECS GLP or GEP: yes Published: no	
8.3.2	Longley M	1996	An extended laboratory test to determine the side-effects of the herbicide Reglone (YF7017A) a soluble concentrate formulation of diquat (220g/l) on adults of the parasitiod *Aphidius rhopalosiphi.* ZEN-96-7 GLP or GEP: yes Published: no	
IIA 8.3.4	Maas C	1990	Anleitung fur die Berichterstattung von versuchen uber Auswirkungen von Pflanzenschutzmitteln auf die Aktivitat der Bodenmikroflora nach Richtlinie Tiel Vi 1-1. BBA No. 30287 5B.3/18 GLP or GEP: no Published: no	
IIA 8.2.5	Rapley JH Hamer MJ	1991	Diquat: chronic toxicity to *Daphnia magna.* RJ0949B 5C.6/7 GLP or GEP: yes Published: no	Italy 1992 Finland 1994 Germany 1994

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 8.2.6	Smyth DV Tapp JF	1988	Diquat : Determination of toxicity to the green alga (*Selenastrum capticornutum*). BL/B/3271 5C.6/4 GLP or GEP: yes Published: no	Italy 1992 Finland 1994 Germany 1994
8.2.6	Smyth D Shillabeer N Magor SEI	1998	Diquat - toxicity to the green alga *Selenastrum capricornutum* in the presence of sediment. BL6471/B GLP or GEP: yes Published: no	
IIA 8.2.2.1	Surprenant DC	1987	The toxicity of diquat concentrate to Fathead minnow (*Pimephales promelas*) embryos and larvae. 981-0287-6113-120 (S-2912) 5C.4/20 GLP or GEP: yes Published: no	
IIA 8.2.1	Tapp JF Caunter JE	1988 a	Diquat: Determination of acute toxicity to Rainbow trout (*Salmo gairdneri*). BL/B/3336 5C.4/15 GLP or GEP: yes Published: no	Italy 1992 Finland 1994 Germany 1994
IIA 8.2.1	Tapp JF Caunter JE	1988 b	Diquat: Determination of acute toxicity to Mirror carp (*Cyprinus carpio*). BL/B/3337 5C.4/16 GLP or GEP: yes Published: no	Italy 1992 Finland 1994 Germany 1994
IIA 8.2.2.2	Tapp JF Sankey SA Caunter JE	1989	Diquat: Determination of the 21 day LC_{50} to Rainbow trout (*Salmo gairdneri*). BL/B/3488 5C.4/17 GLP or GEP: yes Published: no	Italy 1992 Germany 1994

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 8.3.5	Wilkinson W Cole JFH Everett CJ Riley D	1993 a	Diquat: Long-term ecological trial at Jealotts Hill UK 1964-90. 1. Description of the trial and observations on vegetation. TMJ3057B 5B.3/13 GLP or GEP: no Published: no	
IIA 8.3.5	Wilkinson W Cole JFH Gough HJ	1993 b	Diquat: Long-term ecological trial at Jealotts Hill UK 1964-90. 4. Effect on soil macroarthropods. TMJ3060B 5B.3/16 GLP or GEP: no Published: no	
IIA 8.3.3.2	WilkinsonW Edwards PJ	1993 c	Diquat: Long term ecological trial at Jealotts Hill UK 1964-90. 5. Effect on and residues in earthworms (*Lumbricidae*). TMJ3061B 5B.3/17 GLP or GEP: no Published: no	
8.3.2, 8.3.5	Wrzeciono SM	1991	A study of the effects of Reglone on *Trichogramma cacoceciae*. ICI-63B67A 5E.3(a)/1	Germany 1994

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

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

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

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

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

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

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

The following declarations were made:

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

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

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

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

Vote : unanimous favourable opinion.

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

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

The following declarations were made:

The Netherlands: Same declaration as for pyridate.

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

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

Commission: Same declaration as for pyridate.

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

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

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

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

The following declarations were made:

The Netherlands: Same declaration as for pyridate.

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

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

This declaration is supported by Spain and Greece.

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

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

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

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

This declaration is supported by Ireland and Greece.

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

Commission: Same declaration as for pyridate.

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

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

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

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

The following declarations were made:

The Netherlands: Same declaration as for pyridate.

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

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

Commission: Same declaration as for pyridate.

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

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

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

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

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

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

The following long term studies have been identified as necessary :

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

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

Vote : unanimous favourable opinion.

