Berichte

aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft

Reports

from the Federal Biological Research Centre for Agriculture and Forestry

IZ-D

Heft 78
2001

EU-Beurteilungsbericht Lambda-Cyhalothrin
Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen
Band D 12

Review Report Lambda-Cyhalothrin
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 12

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Herausgeber

Biologische Bundesanstalt für Land- und Forstwirtschaft
Braunschweig, Deutschland

Verlag
Eigenverlag

Vertrieb
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ISSN 0947-8809

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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 12. Heft dieser Reihe (Band D 12) 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 Lambda-Cyhalothrin war Schweden 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 12th report belonging to this series (Volume D 12) 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 Lambda-Cyhalothrin Sweden 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 2000/80/EG DER KOMMISSION

vom 4. Dezember 2000

zur Änderung von Anhang I der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln und infolgedessen zur Konsolidierung dieses Anhangs sowie zur Aufnahme eines weiteren Wirkstoffs (Lambda-Cyhalothrin)

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 2000/68/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 mit Durchführungsbestimmungen für die erste Stufe des Arbeitsprogramms gemäß Artikel 8 Absatz 2 der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln [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 (im Folgenden „die Richtlinie" genannt) erlassen. Auf der Grundlage dieser 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 von 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 davon auszugehen ist, dass die Anwendung der diesen Wirkstoff enthaltenden Pflanzenschutzmittel und ihre Rückstände keine schädlichen Auswirkungen auf die Gesundheit von Mensch und Tier oder auf das Grundwasser und keine nicht vertretbaren Auswirkungen auf die Umwelt haben werden.

(3) Die Auswirkungen von Lambda-Cyhalothrin 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. Schweden wurde gemäß der Verordnung (EG) Nr. 491/95 der Kommission [7] 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 zum berichterstattenden Mitgliedstaat ernannt. Es hat der Kommission am 12. Juni 1996 gemäß Artikel 7 Absatz 1 Buchstabe c) der Verordnung (EWG) Nr. 3600/92 den entsprechenden Bewertungsbericht mit Empfehlungen übermittelt.

(4) Der Bewertungsbericht wurde von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses für Pflanzenschutz geprüft. Diese Prüfung wurde am 19. Oktober 2000 in Form eines Prüfungsberichts der Kommission für Lambda-Cyhalothrin abgeschlossen. Sollte der Prüfungsbericht unter Berücksichtigung technischer und wissenschaftlicher Entwicklungen aktualisiert werden müssen, so sind auch die Bedingungen für die Aufnahme von Lambda-Cyhalothrin in Anhang I der Richtlinie gemäß der Richtlinie zu ändern.

(5) Die Unterlagen und die Ergebnisse der Prüfung wurden auch dem Wissenschaftlichen Pflanzenausschuss zur Beratung vorgelegt. Der Ausschuss hat in seiner Stellungnahme [8] vom 28. Januar 2000 erklärt, dass das akute Risiko der Aufnahme mit der Nahrung für den Verbraucher bewertet und eine akute Referenzdosis festgelegt werden sollte. Was den Umweltschutz betrifft, so hat der Ausschuss darauf hingewiesen, dass geeignete Risikominimierungsmaßnahmen getroffen werden müssen, um unvertretbare Auswirkungen auf Wasserorganismen und Nichtzielarthropoden, einschließlich Bienen, zu verhindern. Diesen Empfehlungen wurde bei der Erarbeitung dieser Richtlinie und des Prüfungsberichts Rechnung getragen.

(6) Die Untersuchungen haben ergeben, dass davon ausgegangen werden kann, dass den betreffenden Wirkstoff enthaltende Pflanzenschutzmittel, insbesondere hinsichtlich der geprüften und im Bericht der Kommission behandelten Anwendungen, im Allgemeinen die Anforderungen gemäß Artikel 5 Absatz 1 Buchstaben a) und b) der Richtlinie erfüllen. Daher sollte der betreffende Wirkstoff in Anhang I aufgenommen werden, damit Pflanzenschutzmittel mit diesem Wirkstoff in allen Mitgliedstaaten gemäß den Bestimmungen der genannten Richtlinie zugelassen werden körnen.

(7) Die Richtlinie sieht vor, dass die Mitgliedstaaten innerhalb eines vorgeschriebenen Zeitraums nach Aufnahme eines Wirkstoffs in Anhang I die Zulassungen der Pflanzenschutzmittel, die den Wirkstoff enthalten, erteilen, ändern bzw. widerrufen müssen. Pflanzenschutzmittel

[1] ABl. L 230 vom 19.8.1991, S. 1.
[2] ABl. L 276 vom 28.10.2000, S. 41.
[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, 28.1.2000.

dürfen nur zugelassen werden, wenn die Bedingungen der Aufnahme des betreffenden Wirkstoffs in Anhang I und die in der Richtlinie festgelegten einheitlichen Grundsätze auf der Grundlage der Unterlagen, die den Datenanforderungen entsprechen, erfüllt sind.

(8) Vor der Aufnahme eines Wirkstoffs in Anhang I ist eine angemessene Frist vorzusehen, damit die Mitgliedstaaten und die interessierten Parteien sich auf die Erfüllung der neuen Anforderungen vorbereiten können, die sich aus der Aufnahme ergeben. Nach der Aufnahme ist den Mitgliedstaaten außerdem eine angemessene Frist einzuräumen, um die Bestimmungen der Richtlinie über Pflanzenschutzmittel, die Lambda-Cyhalothrin 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 vollständigen Unterlagen für jedes Pflanzenschutzmittel gemäß den in der Richtlinie festgelegten einheitlichen Grundsätzen ist ein längerer Zeitraum vorzusehen. Bei Pflanzenschutzmitteln, die mehrere Wirkstoffe enthalten, kann die vollständige Bewertung auf der Grundlage der einheitlichen Grundsätze erst dann vorgenommen werden, wenn alle enthaltenen Wirkstoffe in Anhang I der Richtlinie aufgenommen sind.

(9) Es ist vorzuschreiben, dass die Mitgliedstaaten den endgültigen Prüfungsbericht (mit Ausnahme von vertraulichen Informationen) allen interessierten Parteien zur Einsicht zur Verfügung stellen oder zugänglich machen.

(10) Der Prüfungsbericht ist 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 des Wirkstoffs in Anhang I der Richtlinie übermittelt wurden.

(11) Einige Stoffe wurden durch verschiedene Richtlinien der Kommission, d. h. durch die Richtlinien 97/73/EG [1], 98/47/EG [2], 1999/1/EG [3], 1999/73/EG [4], 1999/80/EG [5], 2000/10/EG [6], 2000/49/EG [7] und 2000/50/EG [8], in Anhang I der Richtlinie aufgenommen. Im Interesse der Klarheit und Übersichtlichkeit sollten die Angaben zu diesen Stoffen tabellarisch aufgeführt werden, und die betreffenden Richtlinien sollten unbeschadet der Pflichten der Mitgliedstaaten hinsichtlich der in Anhang II genannten Fristen für die Umsetzung und Anwendung aufgehoben werden.

(12) Zur Gewährleistung der Übereinstimmung und der einheitlichen Anwendung ist vorzusehen, dass bei der Anwendung der einheitlichen Grundsätze für die Bewertung und Zulassung von Pflanzenschutzmitteln gemäß Anhang VI der Richtlinie der endgültige Prüfungsbericht für jeden Stoff berücksichtigt werden sollte. Ferner haben die Mitgliedstaaten die Prüfungsberichte (mit Ausnahme von vertraulichen Informationen) allen interessierten Parteien zur Einsicht zur Verfügung zu stellen oder zugänglich zu machen.

(13) Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz vom 19. Oktober 2000 —

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

Anhang I der Richtlinie 91/414/EWG erhält die Fassung von Anhang I der vorliegenden Richtlinie.

Artikel 2

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

Gemäß der Richtlinie 91/414/EWG ändern oder widerrufen sie erforderlichenfalls bis zu diesem Zeitpunkt insbesondere bestehende Zulassungen für Pflanzenschutzmittel, die Lambda-Cyhalothrin als Wirkstoff enthalten.

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 des Entscheidungsverfahrens 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 Lambda-Cyhalothrin als einzigen Wirkstoff enthalten, bis zum 1. Januar 2006.

(3) Bei Pflanzenschutzmitteln, die Lambda-Cyhalothrin zusammen mit einem anderen 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 über die Aufnahme des letzten dieser Wirkstoffe in Anhang I ab.

[1] ABl. L 353 vom 24.12.1997, S. 26.
[2] ABl. L 191 vom 7.7.1998, S. 50.
[3] ABl. L 21 vom 28.1.1999, S. 21.
[4] ABl. L 206 vom 5.8.1999, S. 16.
[5] ABl. L 210 vom 10.8.1999, S. 13.
[6] ABl. L 57 vom 2.3.2000, S. 28.
[7] ABl. L 197 vom 3.8.2000, S. 32.
[8] ABl. L 198 vom 4.8.2000, S. 39.

Artikel 3

Die in der dritten Spalte von Anhang II genannten Richtlinien werden aufgehoben; die Pflichten der Mitgliedstaaten hinsichtlich der Umsetzungsfristen und der Sonderbestimmungen, die in Anhang II aufgeführt sind, bleiben unberührt.

Artikel 4

Diese Richtlinie tritt am zwanzigsten Tag nach ihrer Veröffentlichung im *Amtsblatt der Europäischen Gemeinschaften* in Kraft.

Die den Wirkstoff Lambda-Cyhalothrin betreffenden Bestimmungen des Artikels 2 sowie die Aufnahme dieses Wirkstoffs in Anhang I der Richtlinie 91/414/EWG gelten ab 1. Januar 2002.

Artikel 5

Diese Richtlinie ist an alle Mitgliedstaaten gerichtet.

Brüssel, den 4. Dezember 2000

Für die Kommission

David BYRNE

Mitglied der Kommission

ANHANG I

„ANHANG I

FÜR DIE VERWENDUNG IN PFLANZENSCHUTZMITTELN ZUGELASSENE WIRKSTOFFE

Allgemeine Bestimmungen für alle in diesem Anhang aufgeführten Stoffe.

Bei der Anwendung der einheitlichen Grundsätze des Anhangs VI auf jeden Stoff sind die Schlussfolgerungen des Prüfungsberichts über den betreffenden Stoff und insbesondere seine Anlagen I und II zu berücksichtigen, den der Ständige Ausschuss für Pflanzenschutz an dem unter ‚Sonderbestimmungen' genannten Datum abgeschlossen hat.

Die Mitgliedstaaten stellen den Prüfungsbericht (mit Ausnahme von vertraulichen Informationen im Sinne des Artikels 14 der Richtlinie) allen interessierten Parteien zur Einsicht zur Verfügung oder manchen ihn gegebenenfalls auf besonderen Antrag zugänglich.