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

8 Any other business.

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

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

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

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

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

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

The measures on which the Committee has given its opinion are subject to the appropriate procedures for formal adoption by the Commission.

A CHECCHI LANG
Director

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate B - Scientific Health Opinions
Unit B2 - Management of scientific committees I

SCIENTIFIC COMMITTEE ON PLANTS

SCP/DIQUAT/002-Final
5 April 2000

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE INCLUSION OF DIQUAT IN ANNEX 1 OF DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

(Opinion adopted by the Scientific Committee on Plants on 17 March 2000)

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1. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE INCLUSION OF DIQUAT IN ANNEX 1 OF DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

2. TERMS OF REFERENCE

In the context of the possible inclusion of diquat in Annex 1 to Directive 91/414/EEC[1], the Commission consulted the Scientific Committee on Plants (SCP) on the following questions:

1. Can the Committee comment on the effects of diquat on bird reproduction and confirm the NOEC[2] of 25 ppm?
2. Considering the slow degradation of diquat in the soil, can the committee comment on the potential long term effects of its use and the adequacy of the available data.
3. Can the Committee comment on the ecotoxicological acceptability of the aquatic uses?
4. Can the Committee comment on the acceptability of the operator exposure for amateur uses?
5. The Committee is requested to comment on the acceptability of desiccant uses from the point of view of dietary exposure.

3. BACKGROUND

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

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

Diquat is a non-selective herbicide used principally for total weed control and for pre-harvest desiccation of seed crops and potatoes. It is also used for the control of aquatic weeds and as a nonselective herbicide in amenity situations. Application rates for terrestrial uses are typically 0.8 – 1 kg a.s./ha, with one or (in some cases) 2-3 applications per season. For aquatic uses, the application rate on banks is 1.3 kg a.s./ha while rates for water bodies range from 1 to 10 kg a.s./ha, depending on water depth and movement and the plants to be controlled.

[1] OJ No 230, 19.8.1991, p. 1
[2] No Observed Effect Concentration
[3] European Community Co-ordination

4. OPINIONS OF THE COMMITTEE

4.1. Question 1

Can the Committee comment on the effects of diquat on bird reproduction and confirm the NOEC of 25 ppm?

Opinion

The SCP cannot confirm a NOEC of 25 mg/kg (= ppm), because of the high likelihood of real differences in some of the mallard reproductive parameters at this concentration and the controls. The Committee proposes a NOEC of 5 mg/kg is a more appropriate endpoint.

Bird reproduction studies on leghorn chicken, bobwhite quail and mallard duck were presented. The chicken study was discounted, as the experiment was not designed to determine the NOEC for bird reproduction. Of the two remaining studies, the mallard duck study had the lowest end point, but there has been considerable debate over how the NOEC is best measured in both of these experiments. Much of this discussion has centred on specific issues relating to the most appropriate statistical techniques to use, on which the Committee comments in the sections below.

The SCP cannot confirm a NOEC of 25 mg/kg (= ppm), because of the high likelihood of real differences in some of the mallard reproductive parameters at this concentration and controls. While not all tests indicated a statistical difference between a given response measured at 25mg/kg and the controls, other approaches, with rather different underlying assumptions indicated a treatment effect. In particular, pairwise comparisons after analysis of variance (albeit with non-significant treatment effect) and randomisation tests, gave some statistically significant indications of an effect at this concentration. Given the results of these tests, the Committee proposes that a NOEC of 5 mg/kg is a more appropriate endpoint.

The philosophy underlying the NOEC approach has been challenged on numerous occasions (e.g. Laskowski 1995). OECD[4] member countries have agreed to phase out the NOEC and replace it by a regression-based parameter (based on an ECx - design). While alternatives to the NOEC approach are under discussion, it is proposed that an estimate of the power of a statistical test to detect a difference would be an extremely useful way of expressing confidence in a derived NOEC.

4.1.1. Scientific Background on which the Opinion is Based

Background

Birds may be exposed to residues of diquat principally through consumption of (a) treated terrestrial or aquatic vegetation; (b) contaminated earthworms; (c) contaminated insects. Reproduction studies on leghorn chicken, bobwhite quail and mallard duck were therefore submitted for evaluation. The details of the chicken experiment were not described in full, it was not conducted to a recognised protocol and it was carried out before GLP[5] was a requirement. However, while it is not stated, the results of this study suggest a NOEC of 1mg/kg.

In the bobwhite quail reproduction study, groups of birds were fed on diets of 0, 5, 25 and 100 mg/kg diquat for 18 weeks with 12 replicates for each treatment. The sample mean number of eggs

[4] Organisation for Economic Co-operation and Development
[5] Good Laboratory Practice

laid and sample mean 14-day survivors/hen in production were actually higher for 5-100 mg/kg treatments than control. ANOVA[6] and subsequent multiple comparisons found no significant effects of treatment, and the Notifiers therefore concluded the NOEC from this study was 100 mg/kg. A subacute feeding study was also conducted, with 3 replicates of 6 treatment levels (0, 100, 215, 464, 1000 and 2150 mg/kg). Analysis of the egg production (both log and square root transformed) using ANOVA and multiple comparisons similarly indicated a NOEC of 100 mg/kg.

The mallard duck reproduction study followed a similar protocol to the bobwhite quail reproduction study (diets of 0, 5, 25 and 100 mg/kg diquat for 18 weeks, 12 replicates for each treatment). The presence of non-proven breeders in the test (birds that do not lay eggs even under normal conditions) may have contributed to a high within-treatment variance, making the detection of treatment effects more difficult than usual. Overall, ANOVA indicated no significant effects of treatment on mortality, bodyweight or potential clinical signs of toxicity. However there was a significant ($p < 0.05$) reduction in food consumption at all concentrations in relation to controls. In the absence of effects on bodyweight this was not considered biologically significant. The original study report compared several additional reproductive parameters between treatments on the basis of pairwise tests, and concluded that 5 mg/kg was the NOEC for reproduction. However, the effects seen at 25 mg/kg were subsequently viewed to be of questionable statistical significance (no overall significant ANOVA). At the 100 mg/kg concentration, there was a significant effect on the numbers of eggs laid, and it was also reported that the number of hatchlings and the number 14-day survivors per pen differed significantly from controls (the Notifier has since reanalysed these data, with rather different conclusions). On the basis of the overall significant effects at the 100mg/kg concentration alone, the NOEC for reproduction was therefore considered to be 25 mg/kg diet.

The Danish EPA[7] has subsequently questioned the statistical basis of the conclusions drawn from both of the studies on bobwhite quail. Similarly, the NOEC suggested by the mallard study has been subject of considerable debate. In the following section the SCP comments on the objections raised, and provides its own opinion of the appropriate NOEC for birds.

Specific Comments

Bobwhite quail reproduction study

The Danish EPA questioned the conclusion of 100 mg/kg NOEC from the bobwhite quail study, on the basis of a highly significant positive correlation between dose and response. One possibility is that typographical mistakes were made. From the data provided it was not obvious whether this was the case, however a re-analysis provided by the Notifier.

The positive correlation reported by the Danish Authorities is surprising, in particular since it centres on relatively high mortality observed in controls. Given the data provided, the SCP provisionally supports the Notifier's and RMS estimation of 100 mg/kg NOEC for this study and species, but suggests that this study would be more convincing if it were supported by a more detailed consideration of the sources and distribution of quail mortality within and between pens.

Bobwhite quail sub-acute feeding study

The Danish EPA pointed out that after fitting a non-linear dose response curve to the egg production data, the EC[8]20 = 89 mg/kg (95% confidence limits 16-163) while the EC30 = 117 mg/kg (95%

[6] Analysis of variance
[7] Environmental Protection Agency
[8] Effective Concentration

confidence limits 34, 201). Therefore on this basis a concentration of 100mg/kg would have an effect and should not be a NOEC.

Dose-response curves offer a very useful way of estimating effects at low concentrations and certainly make better use of the data available. However, in terms of NOEC philosophy at least, what is important is whether the difference in the response between control and a given treatment concentration is statistically significant. Therefore, the SCP support the Notifier's and RMS' estimation of 100 ppm NOEC for this study and species.

Mallard duck reproduction study

The Danish EPA has analysed the data on 14-day old survivors/hen in production and using a multiple comparison test have found evidence for a difference between the controls and the 25 mg/kg treatment, which is contrary to same analysis conducted by the Notifier. The SCP agrees with the analysis of the Danish EPA. Performing individual significance tests when the overall ANOVA is not significant is not common practice, since it will tend to increase the probability of type I errors (rejecting a null hypothesis when it is true). This is particularly the case when there are a number of treatment levels. However, the Committee does not consider this approach entirely inappropriate in those cases where Type II errors (acceptance of a false null hypothesis) are even more undesirable.