Nr.	Gemeinsamer Name, Kennnummern	IUPAC-Bezeichnung	Reinheit (1)	Inkrafttreten	Befristung der Eintragung	Sonderbestimmungen
1	Imazalil CAS-Nr. 7390-28-0, 35554-44-0 CIPAC-Nr. 335	(±)-1-(β-Allyloxy-2,4-dichlorphenylethyl)imidazol oder (±)-Allyl-1-(2,4-dichlorphenyl)-2-imidazol-1-yl-ethyl-ether	975 g/kg	1.1.1999	31.12.2008	Nur Anwendungen als Fungizid dürfen zugelassen werden Für nachstehende Anwendungen gelten die folgenden besonderen Bedingungen: — Nacherntebehandlung von Obst, Gemüse und Kartoffeln darf nur zugelassen werden, wenn ein geeignetes Dekontaminierungsverfahren besteht oder bei der Risikobewertung dem zulassenden Mitgliedstaat gegenüber nachgewiesen wurde, dass das Austreten der Behandlungslösung kein nicht vertretbares Risiko für die Umwelt, insbesondere für Wasserorganismen, mit sich bringt; — Nacherntebehandlung von Kartoffeln darf nur zugelassen werden, wenn bei der Risikobewertung dem zulassenden Mitgliedstaat gegenüber nachgewiesen wurde, dass das Austreten von Verarbeitungsabfällen von behandelten Kartoffeln kein nicht vertretbares Risiko für die Umwelt, insbesondere für Wasserorganismen, mit sich bringt; — Blattspritzungen im Freiland dürfen nur zugelassen werden, wenn bei der Risikobewertung dem zulassenden Mitgliedstaat gegenüber nachgewiesen wurde, dass die Anwendung kein nicht vertretbares Risiko für die Gesundheit von Mensch und Tier sowie für die Umwelt mit sich bringt Abschluss des Prüfungsberichts durch den Ständigen Ausschuss für Pflanzenschutz am 11.7.1997
2	Azoxystrobin CAS-Nr. 131860-33-8 CIPAC-Nr. 571	Methyl-(E)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy] phenyl}-3-methoxyacrylat	930 g/kg (Z-Isomeres max. 25 g/kg	1.7.1998	1.7.2008	Nur Anwendungen als Fungizid dürfen zugelassen werden Beim Entscheidungsverfahren nach den einheitlichen Grundsätzen ist besonders auf die Auswirkungen auf Wasserorganismen zu achten. Die Zulassungsbedingungen sollten geeignete Risikominimierungsmaßnahmen umfassen Abschluss des Prüfungsberichts durch den Ständigen Ausschuss für Pflanzenschutz am 22. April 1998

Nr.	Gemeinsamer Name, Kennnummern	IUPAC-Bezeichnung	Reinheit (1)	Inkrafttreten	Befristung der Eintragung	Sonderbestimmungen
3	Kresoxim-Methyl CAS-Nr. 143390-89-0 CIPAC-Nr. 568	Methyl-(E)-2-methoxyimino-2-[2-(o-tolyloxymethyl)phenyl]acetat	910 g/kg	1.2.1999	31.1.2009	Nur Anwendungen als Fungizid dürfen zugelassen werden Beim Entscheidungsverfahren nach den einheitlichen Grundsätzen achten die Mitgliedstaaten besonders auf den Schutz des Grundwassers unter empfindlichen Verhältnissen Abschluss des Prüfungsberichts durch den Ständigen Ausschuss für Pflanzenschutz am 16.10.1998
4	Spiroxamin CAS-Nr. 1181134-30-8 CIPAC-Nr. 572	(8-tert-Butyl-1,4-dioxaspiro[4,5]decan-2-ylmethyl)-ethylpropylamin	940 g/kg (Diastereomere A und B zusammen)	1.9.1999	1.9.2009	Nur Anwendungen als Fungizid dürfen zugelassen werden Beim Entscheidungsverfahren nach den einheitlichen Grundsätzen müssen die Mitgliedstaaten — besonders auf die Sicherheit des Anwenders achten und dafür sorgen, dass die Zulassungsbedingungen geeignete Schutzmaßnahmen umfassen, und — besonders auf die Auswirkungen auf Wasserorganismen achten und dafür sorgen, dass die Zulassungsbedingungen gegebenenfalls Risikominimierungsmaßnahmen umfassen Abschluss des Prüfungsberichts durch den Ständigen Ausschuss für Pflanzenschutz am 12 Mai 1999
5	Azimsulfuron CAS-Nr. 120162-55-2 CIPAC-Nr. 589	1-(4,6-Dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-pyrazol-5-ylsulfonyl]-harnstoff	980 g/kg	1.10.1999	1.10.2009	Nur Anwendungen als Herbizid dürfen zugelassen werden Aviotechnische Ausbringungen dürfen nicht zugelassen werden Beim Entscheidungsverfahren nach den einheitlichen Grundsätzen müssen die Mitgliedstaaten besonders auf die Auswirkungen auf Wasserorganismen und nicht zu den Zielgruppen gehörende Landpflanzen achten und dafür sorgen, dass die Zulassungsbedingugnen gegebenenfalls Risikominimierungsmaßnahmen umfassen (zum Beispiel im Reisanbau eine Mindestwartezeit vor Ableiten des Wassers) Abschluss des Prüfungsberichts durch den Ständigen Ausschuss für Pflanzenschutz am 2. Juli 1999
6	Fluroxypyr CAS-Nr. 69377-81-7 CIPAC-Nr. 431	(4-Amino-3,5-dichlor-6-fluor-2-pyridyloxy)essigsäure	950 g/kg	1.10.2000	30.11.2010	Nur Anwendungen als Herbizid dürfen zugelassen werden Beim Entscheidungsverfahren nach den einheitlichen Grundsätzen müssen die Mitgliedstaaten — die unter Nummer 7 des Prüfungsberichts angeforderten zusätzlichen Angaben berücksichtigen; — dem Grundwasserschutz besondere Aufmerksamkeit widmen; — insbesondere die Auswirkungen auf Wasserorganismen berücksichtigen und dafür sorgen, dass die Zulassungsbedingungen gegebenenfalls Risikominimierungsmaßnahmen umfassen Die Mitgliedstaaten informieren die Kommission, wenn die geforderten zusätzlichen Versuche und Angaben gemäß Nummer 7 des Prüfungsberichts bis zum 1.12.2000 noch nicht vorliegen Abschluss des Prüfungsberichts durch den Ständigen Ausschuss für Pflanzenschutz am 30.11.1999

Nr.	Gemeinsamer Name, Kennnummern	IUPAC-Bezeichnung	Reinheit (1)	Inkrafttreten	Befristung der Eintragung	Sonderbestimmungen
7	Metsulfuron-Methyl CAS-Nr. 74223-64-6 EEC-Nr. 441	Methyl-2-(4-methoxy-6-methyl-1,3,5,-triazin-2-ylcarbamoylsulfamoyl)benzoat	960 g/kg	1.7.2001	30.6.2001	Nur Anwendungen als Herbizid dürfen zugelassen werden Beim Entscheidungsverfahren nach den einheitlichen Grundsätzen müssen die Mitgliedstaaten — dem Grundwasserschutz besondere Aufmerksamkeit widmen; — insbesondere die Auswirkungen auf Wasserorganismen berücksichtigen und dafür sorgen, dass die Zulassungsbedingungen gegebenenfalls Risikominimierungsmaßnahmen umfassen Abschluss des Prüfungsberichts durch den Ständigen Ausschuss für Pflanzenschutz am 16.6.2000
8	Prohexadion Calcium CAS-Nr. 127277-53-6 CIPAC-Nr. 567	Calcium-3,5-dioxo-4-propionylcyclohexancarboxylat	890 g/kg	1.10.2000	1.10.2010	Nur Anwendungen als Wachstumsregler dürfen zugelassen werden Abschluss des Prüfungsberichts durch den Ständigen Ausschuss für Pflanzenschutz am 16.6.2000
9	Triasulfuron CAS-Nr. 82097-50-5 CIPAC-Nr. 480	1-[2-(2-Chlorethoxy) phenylsulfonyl]-3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)harnstoff	940 g/kg	1.8.2001	31.7.2011	Nur Anwendungen als Herbizid dürfen zugelassen werden Beim Entscheidungsverfahren nach den einheitlichen Grundsätzen müssen die Mitgliedstaaten — dem Grundwasserschutz besondere Aufmerksamkeit widmen; — insbesondere die Auswirkungen auf Wasserorganismen berücksichtigen und dafür sorgen, dass die Zulassungsbedingungen gegebenenfalls Risikominimierungsmaßnahmen umfassen Abschluss des Prüfungsberichts durch den Ständigen Ausschuss für Pflanzenschutz am 13.7.2000
10	Esfenvalerat CAS-Nr. 66230-04-4 CIPAC-Nr. 481	(S)-α-Cyano-3-phenoxybenzyl-(S)-2-(4-chlorphenyl)-3-methylbutyrat	830 g/kg	1.8.2001	31.7.2011	Nur Anwendungen als Insektizid dürfen zugelassen werden Beim Entscheidungsverfahren nach den einheitlichen Grundsätzen müssen die Mitgliedstaaten — insbesondere die potenziellen Auswirkungen auf Wasserorganismen und Nichtzielarthropoden berücksichtigen und dafür sorgen, dass die Zulassungsbedingungen gegebenenfalls Risikominimierungsmaßnahmen umfassen Abschluss des Prüfungsberichts durch den Ständigen Ausschuss für Pflanzenschutz am 13.7.2000.
11	Bentazon CAS-Nr. 25057-89-0 CIPAC-Nr. 366	3-Isopropyl-(1H)-2,1,3-benzothiadiazin-4-(3H)-on-2,2-dioxid	960 g/kg	1.8.2001	31.7.2011	Nur Anwendungen als Herbizid dürfen zugelassen werden Beim Entscheidungsverfahren nach den einheitlichen Grundsätzen müssen die Mitgliedstaaten dem Grundwasserschutz besondere Aufmerksamkeit widmen Abschluss des Prüfungsberichts durch den Ständigen Ausschuss für Pflanzenschutz am 13.7.2000

Nr.	Gemeinsamer Name, Kennnummern	IUPAC-Bezeichnung	Reinheit [1]	Inkrafttreten	Befristung der Eintragung	Sonderbestimmungen
12	Lambda-Cyhalothrin CAS-Nr. 91465-08-6 CIPAC-Nr. 463	Eine Mischung im Verhältnis 1:1 von: (S)-α-Cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chlor-3,3,3-trifluorpropenyl)-2,2-dimethylcyclopropancarboxylat und (R)-α-Cyano-3-phenoxybenzyl (Z)-(1S,3S)-3-(2-chlor-3,3,3-trifluorpropenyl)-2,2-dimethylcyclopropancarboxylat	810 g/kg	1.1.2002	31.12.2011	Nur Anwendungen als Insektizid dürfen zugelassen werden Beim Entscheidungsverfahren nach den einheitlichen Grundsätzen müssen die Mitgliedstaaten — der Anwendersicherheit besondere Aufmerksamkeit widmen; — insbesondere die potenziellen Auswirkungen auf Wasserorganismen und Nichtzielarthropoden, einschließlich Bienen, berücksichtigen und dafür sorgen, dass die Zulassungsbedingungen gegebenenfalls Risikominimierungsmaßnahmen umfassen; — Rückständen in Lebensmitteln und vor allem ihren akuten Auswirkungen besondere Aufmerksamkeit widmen. Abschluss des Prüfungsberichts durch den Ständigen Ausschuss für Pflanzenschutz am 19. Oktober 2000

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

ANHANG II

FRISTEN FÜR UMSETZUNGSMASSNAHMEN IN DEN MITGLIEDSTAATEN FÜR ZUR VERWENDUNG IN PFLANZENSCHUTZMITTELN ZUGELASSENE WIRKSTOFFE

Nr.	Gemeinsamer Name	Aufnahmerichtlinie	Umsetzungsfrist	Sonderbestimmungen
1	Imazalil	Richtlinie 97/73/EG	30.6.1999	Gemäß den Bestimmungen der Richtlinie 91/414/EWG ändern oder widerrufen die Mitgliedstaaten innerhalb der Umsetzungsfrist erforderlichenfalls bestehende Zulassungen für Pflanzenschutzmittel, die Imazalil enthalten Hinsichtlich der Bewertung und des Entscheidungsverfahrens gemäß den einheitlichen Grundsätzen von Anhang VI der Richtlinie 91/414/EWG auf der Grundlage von Unterlagen, die die Anforderungen des Anhangs III der genannten Richtlinie erfüllen, wird die Umsetzungsfrist jedoch wie folgt verlängert: — bei Pflanzenschutzmitteln, die Imazalil als einzigen Wirkstoff enthalten und nicht für Blattspritzungen im Freiland bestimmt sind, bis zum 1.1.2003; — bei Pflanzenschutzmitteln, die Imazalil und weitere, noch nicht in Anhang I aufgenommene Wirkstoffe enthalten, und die nicht für Blattspritzungen im Freiland besimmt sind, auf vier Jahre ab dem Inkrafttreten der Richtlinie über die Aufnahme des letzten dieser Wirkstoffe in Anhang I
2	Azoxystrobin	Richtlinie 98/47/EG	1.1.1999	Bei Pflanzenschutzmitteln, die Azoxystrobin und einen anderen in Anhang I der Richtlinie 91/414/EWG aufgenommenen Wirkstoff enthalten, wird die Umsetzungsfrist insoweit verlängert, als die Vorschriften der Richtlinie über die Aufnahme dieses anderen Wirkstoffs in Anhang I der Richtlinie 91/414/EWG eine längere Umsetzungsfrist vorsehen
3	Kresoxim-Methyl	Richtlinie 1999/1/EG	31.7.1999	Bei Pflanzenschutzmitteln, die Krexosim-Methyl und einen anderen in Anhang I der Richtlinie 91/414/EWG aufgenommenen Wirkstoff enthalten, wird die Umsetzungsfrist insoweit verlängert, als die Vorschriften der Richtlinie über die Aufnahme dieses anderen Wirkstoffs in Anhang I der Richtlinie 91/414/EWG eine längere Umsetzungsfrist vorsehen
4	Spiroxamin	Richtlinie 1999/73/EG	1.1.2000	Bei Pflanzenschutzmitteln, die Spiroxamin und einen anderen in Anhang I der Richtlinie 91/414/EWG aufgenommenen Wirkstoff enthalten, wird die Umsetzungsfrist insoweit verlängert, als die Vorschriften der Richtlinie über die Aufnahme dieses anderen Wirkstoffs in Anhang I der Richtlinie 91/414/EWG eine längere Umsetzungsfrist vorsehen
5	Azimsulfuron	Richtlinie 1999/80/EG	1.4.2000	Hinsichtlich der Bewertung und des Entscheidungsverfahrens gemäß den einheitlichen Gründsätzen des Anhangs VI der Richtlinie 91/414/EWG auf der Grundlage von Unterlagen, die die Anforderungen des Anhangs III der genannten Richtlinie erfüllen, wird die Umsetzungsfrist für vorläufige Zulassungen von Pflanzenschutzmitteln, die Azimsulfuron enthalten, bis zum 1.4.2001 verlängert Bei Pflanzenschutzmitteln, die Azimsulfuron und einen anderen in Anhang I der Richtlinie 91/414/EWG aufgenommenen Wirkstoff enthalten, wird die Umsetzungsfrist insoweit verlängert, als die Vorschriften der Richtlinie über die Aufnahme dieses anderen Wirkstoffs in Anhang I der Richtlinie 91/414/EWG eine längere Umsetzungsfrist vorsehen

Nr.	Gemeinsamer Name	Aufnahmerichtlinie	Umsetzungsfrist	Sonderbestimmungen
6	Fluroxypyr	Richtlinie 2000/10/EG	1.6.2000	Gemäß den Bestimmungen der Richtlinie 91/414/EWG ändern oder widerrufen die Mitgliedstaaten innerhalb der Umsetzungsfrist erforderlichenfalls bestehende Zulassungen für Pflanzenschutzmittel, die Fluroxypyr als Wirkstoff enthalten Hinsichtlich der Bewertung und des Entscheidungsverfahrens 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, wird die Umsetzungsfrist jedoch wie folgt verlängert: — bei Pflanzenschutzmitteln, die Fluroxypyr als einzigen Wirkstoff enthalten, auf den 1.12.2004; — bei Pflanzenschutzmitteln, die Fluroxypyr und einen anderen in Anhang I der Richtlinie 91/414/EWG aufgenommenen Wirkstoff enthalten, auf vier Jahre ab dem Inkrafttreten der Richtlinie über die Aufnahme des letzten dieser Wirkstoffe in Anhang I
7	Metsulfuron-Methyl	Richtlinie 2000/49/EG	31.11.2001	Gemäß den Bestimmungen der Richtlinie 91/414/EWG ändern oder widerrufen die Mitgliedstaaten innerhalb der Umsetzungsfrist erforderlichenfalls bestehende Zulassungen für Pflanzenschutzmittel, die Metsulfuron-Methyl als Wirkstoff enthalten. Hinsichtlich der Bewertung und des Entscheidungsverfahrens 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, wird der in Absatz 1 festgelegte Zeitraum jedoch wie folgt verlängert: — bei Pflanzenschutzmitteln, die Metsulfuron-Methyl asl einzigen Wirkstoff enthalten bis zum 1. Juli 2005; — bei Pflanzenschutzmitteln, die Metsulfuron-Methyl und einen anderen in Anhang I der Richtlinie 91/414/EWG aufgenommenen Wirkstoff enthalten, auf vier Jahre ab dem Inkrafttreten der Richtlinie über die Aufnahme des letzten dieser Wirkstoffe in Anhang I
8	Prohexadion-Calcium	Richtlinie 2000/50/EG	1.1.2001	Hinsichtlich der Bewertung und des Entscheidungsverfahrens gemäß den einheitlichen Grundsätzen des Anhangs VI der Richlinie 91/414/EWG auf der Grundlage von Unterlagen, die die Anforderungen des Anhangs III der genannten Richtlinie erfüllen, wird die Umsetzungsfrist für vorläufige Zulassungen von Pflanzenschutzmitteln, die Prohexadion-Calcium enthalten, bis zum 1.1.2002 verlängert Bei Pflanzenschutzmitteln, die Prohexadion-Calcium und einen anderen in Anhang I der Richtlinie 91/414/EWG aufgenommenen Wirkstoff enthalten, wird die Umsetzungsfrist insoweit verlängert, als die Vorschriften der Richtlinie über die Aufnahme dieses anderen Wirkstoffs in Anhang I der Richtlinie 91/414/EWG eine längere Umsetzungsfrist vorsehen
9	Triasulfuron	Richtlinie 2000/66/EG	31.1.2002	Gemäß den Bestimmungen der Richtlinie 91/414/EWG ändern oder widerrufen sie innerhalb der Umsetzungsfrist erforderlichenfalls bestehende Zulassungen für Pflanzenschutzmittel, die Triasulfuron als Wirkstoff enthalten Hinsichtlich der Bewertung und des Entscheidungsverfahrens 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, wird die Umsetzungsfrist jedoch wie folgt verlängert: — bei Pflanzenschutzmitteln, die Triasulfuron als einzigen Wirkstoff enthalten bis zum 1.8.2005; — bei Pflanzenschutzmitteln, die Triasulfuron und einen anderen in Anhang I der Richtlinie 91/414/EWG aufgenommenen Wirkstoff enthalten, auf vier Jahre ab dem Inkrafttreten der Richtlinie über die Aufnahme des letzten dieser Wirkstoffe in Anhang I

Nr.	Gemeinsamer Name	Aufnahmerichtlinie	Umsetzungsfrist	Sonderbestimmungen
10	Esfenvalerat	Richtlinie 2000/67/EG	31.1.2002	Gemäß den Bestimmungen der Richtlinie 91/414/EWG ändern oder widerrufen die Mitgliedstaaten innerhalb der Umsetzungsfrist erforderlichenfalls bestehende Zulassungen für Pflanzenschutzmittel, die Esfenvalerat als Wirkstoff enthalten Hinsichtlich der Bewertung und des Entscheidungsverfahrens 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, wird die Umsetzungsfrist jedoch wie folgt verlängert: — bei Pflanzenschutzmitteln, die Esfenvalerat als einzigen Wirkstoff enthalten bis zum 1.8.2005; — bei Pflanzenschutzmitteln, die Esfenvalerat und einen anderen in Anhang I der Richtlinie 91/414/EWG aufgenommenen Wirkstoff enthalten, auf vier Jahre ab dem Inkrafttreten der Richtlinie über die Aufnahme des letzten dieser Wirkstoffe in Anhang I
11	Bentazon	Richtlinie 2000/68/EG	31.1.2002	Gemäß den Bestimmungen der Richtlinie 91/414/EWG ändern oder widerrufen die Mitgliedstaaten innerhalb der Umsetzungsfrist erforderlichenfalls bestehende Zulassungen für Pflanzenschutzmittel, die Bentazon als Wirkstoff enthalten Hinsichtlich der Bewertung und des Entscheidungsverfahrens 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, wird die Umsetzungsfrist jedoch wie folgt verlängert: — bei Pflanzenschutzmitteln, die Bentazon als einzigen Wirkstoff enthalten, bis zum 1.8.2005; — bei Pflanzenschutzmitteln, die Bentazon und einen anderen Wirkstoff in Anhang I der Richtlinie 91/414/EWG aufgenommenen Wirkstoff enthalten, auf vier Jahre ab dem Inkrafttreten der Richtlinie über die Aufnahme des letzten dieser Wirkstoffe in Anhang I

COMMISSION DIRECTIVE 2000/80/EC

of 4 December 2000

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, so as to consolidate that Annex and include a further active substance (lambda-cyhalothrin)

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 2000/68/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 Council 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 States for the implementation of Commission 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 lambda-cyhalothrin 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 notifiers. Sweden was designated as rapporteur Member State under Commission 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. Sweden submitted the relevant assessment report and recommendation to the Commission on 12 June 1996, in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(4) That assessment report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. That review was finalised on 19 October 2000 in the format of the Commission review report for lambda-cyhalothrin. If the review report has to be updated to take account of technical and scientific developments, the conditions for the inclusion of lambda-cyhalothrin 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 have also been submitted to the Scientific Committee on Plants for consultation. In its opinion of 28 January 2000 [8], the Committee noted that an acute dietary risk assessment for consumers should be conducted and an acute reference dose should be defined. Further, with regard to the protection of the environment, the Committee emphasised that appropriate risk mitigation measures must be applied to avoid unacceptable effects on aquatic organisms and non-target arthropods including bees. Those recommendations were taken into consideration in the measures provided for in this Directive and in the relevant review report.

(6) It has appeared from the various examinations made that plant protection products containing the active substance 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 review report. It is therefore appropriate to include the active substance concerned in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing the active substance concerned can be granted in accordance with the provisions of the said Directive.

(7) 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

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 276, 28.10.2000, p. 41.
[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, 28.1.2000.

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.

(8) 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 lambda-cyhalothrin. 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.

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

(10) The review report is 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 substance in Annex I to the Directive.

(11) A number of substances have been included in Annex I to the Directive by a series of Commission Directives, namely Directive 97/73/EC [1], 98/47/EC [2], 1999/1/EC [3], 1999/73/EC [4], 1999/80/EC [5], 2000/10/EC [6], 2000/49/EC [7], 2000/50/EC [8]. For the sake of clarity and rationality, the details concerning those substances should be set out in tabular form and those Directives should be repealed without prejudice to the obligations of the Member States concerning the time limits for transposition and application set out in Annex II.

(12) To ensure consistency and uniform application, it is appropriate to provide that the finalised review report on each substance should be taken into account in applying the uniform principles for the evaluation and authorisation of plant protection products under Annex VI to the Directive. Similarly, all review reports (except for confidential information) should be kept available or made available by the Member States for consultation by any interested parties.

(13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health delivered on 19 October 2000,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is replaced by the text in Annex I 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 lambda-cyhalothrin as an active substance by that date.

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 lambda-cyhalothrin as the only active substance shall be 1 January 2006.

3. For plant protection products containing lambda-cyhalothrin 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 includes the last of those substances in Annex I.

[1] OJ L 353, 24.12.1997, p. 26.
[2] OJ L 191, 7.7.1998, p. 50.
[3] OJ L 21, 28.1.1999, p. 21.
[4] OJ L 206, 5.8.1999, p. 16.
[5] OJ L 210, 10.8.1999, p. 13.
[6] OJ L 57, 2.3.2000, p. 28.
[7] OJ L 197, 3.8.2000, p. 32.
[8] OJ L 198, 4.8.2000, p. 39.

Article 3

The Directives listed in the third column of Annex II are hereby repealed without prejudice to the obligations of the Member States concerning the transposition deadline and the specific provisions set out in Annex II.

Article 4

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities.*

The provisions in Article 2 concerning the active substance lambda-cyhalothrin together with the inclusion of this active substance in Annex I to Directive 91/414/EEC apply from 1 January 2002.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 4 December 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

'ANNEX I

ACTIVE SUBSTANCES AUTHORISED FOR USE IN PLANT PROTECTION PRODUCTS

General provisions applying to all substances listed in this Annex:

For the implementation of the uniform principles of Annex VI in relation to each substance, the conclusions of the review report on it, and in particular the Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on the date indicated under "specific provisions" for that substance shall be taken into account.

Member States shall keep available all review reports (except for confidential information within the meaning of Article 14 of the Directive) for consultation by any interested parties or shall make it available to them on specific request.