Due to the uncertainty surrounding this study, the RMS consulted an independent statistician. After Monte Carlo re-sampling from the data (Manly 1991), it was found that the average size of differences in 14 day old survivorship between 25mg/kg and controls would arise on only 0.046 of occasions if there were no treatment effect ($P < 0.05$). Similar simulations were conducted for differences in the number of hatchlings between 25 mg/kg treatment and control, generating a 0.054 significance probability. As both values were borderline, and 3 separate tests were made, the independent statistician argued that 25 mg/kg should be the NOEC.

In the opinion of the SCP, the randomisation tests were well conducted and entirely appropriate. The exact methodology is unclear, but as the direction of the response could be anticipated *a priori* then one-tailed significance tests would have served to reduce significance probabilities further (if they were not already assumed). Given that 2 out of the 3 tests conducted on quasi-independent variables were of borderline significance, the Committee cannot be totally confident that spurious significance has arisen through repeated sampling. However, it is noted the 3 variables analysed were chosen *a posteriori* from a longer list on the basis of perceived effects. Overall, on the basis of the data provided, and borderline significance of effects at 25 mg/kg, the SCP proposes that a precautionary NOEC of 5mg/kg be taken for this study and cannot therefore confirm a NOEC of 25 mg/kg for birds.

The NOEC approach

The philosophy underlying the NOEC approach has been challenged on numerous occasions (e.g. see Laskowski 1995), not least because it depends directly on the specific concentrations tested. Furthermore, since ecotoxicity tests often encounter high variation, it would be unlikely that studies with low replication would detect significant differences in population means even if they existed. This is unfortunate because it means that trials conducted at a few concentration levels and/or with low replication will tend to generate higher NOEC values.

While alternatives to NOEC are under discussion, an additional summary statistic that could be introduced immediately is an indication of the power of the test to detect a difference, should one exist. Most scientific analyses are primarily concerned not to reject a null hypothesis without good justification, hence the type I error rate (rejecting a NH when it is true) is generally set at $\alpha < 0.05$ and quoted extensively. However in NOEC tests, it may be more important to avoid type II errors (accepting a NH when it is false). Despite the fact that the estimated probability of a type II error (β) is often (not always) straightforward to calculate, and readily provided by statistical software packages, this statistic is rarely quoted. The SCP urges that more emphasis be placed on evaluating the power of tests when deriving NOEC values.

4.1.2. REFERENCES

Laskowski, R. (1995) Some good reasons to ban the use of NOEC, LOEC and related concepts in ecotoxicology. *Oikos*, **73**, 140-144

Manly, B.F.J. (1991) Randomisation and Monte Carlo Methods in Biology. Chapman & Hall.

4.2. Question 2

Considering the slow degradation of diquat in the soil, can the Committee comment on the potential long term effects of its use and the adequacy of the available data.

Opinion

As diquat is extremely strongly bound to soil it is practically immobile in soil and will not contaminate groundwater. The Committee concludes that there are no indications that residues of diquat in soil will contaminate groundwater or have harmful effects on succeeding crops, non-target soil-dwelling organisms or microbial activity.

All studies show a very fast, strong and extensive adsorption of diquat by soil, in particular by the clay fraction. Dissipation in the field is very slow. The non-adsorbed amount of diquat is capable of being mineralised to $^{14}CO_2$ by soil micro-organisms. The rate at which degradation occurs is controlled by the adsorption of diquat to clay minerals, i.e. by the relative amounts of adsorbed and non-adsorbed (i.e., bio-available) diquat.

4.2.1. Scientific Background on which the Opinion is Based

Fate and Behaviour in Soil

All studies show a very fast, strong and extensive adsorption of diquat by soil, in particular by the clay fraction. In laboratory studies no measurable degradation in soil after one year could be observed. Therefore it is impossible, to create DT[9]50 or DT90 values under laboratory conditions at 10 or 20 °C . Long-term field soil dissipation studies in the UK and USA indicated a very slow dissipation after applications of either single high rates or repeated annual normal rates. The UK studies show a decline of 5-7% per year, corresponding to DT50 values of 9.5 – 13.5 years.
The maximum concentration in soil residue studies for various Western European Countries is 0.11 mg/kg, in average 0.03 mg/kg. Only a study in Denmark gave values up to 2.3 mg/kg but even this concentration represents a saturation of < 1% of the SAC-WB (Strong Adsorption Capacity of soils determined by a Wheat Bioassay) of the respective soil. Repeated applications of diquat will result in PECs[10] which are typically not more than approximately 2.4 or 3.9 mg/kg as a worst case, depending on the degree of plant interception. Studies with cultures of soil microbes (soil fungi) show that diquat is capable of being mineralised to $^{14}CO_2$ by soil micro-organisms. The rate at which degradation occurs is controlled by the adsorption of diquat to clay minerals i.e. the availability of diquat for micro-organisms. Diquat is strongest adsorbed onto the clay mineral montmorillonite followed by vermiculite, illite and kaolinite.