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
1	Imazalil CAS No 73790-28-0, 35554-44-0 CIPAC No 335	(±)-1-(β-allyloxy-2,4-dichlorophenylethyl)imidazole or (±)-allyl 1-(2,4-dichlorophenyl)-2-imidazol-1-ylethyl ether	975 g/kg	1.1.1999	31.12.2008	Only uses as fungicide may be authorised For the following uses the following particular conditions apply: — post harvest fruit, vegetable and potato treatments may only be authorised when an appropriate decontamination system is available or a risk assessment has demonstrated to the authorising Member State that the discharge of the treatment solution does not have an unacceptable risk to the environment and in particular to aquatic organisms, — post harvest treatment of potatoes may only be authorised when a risk assessment has demonstrated to the authorising Member State that the discharge of the processing waste from treated potatoes does not have an unacceptable risk to aquatic organisms, — outdoor foliar uses may only be authorised when a risk assessment has demonstrated to the authorising Member State that the use has no unacceptable effects on human and animal health and the environment Date of Standing Committee on Plant Health at which the review report was finalised: 11.7.1997.
2	Azoxystrobin CAS No 131860-33-8 CIPAC No 571	Methyl (E)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy] phenyl}-3-methoxyacrylate	930 g/kg (Z isomer max. 25 g/kg)	1.7.1998	1.7.2008	Only uses as fungicide may be authorised In the decision-making according to the uniform principles, particular attention should be given to the impact on aquatic organisms. Authorisation conditions should include appropriate risk mitigation measures Date of Standing Committee on Plant Health at which the review report was finalised: 22.4.1998

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
3	Kresoxim-methyl CAS No 143390-89-0 CIPAC No 568	Methyl (E)-2-methoxyimino-2-[2-(o-tolyloxymethyl) phenyl] acetate	910 g/kg	1.2.1999	31.1.2009	Only used as fungicide may be authorised In their decision-making according to the uniform principles, Member States shall pay particular attention to the protection of groundwater under vulnerable conditions Date of Standing Committee on Plant Health at which the review report was finalised: 16.10.1998
4	Spiroxamine CAS No 1181134-30-8 CIPAC No 572	(8-tert-Butyl-1,4-dioxa-spiro [4.5] decan-2-ylmethyl)-ethyl-propylamine	940 g/kg (diastereomers A and B combined)	1.9.1999	1.9.2009	Only uses as a fungicide may be authorised In their decision-making according to the uniform principles, Member States: — must pay particular attention to operator safety and must ensure that the conditions of authorisation include appropriate protective measures, and — must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Date of Standing Committee on Plant Health at which the review report was finalised: 12.5.1999
5	Azimsulfuron CAS No 120162-55-2 CIPAC No 584	1-(4,6-dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-pyrazol-5-ylsulfonyl]-urea.	980 g/kg	1.10.1999	1.10.2009	Only uses as herbicide may be authorised Aerial application may not be authorised In their decision making according to the uniform principles, Member States must pay particular attention to the impact on aquatic organisms and terrestrial non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures (e. g. in rice cultivation minimum holding periods for water prior to discharge) Date of Standing Committee on Plant Health at which the review report was finalised: 2.7.1999
6	Fluroxypyr CAS No 69377-81-7 CIPAC No 431	4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid	950 g/kg	1.12.2000	30.11.2010	Only uses as herbicide may be authorised In their decision-making according to the uniform principles, Member States: — shall take into account the additional information requested in point 7 of the review report, — must pay particular attention to the protection of groundwater, — must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Member States shall inform the Commission if the requested additional trials and information as outlined in point 7 of the review report were not submitted by 1.12.2000 Date of Standing Committee on Plant Health at which the review report was finalised: 30.11.1999

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
7	Metsulfuron-methyl CAS No 74223-64-6 EEC No 441	Methyl-2-(4-methoxy-6-methyl-1,3,5,-triazin-2-ylcarbamoylsulfamoyl)benzoate	960 g/kg	1.7.2001	30.6.2011	Only uses as herbicide may be authorised In their decision making according to the uniform principles, Member States: — must pay particular attention to the protection of groundwater, — must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Date of Standing Committee on Plant Health at which the review report was finalised: 16.6.2000
8	Prohexadione-calcium CAS No 127277-53-6 CIPAC No 567	Calcium 3,5-dioxo-4-propionylcyclohexanecarboxylate	890 g/kg	1.10.2000	1.10.2010	Only uses as plant growth regulator may be authorised Date of Standing Committee on Plant Health at which the review report was finalised: 16.6.2000
9	Triasulfuron CAS No 82097-50-5 CIPAC No 480	1-[2-(2-chloroethoxy) phenylsulfonyl]-3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)urea	940 g/kg	1.8.2001	31.7.2011	Only uses as herbicide may be authorised In their decision making according to the uniform principles, Member States: — must pay particular attention to the protection of groundwater, — must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Date of Standing Committee on Plant Health at which the review report was finalised: 13.7.2000
10	Esfenvalerate CAS No 66230-04-4 CIPAC No 481	(S)-α-Cyano-3-phenoxybenzyl-(S)-2-(4-chlorophenyl)-3-methylbutyrate	830 g/kg	1.8.2001	31.7.2011	Only uses as insecticide may be authorised In their decision making according to the uniform principles, Member States: — must pay particular attention to the potential impact on aquatic organisms and non-target arthropods and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Date of Standing Committee on Plant Health at which the review report was finalised: 13.7.2000
11	Bentazone CAS No 25057-89-0 CIPAC No 366	3-isopropyl-(1H)-2,1,3-benzothiadiazin-4-(3H)-one-2,2-dioxide	960 g/kg	1.8.2001	31.7.2011	Only uses as herbicide may be authorised In their decision-making according to the uniform principles, Member States must pay particular attention to the protection of groundwater Date of Standing Committee on Plant Health at which the review report was finalised: 13.7.2000

Number	Common name, identification numbers	IUPAC name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
12	Lambda-cyhalothrin CAS No 91465-08-6 CIPAC No 463	A 1:1 mixture of: (S)-α-cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropane-carboxylate, and (R)-α-cyano-3-phenoxybenzyl (Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropane-carboxylate	810 g/kg	1.1.2002	31.12.2011	Only uses as insecticide may be authorised In their decision-making according to the uniform principles, Member States: — must pay particular attention to operator safety, — must pay particular attention to the potential impact on aquatic organisms and non-target arthropods including bees and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures, — must pay particular attention to the residues in food and especially the acute effects thereof Date of Standing Committee on Plant Health at which the review report was finalised: 19.10.2000

[1] Further details on identity and specification of active substances are provided in their review reports.'

ANNEX II

DEADLINES FOR IMPLEMENTATION MEASURES IN MEMBER STATES FOR ACTIVE SUBSTANCES AUTHORISED FOR USE IN PLANT PROTECTION PRODUCTS

Number	Common name	Inclusion Directive	Transposition deadline	Specific provisions
1	Imazalil	Directive 97/73/EC	30.6.1999	Member States shall, in accordance with the provisions of Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing imazalil by the transposition deadline However, with regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto, transposition deadline is extended: — for plant protection products containing only imazalil, and not intended for outdoor foliar uses, to 1.1.2003, — for plant protection products containing imazalil and other active substances not yet included in Annex I, and not intended for outdoor foliar uses, to four years from the entry into force of such Directive as shall include the last of those substances in Annex I
2	Azoxystrobin	Directive 98/47/EC	1.1.1999	For plant protection products containing azoxystrobin together with another active substance included in Annex I to Directive 91/414/EEC the transposition deadline is extended to the extent that a longer implementation period is provided for by the provisions laid down in the Directive concerning the inclusion of this other active substance in Annex I to Directive 91/414/EEC
3	Kresoxim-methyl	Directive 1999/1/EC	31.7.1999	For plant protection products containing kresoxim-methyl together with another active substance included in Annex I to Directive 91/414/EEC, the transposition deadline is extended to the extent that a longer implementation period is provided for by the provisions laid down in the Directive concerning the inclusion of this other active substance in Annex I to Directive 91/414/EEC
4	Spiroxamine	Directive 1999/73/EC	1.1.2000	For plant protection products containing spiroxamine together with another active substance included in Annex I to Directive 91/414/EEC, the transposition deadline is extended to the extent that a longer implementation period is provided for by the provisions laid down in the Directive concerning the inclusion of this other active substance in Annex I to Directive 91/414/EEC
5	Azimsulfuron	Directive 1999/80/EC	1.4.2000	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 transposition deadline is extended for existing provisional authorisations of plant protection products containing azimsulfuron to 1.4.2001 For plant protection products containing azimsulfuron together with another active substance which is in Annex I to Directive 91/414/EEC, the transposition deadline is extended to the extent that a longer implementation period is provided for by the provisions laid down in the Directive concerning the inclusion of this other active substance in Annex I to Directive 91/414/EEC

Number	Common name	Inclusion Directive	Transposition deadline	Specific provisions
6	Fluroxypyr	Directive 2000/10/EC	1.6.2000	Member States shall, in accordance with the provisions of Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing fluroxypyr as an active substance within the transposition deadline However, with regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto, the transposition dealdine is extended: — for plant protection products containing only fluroxypyr to 1.12.2004, — for plant protection products containing fluroxypyr together with another active substance which is in Annex I to Directive 91/414/EEC, to four years from the entry into force of such Directive as shall include the last of those substances in Annex I
7	Metsulfuron-methyl	Directive 2000/49/EC	31.12.2001	Member States shall, in accordance with the provisions of Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing metsulfuron-methyl as an active substance within the transposition deadline However, with regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto, the period laid down in the first paragraph is extended: — for plant protection products containing metsulfuron-methyl as the only active substance to 1.7.2005, — for plant protection products containing metsulfuron-methyl together with another active substance which is in Annex I to Directive 91/414/EEC, to four years from the entry into force of such Directive as shall include the last of those substances in Annex I
8	Prohexadione-calcium	Directive 2000/50/EC	1.1.2001	With regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Council Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto, the transposition deadline is extended for existing provisional authorisations of plant protection products containing prohexadione-calcium to 1.1.2002 For plant protection products containing prohexadione-calcium together with another active substance which is in Annex I to Directive 91/414/EEC, the transposition deadline is extended to the extent that a longer implementation period is provided for by the provisions laid down in the Directive concerning the inclusion of this other active substance in Annex I to Directive 91/414/EEC
9	Triasulfuron	Directive 2000/66/EC	31.1.2002	Member States shall, in accordance with the provisions of Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing triasulfuron as an active substance with the transposition deadline However, with regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto, the transposition deadline is extended: — for plant protection products containing triasulfuron as the only active substance to 1.8.2005, — for plant protection products containing triasulfuron together with another active substance which is in Annex I to Directive 91/414/EEC, to four years from the entry into force of such Directive as shall include the last of those substances in Annex I

Number	Common name	Inclusion Directive	Transposition deadline	Specific provisions
10	Esfenvalerate	Directive 2000/67/EC	31.1.2002	Member States shall, in accordance with the provisions of Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing esfenvalerate as an active substance within the transposition deadline However, with regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto, the transposition deadline is extended: — for plant protection products containing esfenvalerate as the only active substance to 1.8.2005, — for plant protection products containing esfenvalerate together with another active substance which is in Annex I to Directive 91/414/EEC, to four years from the entry into force of such Directive as shall include the last of those substances in Annex I
11	Bentazone	Directive 2000/68/EC	31.1.2002	Member States shall, in accordance with the provisions of Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing bentazone as an active substance within the transposition deadline However, with regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto, the transposition deadline is extended: — for plant protection products containing bentazone as the only active substance to 1.8.2005, — for plant protection products containing bentazone together with another active substance which is in Annex I to Directive 91/414/EEC, to four years from the entry into force of such Directive as shall include the last of those substances in Annex I

EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH & CONSUMER PROTECTION

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

lambda-cyhalothrin

7572/VI/97-final

25 January 2001

FINAL

Review report for the active substance ***lambda*-cyhalothrin**

Finalised in the Standing Committee on Plant Health at its meeting on 19 October 2000 in view of the inclusion of *lambda*-cyhalothrin 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 *lambda*-cyhalothrin, 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. *lambda*-Cyhalothrin 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 Stefes Pflanzenschutz GmbH on 9 and 20 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance *lambda*-cyhalothrin 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)

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

[2] OJ No L 244, 16.9.1999, p. 41.