- Relevance to groundwater
  All studies show the very strong adsorption in all the soils tested, Koc[11] values ranged from 32,000 to 7,900,000 L/kg.
  As diquat is extremely strongly bound to soil it is practically immobile. Diquat will not occur in groundwater as a result of leaching and the predicted environmental concentration in groundwater PECgw is << 0.1 µg/l (practically zero).

- Adequacy of the available data
  Although the diquat dossier submitted by the applicant is non-standard and is not entirely performed in accordance with the requirements stated in the Directive 91/414/EEC, it is possible to assess the fate and behaviour of diquat in soil. Therefore additional data are not necessary.

Potential long term effects of the use of diquat

- Succeeding crops
  The effects which might be expected from repeated applications of diquat is a shift of the adsorption equilibrium with higher amounts of the active substance in the soil solution in particular in soils with a low clay content and thus leading to damages of crop plants. A measure of this is the SAC[12]. The SAC of soils is determined by a Wheat Bioassay (SAC-WB). Diquat is mixed into the soils in different concentrations, then wheat seedlings are planted into the treated soils and the concentration is determined where the growth of the seedling roots is reduced to 50 %. SAC values of "normal" soils lay in the range of 50 – 1000 mg/kg, for sandy soils with extremely low clay content at 10 mg/kg and for heavy clay soils in the range of 3000 mg/kg.

[9] DT50/90: disappearance time for first 50/90% of compound
[10] Predicted Environmental Concentration
[11] Organic Carbon Adsorption Coefficient
[12] Strong Adsorption Capacity

Assuming a degradation rate of 5 % per year (p. 243 and 253 of the monograph) which corresponds to DT50 value of 13.5 years, after "infinite" applications of 360 g diquat per hectare and year – this is a worst case assumption for hops which is a permanent crop where an application can take place every year – a plateau concentration of 4.8 mg/kg is calculated taking into account a soil depth of 10 cm. This concentration is well below the normal SAC values. Corresponding calculations for other crops e. g. clover and alfalfa for seed production, seed potatoes, food potatoes, winter rape, field beans and field peas – taking into account that these crops are not cultivated every year – resulted in plateau concentrations of 1.3, 3.8 (seed potatoes with an application rate of 1000 g as/ha), 1.9, 1.2 and 1.8 mg/kg respectively.

In addition, plant damages have never been observed in practice although diquat containing plant protection products have been in use for more than 30 years. Furthermore, the amount of the active substance which is not adsorbed is available to microbial degradation which could be demonstrated with ^{14}C-diquat in culture suspensions (p. 235 ff of the monograph).
Taking into account all these facts no unjustifiable long term effects may be expected from repeated use of diquat-containing plant protection products.

- Effects on terrestrial organisms
  No specific risk was identified with regard to birds and mammals. In the context of this question (slow degradation of diquat in soil), only soil-dwelling arthropods have to be considered. Both laboratory and field data are available.

  - Laboratory data: Two ground-dwelling predators, the carabid beetle *Poecilus melanarius* and the Lycosid spider *Pardosa* spp were tested at an application rate of 1.6 kg a.s./ha (twice the typical dose), with no lethal or sublethal effects. For earthworms, acute toxicity was 121 times higher than the initially expected concentration in soils treated with 0.8 kg a.s./ha, thus indicating a low risk Microbial activity was not affected by up to 50 kg a.s./ha.

  - Field data: Two long-term field studies (up to 8 years) have been conducted at excessive dose rates (up to 720 kg a.s./ha, equivalent to 400% of the SAC). Only at dose rates of 198 kg a.s./ha and above (i.e., ca. 200x of the normal application rate) could the analysis detect slight differences on some groups of a wide range of soil microarthropods. In the same studies, microbial activity and populations were unaffected, with only minor differences with fungi at 720 kg a.s./ha.