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

No 2230/95([4]), designated Sweden as rapporteur Member State to carry out the assessment of *lambda*-cyhalothrin 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 *lambda*-cyhalothrin this deadline was 30 April 1995.

Only Zeneca Agrochemicals submitted a dossier to the rapporteur Member State which was considered as complete. Stefes Pflanzenschutz GmbH did not submit a dossier.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Sweden submitted on 12 June1996 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 *lambda*-cyhalothrin 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 *lambda*-cyhalothrin from Zeneca Agrochemicals, on 31 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 Pesticide Safety Directorate (PSD) in York, United Kingdom, 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 13 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 February 1998 to August 2000, and was finalised in the meeting of the Standing Committee on 19 October 2000.

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

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 29 February 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 2000/80/EC concerning the placing of plant protection products on the market, so as to consolidate that Annex and include a further active substance (lambda-cyhalothrin), and to assist the Member States in decisions on individual plant protection products containing *lambda*-cyhalothrin 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 *lambda*-cyhalothrin 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

[5] Opinion of the scientific Committee on Plants regarding the inclusion of *lambda*-cyhalothrin in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. SCP/LAMBDA/002-Final.

Annex VI of Directive 91/414/EEC, for each *lambda*-cyhalothrin containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of a range of uses, which were proposed and supported by the main data submitter, as outlined in Background document C of this report.

Extension of the use pattern beyond those reviewed will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 30 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Provisional estimates of acute dietary exposure of adults and toddlers revealed that the Acute Reference Dose (ARfD) might be exceeded for few, individual commodities[6]. These possible exceedances should be addressed in the framework of Council Directive 90/642/EEC on the setting of maximum residues of pesticides in fruit and vegetables.

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 *lambda*-cyhalothrin 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.

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[6] Adults: Spinach; Toddlers: Apples, pears, grapes, spinach. Worst case estimates on the basis of provisional residue data.

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 *lambda*-cyhalothrin

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:

- Member States in granting authorisations must pay particular attention to the operator safety and must ensure that the conditions of authorisation include appropriate protective measures.

- Member states should observe the acute dietary exposure situation of consumers in view of future revisions of Maximum Residue Levels.

- For the protection of aquatic organisms, risk mitigation measures should be applied where appropriate.

- For the protection of bees Member States should prescribe appropriate risk mitigation measures (e.g. buffer zones) if products containing *lambda*-cyhalothrin are applied at high doses.

- Depending on crop and application rate, Member States should prescribe appropriate risk mitigation measures to avoid unacceptable effects on non-target arthropods when authorisations are granted for plant protection products containing this active substance.

7. List of studies to be generated

No further studies were identified which at this stage were considered necessary in relation to the inclusion of *lambda*-cyhalothrin 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

- residue data supporting the current critical GAP, and
- further laboratory and/or field studies on bees and non-target arthropods.

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.

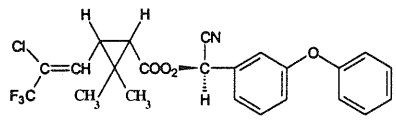
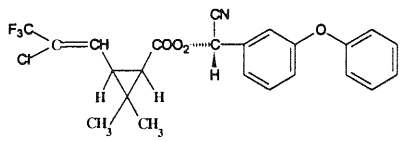
9. Updating of this review report

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 *lambda*-cyhalothrin in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

lambda-CYHALOTHRIN

Common name (ISO)	*lambda*-Cyhalothrin
Chemical name (IUPAC)	A 1:1 mixture of: (*S*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropane-carboxylate, and (*R*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropane-carboxylate
Chemical name (CA)	[1-α (*S**), 3-α (*Z*)]-(±)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate
CIPAC No	463
CAS No	91465-08-6
EEC No	Not allocated
FAO SPECIFICATION	The technical material shall consist of lambda-cyhalothrin together with related manufacturing impurities and shall be a viscous brown/green semi-solid mass, which is liquid at 50°C and contains not more than a trace of insoluble material, and shall be free from extraneous matter and added modifying agents. (Draft FAO Specification, May 2000.)
Minimum purity	810 g/kg
Molecular formula	$C_{23}H_{19}ClF_3NO_3$
Molecular mass	449.9
Structural formula	(R) (Z) - (1S) - cis - isomer:   (S) (Z) - (1R) - cis - isomer

Melting point	49.2 °C (322.4 K)
Boiling point	No measurable boiling point (decomposes)
Appearance	Beige solid without any characteristic odour (technical grade)
Relative density	1.33 g/cm^3 (1330 kg/m^3) at 25 °C
Vapour pressure	$2 \cdot 10^{-7}$ Pa at 20 °C (extrapolated)
Henry's law constant	0.02 Pa·m^3·mol^{-1} at 20 °C
Solubility in water	At 20 °C: pH 5: $4 \cdot 10^{-3}$ mg/l pH 6.5: $5 \cdot 10^{-3}$ mg/l pH 9.2: $4 \cdot 10^{-3}$ mg/l
Solubility in organic solvents	At 21 °C: hexane, toluene, dichloromethane, methanol, acetone and ethyl acetate: > 500 g/l
Partition co-efficient (log P_{OW})	log P_{OW} = 7.0
Hydrolytic stability (DT_{50})	There is no significant hydrolysis at pH 5.2 and 6.9. After 7 days at pH 9.0, 43 – 45 % of PP321 remains intact, thus half-life is approximately 7 days.
Dissociation constant	Not applicable
Quantum yield of direct photo-transformation in water:acetonitrile	0.092 (at wavelengths 270-290 nm)
Flammability	Flammability, in terms of flash point: 83 ± 2°C (substance heated before test)
Explosive properties	Not explosive (expert judgement based on structure)
UV/VIS absorption (max.)	Two absorption maxima, at 210 nm and 275-280 nm, with an absorption tail up to 300 nm.
Photostability (DT_{50})	Indicated DT_{50} in water 13 days (latitudes 40 and 50°N). Average quantum yield at 270-290 nm 0.092. Calculated DT_{50} in European waters 5 days (summer) to 75 days (winter). Calculated photochemical oxidative DT_{50} in air 4.1 h.

APPENDIX II

END POINTS AND RELATED INFORMATION

lambda-CYHALOTHRIN

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Oral, < 2 d man, 50 %
Distribution:	Wide, with concentration in adipose tissue
Potential for accumulation:	Half-life: 23 d
Rate and extent of excretion:	2 d, 90 %
Toxicologically significant compounds:	Parent
Metabolism in animals:	Mainly by cleavage of ester bond and further transformation to conjugated metabolites

Acute toxicity

Rat LD_{50} oral:	LD_{50} = 56 (f) - 79 (m) mg/kg bw	R25
Rat LD_{50} dermal:	LD_{50} = 632 (m) – 696 (f) mg/kg bw	R21
Rat LC_{50} inhalation:	LC_{50} = 0.06 mg/l	R26
Skin irritation:	Slight irritation. Non-irritant according to criteria.	
Eye irritation:	Slight irritation. Non-irritant according to criteria.	
Sensitisation (test method used and result):	Not sensitising at a 1% challenge dose. Higher doses not possible due to paraesthesia Guinea pig maximisation test	

Short term toxicity

Target / critical effect:	Organs liver, CNS
Lowest relevant oral NOAEL / NOEL:	0.5 mg/kg bw/d, oral, 1 y dog
Lowest relevant dermal NOAEL / NOEL:	No study available
Lowest relevant inhalation NOAEL / NOEL:	No study available

Genotoxicity

Negative

Long term toxicity and carcinogenicity

Target / critical effect:	Liver
Lowest relevant NOAEL:	NOEL 1.7 mg/kg bw/d, 2 y rat (cyhalothrin)
Carcinogenicity:	Negative

Reproductive toxicity

Target / critical effect - Reproduction:	Negative. Parental, slightly reduced bw gain and slightly reduced bw gain of the pups.
Lowest relevant reproductive NOAEL / NOEL:	NOEL 1.5 mg/kg bw/d (parental) NOEL 1.5 mg/kg bw/d (foetal)
Target / critical effect - Developmental toxicity:	Negative. No treatment related embryotoxic or teratogenic effects were observed.
Lowest relevant developmental NOAEL / NOEL:	NOEL 10 mg/kg bw/d based on maternal toxicity (decreased bw gain and loss of limb coordination).

Delayed neurotoxicity

Not relevant

Other toxicological studies

None

Medical data

Information supplied

Summary

	Value	Study	Safety factor
ADI:	0.005 mg/kg bw/d	1 y dog	100
AOEL systemic:	0.0025 mg/kg bw/d	1 y dog (50 % oral absorption)	100
AOEL inhalation:			
AOEL dermal:			
ARfD (acute reference dose):	0.0075 mg/kg bw	6-week oral dog study; NOEL 0.75 mg/kg bw	100

Dermal absorption

12 % EC formulation, in-use dilution: 4 %, *in vivo* rat

5 % EC formulation, in-use dilution: <0.3%, *in vivo* man

5 % EC formulation, in-use dilution: 0.055%, *in vitro* man

0.3% used for model calculations (concentrate and dilution) (See Doc. 5684/VI/97-app.4)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	25-59% after 90-92 days, mean 39% (n=4) (^{14}C-cyclopropane labelled)
Non-extractable residues after 100 days:	12-19% after 90-92 days, mean 16% (n=4)
Relevant metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	Only compound XV (hydroxylated *lambda*-cyhalothrin)[7] identified as "major": max. 11 and 12% in two different soils, after 35 and 63 days. Declined to 2-3% after 90 days.

Supplemental studies

Anaerobic:	< 1% $^{14}CO_2$ after 131 days (^{14}C-cyclopropane labelled). Bound residues 3% after 131 days. Compound Ia (ester cleavage product)[8] max. 18% after 131 days.
Soil photolysis:	Negligible
Remarks:	Major degradation is by ester cleavage to produce compound Ia and V[9]. Compound Ia detected as <10% from ^{14}C-cyclopropanre labelling. Mineralisation of V shown in studies on pyrethroids generating the same metabolite.

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	29, 34, 62, 100 d, (first order, r^2 0.96-1.0) mean 56 d (n=4) Compound XV: 7, 10, 16 days (mean 11 d)[10]
DT_{90}lab (20 °C, aerobic):	96, 113, 206, 332 d, mean 187 d (n=4)
DT_{50}lab (10 °C, aerobic):	63 d (n=1) (first order, r^2 0.99)
DT_{50}lab (20 °C, anaerobic):	101 d (n=1) (first order, r^2 0.98)

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[7] Compound XV: (RS)-α-cyano-3-(4-hydroxyphenoxy)benzyl-(Z)-(1RS)-cis-3-(2-chloro-3, 3, 3-trifluoropropenyl)-2, 2-dimethylcyclopropanecarboxylate. (IUPAC)

[8] Compound Ia (cyclopropane acid): (Z)-3-(2-chloro-3, 3, 3-trifluoropropenyl)-2, 2-dimethylcyclopropanecarboxylic acid. (IUPAC)

[9] Compound V: 3-phenoxybenzoic acid. (IUPAC)

[10] DT_{50s} for soil metabolite XV inserted as agreed by Working Group Legislation, October 2000. Data provided by CTB (The Netherlands), not evaluated by the RMS. DT_{50s} in original report were 4, 3 and 4 days but recalculated into the figures in the table by CTB, assuming first order kinetics (r^2 0.75-0.96).

Field studies (country or region)	US and Germany: Detected in the upper 10 cm of soil, < 4 % below 5 cm depth
DT_{50f} from soil dissipation studies:	Germany: 6, 26, 28, 40 d (best fit model) US study I: 2, 37 d (best fit model) US study II: 19, 20, 21, 35 d (best fit model) Mean 23 d (n=10)
DT_{90f} from soil dissipation studies:	Germany: 68, 85, 92, 207 d (best fit model) US study I: approx. 30, > 279 d (graphical) US study II: 62, 67, 108, 117d (best fit model) Mean 112 days (n=10)
Soil accumulation studies:	Not submitted, not required
Soil residue studies:	Not submitted, not required
Remarks	US study I used ^{14}C-cyclopropane and ^{14}C-phenyl label; bound residues as 22-32% after 115 days, and as 17-27% after 279 days.

Adsorption/desorption

K_f / K_{oc}:	K_{OC} = 38000, 47800, 199000, 345000 ml/g, mean 157000 (n=4)
K_d	K_d = 464, 1290, 1470, 5350, mean 2144 (n=4) %OC: 0.7 - 2.7, pH 6.0 - 6.6, % sand 2 – 72
pH dependence:	No pH dependency expected Compound XV: K_{om} 36000, 39000, 39000, 42000, 46000, 61000 (mean 44000)[11]

Mobility

Laboratory studies:

Column leaching:	No significant leaching
Aged residue leaching:	No significant leaching

Field studies:

Lysimeter/Field leaching studies:	Not submitted, not requested No leaching in field dissipation studies
Remarks:	None

[11] Kom values for soil metabolite XV inserted as agreed by Working Group Legislation, October 2000. Data provided by CTB (The Netherlands), not evaluated by the RMS. Koc values in original report were 60000, 67000, 68000, 75000, 78000 and 110000, but recalculated into the values in the table by CTB.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	Not significant at pH 5.2 and pH 6.9, DT_{50} approx. 1 week at pH 9.0
Relevant metabolites:	At pH 9.0: Compounds Ia[12] and IV[13] identified as "major" (>10%)
Photolytic degradation:	DT_{50}: a few weeks, expected to be negligible under field conditions.
Relevant metabolites:	At laboratory: Compounds Ia and V[14] identified as "major" (>10%)

Biological degradation

Ready biological degradability:	Not submitted, not requested
Water/sediment study:	at 20 °C, 2 systems, pH 7.2-7.8: 5 and 11 h
DT_{50} water:	15 and 7 days
DT_{50} whole system:	3.3 and 4.6 days
DT_{90} water:	151 and 45 days
DT_{90} whole system:	
Distribution in water / sediment systems (active substance)	Parent compound, as % of applied radioactivity in the two water/sed. systems:

	Day 0	Day 1	Day 7
Water	72/49	10/13	3.7/2.6
Sediment	14/30	70/30	53/43
Total	86/79	80/43	57/46

Distribution in water / sediment systems (metabolites)	Compound Ia was found at max. 18/22% of applied radioactivity days 14/30, whereof 3/11% in sediment and 14/11% in water. After 98 days compound Ia had declined to 0.4/3%. Compounds V, VI[15], XV[16] each <10%. Bound residues 17/24% and $^{14}CO_2$ 15/48% after 98 days.
Accumulation in water and/or sediment:	Disappearance rate from water phase is even more rapid in the presence of plants, since extensive adsorption and enhanced degradation was shown in the presence of plants.

Degradation in the saturated zone

Not submitted, not requested

Remarks:

None

[12] Compound Ia (cyclopropane acid): (Z)-3-(2-chloro-3, 3, 3-trifluoropropenyl)2, 2-dimethylcyclopropanecarboxylic acid. (IUPAC).
[13] Compound IV: 3-phenoxybenzaldehyde. (IUPAC)
[14] Compound V: 3-phenoxybenzoic acid. (IUPAC)
[15] Compound VI: 3-phenoxybenzylalcohol. (IUPAC)
[16] Compound XV (hydroxylated *lambda*-cyhalothrin): (RS)-α-cyano-3-(4-hydroxyphenoxy)benzyl-(Z)-(1RS)-cis-3-(2-chloro-3, 3, 3-trifluoropropenyl)-2, 2-dimethylcyclopropanecarboxylate. (IUPAC)

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	$2 \cdot 10^{-7}$ Pa at 20 °C (extrapolated)
Henry's law constant:	0.02 Pa $m^3 \cdot mol^{-1}$ at 20 °C

Photolytic degradation

Direct photolysis in air:	Not submitted and not requested, but possible theoretically due to absorption "tail" to 300 nm.
Photochemical oxidative degradation in air:	DT_{50} 4.1 h (calculated)
Volatilisation:	Volatilisation from soil not significant, from leaves low rate of volatilisation observed (88% of applied amount remaining on leaves after 24 hours).

Remarks:	None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD_{50} = 20 mg/kg bw (mice)
Acute toxicity to birds:	LD_{50} > 3950 mg/kg bw (mallard duck)
Dietary toxicity to birds:	LC_{50} > 5300 mg/kg food (bobwhite quail)
Reproductive toxicity to birds:	NOEC > 30 mg/kg food (mallard duck)
Short term oral toxicity to mammals:	NOEL = 0.7 mg/kg bw/day (male rat, 90-day)

Aquatic Organisms

Acute toxicity fish:	LC_{50} (96 h) = 0.21 µg/l (*Lepomis macrochirus*) Major transformation products: Compound Ia[17]: LC_{50} (96 h) > 14 mg/l, 2 species Compound V[18]: LC_{50} (96 h) = 13 - 36 mg/l, 2 species
Long term toxicity fish:	NOEC (28 d) 0.25 µg/l (*Cyprinodon variegatus*) (flow-through early life stage toxicity test)
Bioaccumulation fish:	BCF: 1660-2240 (whole fish)
Acute toxicity invertebrate:	EC_{50} (48 h) = 0.36 µg/l (*Daphnia magna*) EC_{50} (96 h) = 0.016 µg/l (*Gammarus pulex* neonates; most sensitive life-stage tested) NOEC (96 h) = 0.006 µg/l (*G. pulex* neonates) Major transformation products: Compound Ia: EC_{50} (48 h) 105 mg/l (*D. pulex*) Compound V: EC_{50} (48 h) 85 mg/l, (*D. magna*)
Acute toxicity algae:	EC_{50} (96 h) > 0.3 mg/l (*Selenastrum capricornutum*)
Chronic toxicity sediment dwelling organism:	*Chironomus riparius*, 28-d studies "spiked water test": NOEC (time to emergence) 0.16 µg/l "spiked sediment test": NOEC (total emergence) 105 µg/kg

[17] Compound Ia (cyclopropane acid): (Z)-3-(2-chloro-3, 3, 3-trifluoropropenyl)2, 2-dimethylcyclopropanecarboxylic acid. (IUPAC).
[18] Compound V: 3-phenoxybenzoic acid. (IUPAC)

Results from mesocosm studies:

Mesocosm study I (UK):	Gammaridae most sensitive taxa: LOEC: 4 events of overspray at 0.17 g/ha Chironomidae, less sensitive: NOEC: 4 events of overspray at 1.7 g/ha
Mesocosm study II (US):	Insecta most sensitive taxa: NOAEC: 12 events of overspray at 0.017 g/ha + 6 events of run-off at 0.05 g/ha Fish, *L. macrochirus*, and sedentary chironomids were less sensitive: NOEC: 12 events of overspray at 1.7 g/ha + 6 events of run-off at 5 g/ha

Honeybees

Acute oral toxicity:	LD_{50} (48 h) = 0.91 µg/bee
Acute contact toxicity:	LD_{50} (48 h) = 0.038 µg/bee

Field study in cereals:	Preliminary results indicate NOAEC = 20 g/ha

Other arthropod species

Foliage dwellers:	
Rhopalosiphum padi	LD_{50} (6 d) 0.004 µg/g bw, contact exposure
Leptyphantes spp. (m)	LD_{50} (6 d) 0.097 µg/g bw, contact exposure
Leptyphantes spp. (f)	LD_{50} (6 d) 0.132 µg/g bw, contact exposure
Bathyphantes spp. (f)	LD_{50} (6 d) 0.012 µg/g bw, contact exposure
Oedothorax spp. (m)	LD_{50} (6 d) 0.058 µg/g bw, contact exposure
Panonychus ulmi	LD_{50} (48 h) 1.9 g/ha
Typhlodromus pyri	LD_{50} (48 h) 0.2 g/ha
Episyrphus balteatus	27% larval mortality after 6 days at 9 g/ha
Soil dwellers:	
Trechus quadristriatus	LD_{50} (6 d) 12.1 µg/g bw, contact exposure
Pterostichus melanarius	23% mortality after 28 days at 7.5 g/ha
Poecilus cupreus	0-10% mortality after 28 days at 7.5 g/ha
Pardosa sp.	90% mortality after 14 days at 7.5 g/ha
Pardosa spp.	83-87% mortality after 14 days at 7.5 g/ha

Field study, autumn application in cereals, UK, at 5 g/ha:	Mean depression in abundance of affected species was 20-60% and lasted for 4-5 weeks.
Field study, summer application in cereals, UK, at 7 g/ha:	Mean depression in abundance of affected species was 75% and lasted for 27±6 days.
Field study, summer application in cereals, UK, at 2.5, 5 and 10 g/ha:	Depression in abundance of the species affected lasted for 1-7 weeks with no statistically significant effects remaining 7 weeks after spraying. Increased selectivity was seen at reduced rates.
Field studies in non-European countries:	Recovery after 3 weeks.

Earthworms

Acute toxicity:	LC_{50} (14 d) > 1000 mg/kg soil NOEC = 100 mg/kg soil
Reproductive toxicity:	Not submitted, not requested

Soil micro-organisms

Nitrogen mineralization:	< 21% effect on ammonification/nitrification at 1.25 kg/ha
Carbon mineralization:	No significant effects at 1.25 kg/ha

APPENDIX III

lambda-CYHALOTHRIN

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

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[2] on previous use in granting national authorizations
AII 1	Duffin MR	1991	*lambda*-Cyhalothrin: Detailed Analysis of Technical Materials Representative of Established Large Scale Production. ZENECA Agrochemicals Report No. RJ0943B. GLP study Not published	
AII 2	Jackson WA	1994	Determination of some Physico-Chemical Properties of *lambda*-cyhalothrin TGAI. Report No. HT94/140. GLP study Not published	
AII 2	Wollerton C	1984	PP321: Physical-Chemical Data File. ICI, Plant Protection Division, Report No. RJ0366B. GLP not relevant Not published	Austria (18/7/91) & the Netherlands.
AII 2.3 AII 2.6 AII 2.8	Wollerton C and Husband R	1988	PP321: Water Solubility, Octanol-Water Partition Coefficient, Vapour Pressure and Henry's Law Constant. ICI Agrochemicals Report No. RJ 0699B. GLP study Not published	
AII 2.5	Tandy MJ, Duffin MR and Stanley PD	1988	PP321 and Cyhalothrin: NMR Spectra of Associated Isomers Detected in Technical Material. ICI Agrochemicals Report Series M4835B. Not GLP study Not published	Austria (18/7/91).

[1] List based on a detailed analysis from Sweden in its submission of 24 October 2000 (background document C).

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[20] on previous use in granting national authorizations
AII 2.9.1 AII 7.2.1.1	Collis WMD and Leahey JP	1984	PP321: Hydrolysis in Water at pH 5, 7 and 9. ICI Report series RJ 0338B. GLP study Not published	Austria (18/7/91), Germany (25/10/90), UK (14/2/1990), the Netherlands.
AII 2.9.2 AII 2.9.3 AII 7.2.1.2	Moffatt F	1994	*lambda*-Cyhalothrin: Environmental Half-life and Quantum Yield for Direct Phototransformation in Aqueous Solution. Zeneca Report Series RJ 1617B. GLP study Not published	
AII 2.9.2 AII 7.2.1.2	Priestley DB and Leahey JP	1988	PP321: Aqueous Photolysis at pH 5. ICI Report Series RJ 0605B. GLP study Not published	Germany (25/10/90), the Netherlands.
AII 2.10	Hayes SE	1998	Lambda-cyhalothrin - calculation of half-life by reaction with atmospheric hydroxyl radicals. Zeneca G:\AOP+lambda-cyhalothrin.AOP. GLP not relevant Not published	
AII 4.1	Duffin MR	1994	The determination of *lambda*-cyhalothrin and associated impurities in technical material by capillary gas chromatography. Zeneca Agrochemicals Analytical Method PAM 721/3. Not GLP study Not published	
AII 4.2	Hadfield ST, Sadler J and Bolygo E	1989	The determination of residues of PP321 in water following sampling by a solid-phase extraction technique. ICI Agrochemical Residue Analytical Method Number 125b. Not GLP study Not published	
AII 4.2	Marsh JR	1995	Determination of *lambda*-cyhalothrin in human blood. Zeneca Central Toxicology Laboratory Report No. CTL/R/1241. Not GLP study Not published	
AII 4.2	Ryan J and Sapiets A	1993	*Lambda*-cyhalothrin: Validation of a stepped model to determine residues in air. Zeneca Agrochemicals Jealott´s Hill Research Station Report No. RJ1525B. GLP study Not published	

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[20] on previous use in granting national authorizations
AII 4.2	Sapiets A	1986a	The determination of residues of PP321 in products of animal origin. A gas-liquid chromatographic method using an internal standard. ICI Chemical Industries PLC, Plant Protection Division Residue Analytical Method Number 86/1. GLP study Not published	
AII 4.2	Sapiets A	1986b	The determination of residues of PP321 in soil. ICI Chemical Industries PLC, Plant Protection Division Residue Analytical Method Number 93. Not GLP study Not published	Germany (25/10/90), Italy (30/12/92).
AII 4.2	Specht and Partner	1990	Uberprüfung der Anwendbarkeit der DFG Multimethode S 19. *Lambda*-cyhalothrin. RIC 2246. Dr Specht & Partner Chemische Laboratorien GMBH. Not GLP study Not published	Germany (25/10/90).
AII 4.2	Swaine H and Sapiets A	1984	The determination of residues of PP321 in crops. A gas-liquid chromatographic method using an internal standard. ICI Chemical Industries PLC, Plant Protection Division Residue Analytical Method No. 81. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.