  For earthworms, two field studies were conducted at rates of up to 500 and 1308 times, respectively, of the typical application rate. While the first study showed reductions in earthworm populations after 1 year by rates of 90 ka a.s./ha (50% of the SAC) and more, there were no effects in the second study over the two year study period (2.2 and 112 kg a.s./ha).

4.3. Question 3

Can the Committee comment on the ecotoxicological acceptability of the aquatic uses?

Opinion

The Committee supports the view of the rapporteur that the supplied data indicate a very high risk to the aquatic environment. Although options for risk reduction exist, no data have been submitted to demonstrate that they would be sufficiently effective to render the aquatic uses acceptable.

In addition to its crop uses, diquat also has intended uses for the control of aquatic plants (both floating and submerged) in canals, ditches and other surface water bodies, as well as on banks along those bodies. Although diquat adsorbs strongly to suspended particles and partitions into the sediment within 1-3 days, the initial concentrations to be expected in the water phase are well in the range of toxicity of aquatic fauna, indicating a very high risk of direct effects to non-target organisms. In addition to those direct effects, indirect effects could be caused by dead plant material if not removed mechanically, decaying and depleting oxygen levels and put surviving animals at risk. The same may be expected for the planktonic algae which cannot be removed mechanically. Effects on the phytoplankton could disrupt food chains for grazers triggering further disruption of the ecological system.

4.3.1 Scientific Background on which the Opinion is Based

Uses: Diquat also has intended uses for control of aquatic plants (both floating and submerged) in canals, ditches and other surface water bodies, as well as on banks along these bodies. Application rates on banks are given in the monograph as 1.3 kg a.s./ha while rates for the water bodies are reported to be 1 – 10 kg a.s./ha. Control of (surface-floating) duckweed is achieved at rates in the lower range while for submerged plants the standard maximum rate is 10 kg a.s./ha for 1 m depth, resulting in a nominal initial concentration of 1 mg/L.

Fate: Diquat adsorbs strongly onto suspended particles and partitions rapidly into the sediment, with DT50 (water phase; field studies) values between 17 hours to 2.3 days. There seem to be no measurable degradation in sediments over 1-9 months. Likewise, there was no observable desorption of diquat from the sediment into the water phase in those studies.

Toxicity: Acute toxicity to fish and *Daphnia* is in the range of the initial PEC, while algae are more susceptible. Long-term toxicity was lower, although the fate of diquat in water suggests that the acute situation is more relevant for organisms of the water phase.

Species	Test design	NOEC [mg/L]	EC/LC[13]50 [mg/L]
Rainbow trout	48 h static	6.7	21
Rainbow trout	96 h flow-through	Not determined (< 1.4)	6.1
Daphnia magna	48 h static	Not determined (< 0.84)	1.2
Algae (*Raphidocellis subcapitata*)	96 h static	0.0068	0.011
Algae (*Raphidocellis subcapitata*)	72 h; in the presence of constantly suspended sediment	>0.32	
Fathead minnow	34 day ELS[14] (flow-through)	0.12	
Daphnia magna	21 day (static)	0.125	0.16
Chironomus riparius	20 days; spiked sediment with 7 days to settle prior to introduction of larvae	< 100 mg/kg dry weight	
Aquatic plants	observations from efficacy trials: wide range of aquatic plants affected or killed at 0.125 – 1 mg/L		

Assessment: Acute TER's[15] for aquatic uses are far below the triggers required by Annex VI (1-10 instead of 100 for fish and *Daphnia*; 0.01 instead of 10 for algae), indicating a very high risk for all those organisms. The study on algae toxicity in the presence of suspended sediment showed lower toxicity due to the adsorption of diquat to sediment particles. However, the test conditions (constantly suspended sediment) clearly favour adsorption, and it seems questionable if such conditions would frequently occur in natural, still or slowly flowing water bodies.
Addendum II of the monograph reports observations for aquatic plants from two efficacy trials where a wide range of emergent and floating aquatic plants were controlled by 0.125 - 1 mg/L. Those data, together with the unspecific description of aquatic uses ('aquatic weeds') and the unspecific mode of action, indicate that diquat is toxic to most if not all aquatic plants and planktonic algae in the concentrations normally applied to achieve efficacy. The same range of concentrations also puts aquatic fauna at high risk.
In addition to direct effects, indirect effects would be caused by the purpose of aquatic diquat applications: dead plant material if not removed mechanically would decay and deplete oxygen levels and put surviving animals at risk. The same can be expected for the planktonic algae which cannot be removed mechanically. Effects on the phytoplankton would also disrupt food chains for grazers, triggering further disruption of the ecological system.
The rapporteur concluded on the basis of similar considerations that mesocosm or field monitoring studies would be required before a listing of diquat into Annex I can be considered. The Committee is aware that specific guidelines for aquatic weed control exist in the rapporteur member state UK (MAFF 1995). Those guidelines also highlight the risk of direct and indirect effects on the nontarget aquatic fauna and flora.