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 on previous use in granting national authorizations
AII 5.1	Harrison MP	1981	Cyhalothrin: The disposition and metabolism of ^{14}C-ICI 146,814 in rats; Part I. Central Toxicology Laboratory Report No. CTL/C/1279A. Not GLP study Not published	Submitted in all Member States except Greece, Ireland, Luxembourg, Portugal & Spain.
AII 5.1	Harrison MP	1983	Cyhalothrin: The metabolism and disposition of ICI 146,814 in the rat; Part IV. Central toxicology Laboratory Report No. CTL/C/1279D. Pharmaceuticals Report No. 6/HC/005683. GLP study Not published	
AII 5.1	Harrison MP	1984a	Cyhalothrin (ICI 146,814): The metabolism and disposition of ICI-146,814 in rats; Part II. Tissue residues derived from [^{14}C-benzyl] or [^{14}C-cyclopropyl]-ICI 146,814, after a single oral dose of 1 or 25 mg/kg. Central Toxicology Laboratory Report No. CTL/C/1279B. GLP study Not published	Submitted in all Member States except Austria, Denmark, Ireland, Luxembourg, Portugal, Spain & Sweden.
AII 5.1	Harrison MP	1984b	Cyhalothrin: The metabolism and disposition of [^{14}C]-ICI-146,814 in rats; Part III. Studies to determine radioactive residues in the rat following 14 days repeated oral administration. Central Toxicology Laboratory Report No. CTL/C/1279C. GLP study Not published	
AII 5.1	Harrison MP	1984c	Cyhalothrin (ICI 146,814): The diposition and metabolism of [^{14}C]-ICI 146,814 in the dog. Central Toxicology Laboratory Report No. CTL/C/1277. Pharmaceuticals Report No. 10/HD/007328. Not GLP study Not published	
AII 5.1	Jones BK	1989a	Cyhalothrin: Tissue distribution and elimination following a single oral dose (1 mg/kg) in the rat. Central Toxicology Laboratory Report No. CTL/P/2489. GLP study Not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 5.1	Jones BK	1989b	Cyhalothrin: Tissue distribution and elimination following a single oral dose (25 mg/kg) in the rat. Central Toxicology Laboratory Report No. CTL/P/2490. GLP study Not published	
AII 5.1	Marsh JR, Woollen BH and Wilks MF	1994	The metabolism and pharmacokinetics of *lambda*-cyhalothrin in man. Central Toxicology Laboratory Report No. CTL/P/4208. GLP study Not published	
AII 5.1	Prout MS	1984	Cyhalothrin: Bioaccumulation in the rat. Central Toxicology Laboratory Report No. CTL/P/1014. GLP study Not published	Submitted in all Member States except Austria, Finland, Greece, Ireland, Luxembourg, Portugal & Spain.
AII 5.1	Prout MS and Howard EF	1985	PP321: Comparative absorption study in the rat (1 mg/kg). Central Toxicology Laboratory Report No. CTL/P/1214. GLP study Not published	Submitted in all Member States except Belgium, Greece, Ireland, Luxembourg, Portugal & Spain.
AII 5.2	Barber JE	1985	PP321: Acute dermal toxicity study. Central Toxicity Laboratory Report No. CTL/P/1149. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal, Spain & Sweden.
AII 5.2	Barber JE	1987	Skin sensitisation Validation: October 1979-December 1983. Central Toxicology Laboratory Report No. CTL/T/2316. Not GLP study Not published	
AII 5.2	Hext PM	1987	PP321: 4-hour acute inhalation toxicity study in the rat. Central Toxicology Laboratory report No. CTL/P/1683. GLP study Not published	Austria (18/7/91), France (2/87), Germany (19/4/89), Italy (30/12/92), Spain.
AII 5.2	Pritchard VK	1984	PP321: Skin sensitisation study. Central Toxicology Laboratory Report No. CTL/P/1054. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg & Portugal.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 5.2	Pritchard VK	1985a	PP321 and cyhalothrin: Skin irritation study. Central Toxicology Laboratory Report No. CTL/P/1139. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.
AII 5.2	Pritchard VK	1985b	PP321: Eye irritation study. Central Toxicology Laboratory Report No. CTL/P/1207. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.
AII 5.2	Southwood J	1985	PP321: Acute oral toxicity studies. Central Toxicology Laboratory Report No. CTL/P1102. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.
AII 5.3	Hart D, Banham PB, Chart IS, Evans DP, Gore CW, Stonard MD, Moreland S, Godley MJ and Robinson M	1985	PP321: 90-day feeding study in rats. Central Toxicology Laboratory Report No. CTL/P/1045. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.
AII 5.3	Lindsay S, Chart IS, Godley MJ, Gore CW, Hall M, Pratt I, Robinson M and Stonard M	1981	Cyhalothrin: 90-day feeding study in rats. Central Toxicology Laboratory Report No. CTL/P/629. GLP study Not published	Submitted in all Member States except Belgium, Denmark, Finland, Greece, Ireland, Luxembourg & Portugal.
AII 5.3	Lindsay S, Doe JE, Godley MJ, Hall M, Pratt I, Robinson M and Stonard MD	1982	Cyhalothrin induced liver changes: Reversibility study in male rats. Central Toxicology Laboratory Report No. CTL/P/668. GLP study Not published	Denmark, Finland (18/1/93), France (9/5/86), Germany (19/4/89), Sweden (30/5/91), UK (14/2/90).
AII 5.3	Stonard MD	1991	First amendment to PP321: 1-year oral dosing study in dogs. Central Toxicology Laboratory Report No. CTL/P/1316. GLP study Not published	Austria (18/7/91), Denmark, Germany (19/4/89), Italy (30/12/92), the Netherlands.
AII 5.4	Callander RD	1984	PP321-An evaluation in the *Salmonella* Mutagenicity Assay. Central Toxicology Laboratory Report No. CTL/P/1000. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg & Portugal.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 5.4	Cross M	1985	PP321: Assessment of mutagenic potential using L5178Y mouse lymphoma cells. Central Toxicology Laboratory Report No. CTL/P/1340. GLP study Not published	Austria (18/7/91), Denmark, Germany (19/4/89), Italy (30/12/92), the Netherlands Sweden (30/5/91).
AII 5.4	Sheldon T, Howard CA and Richardson CR	1985	PP321: A cytogenic study in human lymphocytes *in vitro*. Central Toxicology Laboratory Report No. CTL/P/1333. GLP study Not published	Submitted in all Member States except Belgium, Greece, Ireland, Luxembourg, Portugal, Spain & UK.
AII 5.4	Sheldon T, Richardson CR, Show J and Barber G	1984	An evaluation of PP321 in the Mouse Micronucleus Test. Central Toxicology Laboratory Report No. CTL/P/1090. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.
AII 5.4	Trueman RW	1989	*lambda*-Cyhalothrin: Assessment for the induction of Unscheduled DNA synthesis in primary rat hepatocyte cultures. Central Toxicology Laboratory Report No. CTL/P/2707. GLP study Not published	
AII 5.5	Colley J, Dawe S, Heywood R, Almond R, Gibson WA, Gregson R and Gopinath C	1984	Cyhalothrin: Potential tumorigenic and toxic effects in prolonged dietary administration to mice. Huntingdon Research Centre Report No. ICI 395/83668/2. Central Toxicology Laboratory Report Reference Numbers CRL/C/1260 Vol. 1-3, addendum 1 & 2 & photomicrography addendum and CTL/P/1185 (Summary Report; Evans, D.P., 1984). GLP study Not published	Submitted in all Member States except Belgium, Ireland, Luxembourg, Portugal, Spain & UK.
AII 5.6	Killick ME	1981a	Cyhalothrin: Oral (gavage) teratology study in the rat. Hazleton Report No: 2661-72/208. Central Toxicology Laboratory Report No. CTL/C/1075. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg & Portugal.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 5.6	Killick ME	1981b	Cyhalothrin: Oral (gavage) teratology study in the New Zealand White rabbit. Hazleton Report No: 2700-72/211. Central Toxicology Laboratory Report No. CTL/C/1072. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg & Portugal.
AII 5.6	Milburn GM, Banham P, Godley MJ, Pigott G and Robinson M	1984	Cyhalothrin: Three generation reproduction study in the rat. Central Toxicology Laboratory Report No. CTL/P/906 and CTL/P/1244 (Summary report; Evans, D.P., 1984). GLP study Not published	Submitted in all Member States except Ireland, Luxembourg & Portugal.
AII 5.6	Pigott GH, Chart IS, Godley MJ, Gore CW, Hollis KJ, Robinson M, Taylor K and Tinston DJ	1984	Cyhalothrin: Two-year feeding study in rats. Central Toxicology Laboratory Report No. CTL/P/980. GLP study Not published	Submitted in all Member States except Ireland, Luxembourg, Portugal & Spain.
AII 5.2.6 AIII 7.1	Barber JE	1987	Skin sensitisation Validation: 1985. Central Toxicology Laboratory Report No: CTL/T/2439. Not GLP study Not published	
AII 5.9 AIII 7.2	Ashdown DM, Chester G and Wollen BH	1994	*lambda*-cyhalothrin- assessment of occupational exposure and effects on the health of workers and livestock during application of 'Karate' 5 EC to cotton in India. ZENECA Agrochemicals report No: TMF 4206B. Not GLP study Not published	
AII 5.8.2	Brammer A	1999	*Lambda*-cyhalothrin: Acute neurotoxicity study in rats. Zeneca Central Toxicology Laboratory Report No. CTL/P/6151. GLP study Not published	
AII 5.8.2	Horner SA	1996a	*Lambda*-cyhalothrin: Maximum clinically tolerated dose study in dogs. Zeneca Central Toxicology Laboratory Report No. CTL/L/7182. Not GLP study Not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 5.8.2	Horner SA	1996b	*Lambda*-cyhalothrin: 6 week oral toxicity study in dogs. Zeneca Central Toxicology Laboratory Report No. CTL/P/5256. GLP study Not published	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 6.1	Burke S and Sapiets A	1988	CYHALOTHRIN: - Storage Stability of the Residue in Frozen Crop and Soil Samples. Jealott's Hill Research Station Report Series M4773B. GLP study Not published	
AII 6.1	Clarke DM and Sapiets A	1990a	*LAMBDA*-CYHALOTHRIN: - Storage Stability of the Insecticide and its Metabolites in Frozen Dried Hops and Brewers Grains. Jealott's Hill Research Station Report Series RJ0886B. GLP study Not published	
AII 6.1	Curl EA and Leahey JP	1983	Cyhalothrin: Metabolism in Cabbage. Jealott's Hill Research Station Report No. RJ0308B. GLP study Not published	Submitted in all Member States except Belgium, Greece, Ireland, Italy, Luxembourg, Portugal & UK.
AII 6.1	French DA and Grout SJ	1990	*lambda*-Cyhalothrin: Quantification and Characterization of Radioactive Residues in Grain from Wheat Treated with ^{14}C-*lambda*-cyhalothrin. Jealott's Hill Research Station Report No. RJ0836B. GLP study Not published	
AII 6.1	French DA and Leahey JP	1986	PP321: Quantification of Radioactive Residues Found in Soya Beans From Plants Treated with ^{14}C-PP321. Jealott's Hill Research Station Report No. RJ0438B. GLP study Not published	Germany (19/4/89), Italy (30/12/92).
AII 6.1	Hall JS and Leahey JP	1979	PP564: Degradation on apples. Jealott's Hill Research Station Report No.TMJ 1728B. Not GLP study Not published	Germany (19/4/89).
AII 6.1	Leahey JP, Collis WMD and French DA	1986	PP321: Quantification and Characterization of Radioactive Residues in Cotton Leaves From Plants Treated with ^{14}C-Benzyl-labelled PP321. Jealott's Hill Research Station Report No. RJ0497B. GLP study Not published	Germany (19/4/89), Italy (30/12/92).