[13] Lethal Concentration, median
[14] Early life stage
[15] Toxicity Exposure Ratio

The Committee supports the view of the rapporteur that the supplied data indicate a very high risk to the aquatic environment which is unacceptable under the criteria of Annex VI. Although the UK guidelines mention several options for risk reduction in the context of restricted authorisations at Member State level, no data have been submitted to demonstrate that they would be sufficiently effective to render the aquatic uses acceptable.

4.3.2. REFERENCE

MAFF (1995): Guidelines for the use of herbicides on weeds in or near watercourses and lakes. Ministry of Agriculture, Fisheries and Food, UK.

4.4. Question 4

Can the Committee comment on the acceptability of the operator exposure for amateur uses?

Opinion

The SCP believes that exposure estimates provided can be used for an approximate risk assessment and risk characterisation of the operator exposure for amateur uses. The use of these estimates indicates compliance with the AOEL[16] . However, the SCP recognises the limitations of such an approximate assessment and recommends that, in the absence of specific models of operator exposure prediction for amateur uses of plant protection products, Member States obtain specific field studies on amateur use for diquat-containing products. Moreover, the SCP is of the opinion that it would be useful to develop specific models of operator exposure prediction for amateur uses of plant protection products in general.

The SCP recommends to the Commission to consider the need for specific risk management measures for the amateur use of these products.

4.4.1. Background

In addition to agricultural uses, other intended uses of diquat include the following:
- total non-residual weed control, in places such as road sides, preparation of seed and flower beds, weed control in the vicinity of buildings and amongst shrubs;
- total weed control, on paths or pavements, drives, on industrial or residential building sites;
- aquatic weed control, to control totally or selectively weeds which are either surface or bottom growing that can be in still or moving water.

The home garden (retail) uses and the amenity and aquatic uses are different in terms of type of users and products applied. Amenity and aquatic users are usually professionally trained to the same standard as agricultural and horticultural workers and normally use high-strength products in the same way as farmers and growers. Retail product users are untrained and treat only small areas at one time. The retail products are sold in smaller low-strength preparations through garden centres, home improvement outlets, hardware shops and supermarkets. They are freely available with no restrictions on availability. Diquat is always sold for amateur use in mixture with paraquat

[16] Acceptable Operator Exposure Level

to optimise efficacy against broad leaved weeds as well as on grasses. The mixture is sold only as a water-dispersible granules and is packed in measured-dose sachets to make up 4.5 litres of dilute solution at one time. All the currently registered diquat products for amateur use are only approved for use through a watering can fitted with a fine rose or dribble bar and are applied at water volumes of about 2,500 litres of water per hectare.

4.4.2 Terms of Reference

During the procedure of evaluation of diquat carried out in application of the EC Regulation 3600/92 under the frame of the EC Directive 91/414[17], it was noted that exposure for amateurs is less than that for professional knapsack use, due to unit dose sachets, short exposure time and directed low level application. The RMS considered the amateur use of diquat-containing products acceptable. It was recommended to consider at Member State level the risk arising from the specific uses in relation to the proposed formulation, rate of use, method of application and packaging before granting an authorisation. Although that amateur uses were proposed to be restricted to watering can application only, with prohibition of knapsack use, still concern was expressed for such an use.

The Committee was therefore asked to comment on the acceptability of the operator exposure for amateur uses.

4.4.3. Scientific Background on which the Opinion is Based

The SCP notes that amateur uses of plant protection products are a special case in the context of Directive 91/414 which mainly focuses on professional uses of plant protection products in agriculture. Amateur uses allow only a limited applicability of the basic concepts normally assumed for the risk assessment in agriculture, in particular as concerns use of GAP[18], risk awareness and training of the users, availability of proper plant protection products application machinery and storing facilities, use of effective personal protection devices and ability to understand and follow the directions of use contained in the labelling of products.

As to the specific question concerning the acceptability of the operator exposure for amateur uses of diquat, the SCP acknowledges that amateur users are different from the professionals because they are untrained and only occasionally use any agrochemical, they generally do not have access to protective clothing, and are likely to treat only small areas at one time. Moreover the plant protection products made available for such uses are different from the formulates intended for agricultural uses, as they contain lower concentrations of diquat and paraquat, are sold only as water-dispersible granules to avoid the problems of liquid spills, and are packed in measured-dose sachets to make up 4.5 litres of dilute solution at one time.
The SCP agrees that all the diquat products intended for amateur use should only be approved for use through a watering can fitted with a fine rose or dribble bar. This reduces the potential for user exposure compared to the use of knapsacks that more easily could produce higher exposure, particularly among unskilled or untrained users.

Since specific exposure models are not available for a watering-can use, a quantitative assessment of operator exposure for amateur uses can only be derived from an adapted application of the models developed for professional uses or, alternatively, from specific field studies. The SCP believes that the exposure estimates provided, combining the U.K. model for the application and the

[17] OJ N° L366, 15.12.1992, p. 10
[18] Good Agricultural Practice

German model for the preparation of the dilute solution are technically adequate and can be used for an approximate risk assessment and risk characterisation of the operator exposure for amateur uses. The use of these estimates indicates the compliance with AOEL.
However, the SCP recognises the limitation of such approximate assessments given the particular nature of the amateur uses which pertain to the field of consumer safety and are not directly comparable to agricultural professional users and the fact that the products also contain paraquat for which a risk assessment was not concomitantly provided. In the circumstances, the SCP recommends the carrying out of specific field studies on amateur uses with these products. Such field monitoring studies should take into account the variability of application practices that may be encountered among an untrained consumer population.

Moreover, the Committee is of the opinion that it would be useful to develop specific models of operator exposure prediction for plant protection product amateur uses.

In addition, the SCP recommends that proper attention be given to the need for specific risk management measures taking into account the free availability of diquat products in shops or supermarkets and the possible inadvertent exposure of children in the treated areas.

4.5. Question 5

The Committee is requested to comment on the acceptability of desiccant uses from the point of view of dietary exposure.

Opinion

Due to insufficient data, the Committee is unable to advise on the acceptability of desiccant uses from the point of view of dietary exposure.

The Committee has interpreted the question to refer to the pre-harvest treatment of small grain cereal crops for the control of weeds and cereal re-growth that may arise from crop lodging and/or delayed harvesting. The resulting grain is normally of poor quality and unlikely to be used for human consumption. Furthermore, these treatments may result in high and variable residue levels in cereal grain.

In addition to the data referred to in the 'Background' to this opinion, the Committee was supplied with an Addendum to the Monograph (dated May 1999) as well as Evaluation tables (dated April 1999). The Addendum includes updated results of an estimation of dietary intake to assess the long term (chronic) dietary exposure for adults, schoolchildren and infants based on UK consumption data and performed according to the UK technical policy as published in the "Registration Handbook"(1). This showed that the total NEDI[19] for infants exceeds the ADI[20].

The SCP examined the assessment carried out by the RMS which was performed according to the information in the "Handbook" which estimated the dietary intake as a sum of the two highest 97.5th percentile intakes for cereals and mean population intakes from other foods. This procedure may lead to an overestimation of dietary intake. However, there are no details of the total NEDI calculation, e.g. mean population intake data used, information about exhausting the ADI by single commodities and the total quantity of food consumption per person per day presented. The

[19] National Estimated Daily Intake
[20] Acceptable Daily Intake

relationship between the residue levels of diquat used by the Rapporteur Member State for the intake calculations and the results of the supervised field trials could not be fully verified by the Committee. In addition, the residue levels used by the Rapporteur Member State for the intake calculation could not be fully verified by the Committee.

The Committee noted, that the RMS made the assumption that "all produce eaten which may have been treated, has been treated". Whilst the Committee feels that this assumption seems to be an overestimation for the desiccant uses in question, it is not possible to be more precise in the absence of Community crop area treatment data for diquat desiccation uses.

The Committee noted also that sufficient processing data for oats for a more refined intake calculation are not yet available.

In addition, estimates of long term dietary intake for young children aged about aged about 1 to 6 years and other national diets were not submitted to the Committee.

4.5.1. REFERENCES

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A guide to the policies, procedures and data requirements relating to their control within the United Kingdom.
Issued jointly by the Pesticides Safety Directorate, an Executive Agency of the Ministry of Agriculture, Fisheries and Food, and the Pesticides Registration Section of the Health and Safety Executive

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