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 6.1	Leahey JP and French DA	1985	PP321: Characterization of Radioactive Residues Found in Cotton Seeds From Plants Treated with ^{14}C-PP321, and Degradation of ^{14}C-PP321 Applied Directly to Cotton Seeds. Jealott's Hill Research Station Report No. RJ0393B. GLP study Not published	Germany (19/4/89), Italy (30/12/92).
AII 6.1	Leahey JP and French DA	1986a	PP321: - Quantification and Characterization of Radioactive Residues Found in Soya Leaves From Plants Treated with ^{14}C-PP321. Jealott's Hill Research Station Report No. RJ0507B. GLP study Not published	Germany (19/4/89), Italy (30/12/92).
AII 6.1	Leahey JP and French DA	1986b	PP321: Quantification and Characterization of Radioactive Residues found in Cotton Leaves From Plants Treated with ^{14}C-Cyclopropane-labelled PP321. Jealott's Hill Research Station Report No. RJ0526B. GLP study Not published	Germany (19/4/89), Italy (30/12/92).
AII 6.1	Leahey JP and Grout SJ	1990	*lambda*-Cyhalothrin: Quantification and Characterization of Radioactive Residues in Foliage from Wheat Treated with ^{14}C-*lambda*-cyhalothrin. Jealott's Hill Research Station Report No. RJ0889B. GLP study Not published	
AII 6.1	Leahey JP and Priestley DB	1987	PP321: Rotational crop study using ^{14}C-radiolabelled PP321. Jealott's Hill Research Station Report No. RJ0593B. GLP study Not published	Germany (19/4/89).
AII 6.1	Lloyd SJ, Curl EA and Leahey JP	1984	PP321: - Measurement of radioactive residues transferring into rotational crops grown in soil treated with ^{14}C-PP321. Jealott's Hill Research Station Report No. RJ0381B. GLP study Not published	Denmark, Finland (18/1/93), Germany (19/4/89), Italy (30/12/92), Sweden (30/5/91).
AII 6.1	Tummon OJ and Sapiets A	1988	PP321: Storage Stability in Frozen Crop Samples (Final Report). Jealott's Hill Research Station Report Series M4845B. GLP study Not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 6.2	Heath J and Leahey JP	1985	PP321: - Metabolism in laying hens. Jealott's Hill Research Station No. RJ0453B. GLP study Not published	France (9/5/86), Germany (19/4/89).
AII 6.2	Leahey JP, French DA and Heath J	1985	PP321: Metabolism in a goat. Jealott's Hill Research Station Report No. RJ0435B. GLP study Not published	France (9/5/86), Germany (19/4/89).
AII 6.2	Sapiets A	1985a	PP321:- Storage Stability in Deep Frozen Milk Samples. Jealott's Hill Research Station Report Series M3893B. GLP study Not published	
AII 6.2	Sapiets A	1985b	PP321:- Storage Stability in Frozen Animal Tissues. Jealott's Hill Research Station Report Series M3959B. GLP study Not published	
AII 6.3	Atger J-C, Ryan J and Sapiets A	1994	*lambda*-Cyhalothrin: Residue Levels in Melon from a Trial carried out in France during 1993. Jealott's Hill Research Station Report Series: RJ1687B. GLP study Not published	
AII 6.3	Benet F and Massenot F	1989	Recherche de Residus de *Lambda* cyhalothrine (ICIA0321) dans des Haricots. ICI Protection de l'Agriculture Report Series RE 8945 H. Not GLP study Not published	
AII 6.3	Benet F and Massenot F	1991	Recherche de Residus de *Lambda*-cyhalothrine dans de la Luzerne. ICI Protection de l'Agriculture Report Bernay RE-9116-E Not GLP study Not published	
AII 6.3	Bonfanti F, Ryan J and Sapiets A	1994a	*lambda*-Cyhalothrin: Residue Levels in Tomatoes From Trials Carried out in Italy During 1993. Jealott's Hill Research Station Report Series: RJ1626B. GLP study Not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 6.3	Bonfanti F, Ryan J and Sapiets A	1994b	*lambda*-Cyhalothrin: Residue Levels in Courgettes from Trials carried out in Italy during 1993. Jealott's Hill Research Station Report Series: RJ1623B. GLP study Not published	
AII 6.3	Bonfanti F, Ryan J and Sapiets A	1994c	*lambda*-Cyhalothrin: Residues Levels in Melon from a Trial carried out in Italy during 1993. Jealott's Hill Research Station Report Series: RJ1625B. GLP study Not published	
AII 6.3	Burke S and Sapiets A	1987a	PP321:-Residue Levels In Almonds From A Trial Carried Out In Italy During 1986. Jealott's Hill Report Series: M4385B. GLP study Not published	France (10/92), Italy (30/12/92).
AII 6.3	Burke S and Sapiets A	1987b	PP321: Residue Levels in Potatoes from a trial carried out in Denmark during 1986. Jealott's Hill Research Station Report Series: M4502B. GLP study Not published	Denmark (26/4/89), the Netherlands (5/2/94).
AII 6.3	Burke S, Tyldesley DJ and Sapiets A	1986	PP321: Residue Levels on Hops from Trials carried out in Germany during 1985 & Addendum. Jealott's Hill Research Station Report Series: M4315B. GLP study Not published	
AII 6.3	Clarke DM and Sapiets A	1990b	*lambda*-Cyhalothrin: Residue Levels of the Insecticide and its Metabolites in Dried Hops and Brewers Grains from Trials carried out in the Federal Republic of Germany during 1989. Jealott's Hill Research Station Report Series: M5114B, and Technical Letter 89JH152/1. GLP study Not published	
AII 6.3	Codd M, Ryan J, and Sapiets A	1994	*Lambda*-cyhalothrin: Residue Levels in Brassicae from Trials carried out in the United Kingdom During 1992-1993. Jealott's Hill Research Station Report RJ1619B. GLP study Not published	

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AII 6.3	Culoto B	1985	Recherche de Residus de PP321 dans des Salades. ICI Protection de l'Agriculture Report Series Bernay E 7-845-P, R 12-834-P, R 4-845-P. RIC1886. Not GLP study Not published	Belgium (8/11/85), France (9/5/86), Italy (30/12/92).
AII 6.3	Grimshaw K and Sapiets A	1987a	PP321: Residue Levels in Apples from a Trial carried out in Switzerland during 1986. Jealott's Hill Report Series: M4541B. Not GLP study Not published	Austria (18/7/91).
AII 6.3	Grimshaw K and Sapiets A	1987b	PP321:- Residue Levels in Strawberries from Trials carried out in Italy during 1986. Jealott's Hill Research Station Report Series: M4547B. GLP study Not published	Austria (18/7/91), France (3/88), Italy (30/12/92).
AII 6.3	Grimshaw K and Sapiets A	1987c	PP321: Residue Levels on Alfalfa from a Trial carried out in Italy during 1987. Jealott's Hill Research Station Report Series: M4556B. GLP study Not published	France (3/88), Italy (30/12/92).
AII 6.3	Jones SD	1995a	Residue Levels in Cauliflower and Broccoli from Trials carried out in the United Kingdom during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ1833B. GLP study Not published	
AII 6.3	Jones SD	1995b	Residue Levels in Courgettes from Trials carried out in France during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ1880B. GLP study Not published	
AII 6.3	Jones SD and Atger JC	1995	Residue Levels in Melons from Trials carried out in France during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ1873B. GLP study Not published	
AII 6.3	Jones SD and Bonfanti F	1996	Residue Levels in Cherries from Trials carried out in Italy during 1995. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2077B. GLP study Not published	

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AII 6.3	Jones SD and Mason R	1996	Residue Levels in Cauliflower from a Trial carried out in Spain during 1995. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2107B. GLP study Not published	
AII 6.3	Jones SD, Mason R and Hughes A	1996	Residue Levels in Lettuce from a Trial carried out in the United Kingdom during 1995. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2133B. GLP study Not published	
AII 6.3	Jones RN and Sapiets A	1987a	PP321: Residue Levels in Carrots from a Trial carried out in Italy during 1987. Jealott's Hill Research Station Report Series: M4558B. GLP study Not published	France (3/88), Italy (30/12/92).
AII 6.3	Jones RN and Sapiets A	1987b	PP321: Residue Levels in Courgettes from a Trial carried out in Italy during 1986. Jealott's Hill Research Station Report Series: M4552B. GLP study Not published	Italy (30/12/92).
AII 6.3	Jones RN and Sapiets A	1988a	PP321: Residue Levels in Apples from a Trial carried out in Greece During 1987. Jealott's Hill Report Series: M4628B. Not GLP study Not published	Greece (2/87), Italy (30/12/92).
AII 6.3	Jones RN and Sapiets A	1988b	PP321: Residue Levels on Peaches from a Trial carried out in Greece during 1987. Jealott's Hill Research Station Report Series: M4631B. GLP study Not published	Greece (2/87), Italy (30/12/92).
AII 6.3	Jones RN and Sapiets A	1988c	PP321: - Residue Levels in Celery from Trials carried out in the United Kingdom during 1987. Jealott's Hill Research Station Report Series: M4634B. GLP study Not published	France (12/93).
AII 6.3	Jones RN and Sapiets A	1991	*Lambda*-cyhalothrin: Residue Levels in Cereals from Trials carried out in the United Kingdom during 1989-90. Jealott's Hill Report Series : RJ0991B. Not GLP study Not published	

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AII 6.3	Jones SD and Tobias A	1995a	Residue Levels in Cauliflower from Trials carried out in France during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ1989B. GLP study Not published	
AII 6.3	Jones SD and Tobias A	1995b	Residue Levels in Cauliflower from Trials carried out in France during 1994 and 1995. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ1990B. GLP study Not published	
AII 6.3	Kennedy G, Murnane D and Sapiets A	1987	PP321:- Residue Levels on Oil Seed Rape from Trials carried out in Germany during 1986. Jealott's Hill Research Station Report Series M4400B. GLP study Not published	
AII 6.3	Kennedy G and Sapiets A	1986	PP321: - Residue Levels in Cauliflower From a 1985 Trial in Germany. Jealott's Hill Research Station Report Series M4226B. GLP study Not published	Italy (30/12/92).
AII 6.3	Kennedy G and Sapiets A	1987a	PP321: Residue Levels in Hazelnuts from a Trial Carried Out in Italy During 1986. Jealott's Hill Report Series: M4407B. GLP study Not published	France (10/92), Italy (30/12/92).
AII 6.3	Kennedy G and Sapiets A	1987b	PP321: Residue Levels on Strawberries from Trials carried out in the United Kingdom during 1986. Jealott's Hill Research Station Report Series: M4496B. GLP study Not published	Austria (18/7/91), France (3/88), Italy (30/12/92).
AII 6.3	Kennedy G and Sapiets A	1987c	PP321: - Residue Levels in Artichokes from a Trial carried out in Italy during 1986. Jealott's Hill Research Station Report Series: M4468B. GLP study Not published	France (3/88), Italy (30/12/92).
AII 6.3	Kennedy G, Napper J and Sapiets A	1987	PP321: Residue Levels on Grass from Trials carried out in Germany during 1986. Jealott's Hill Research Station Report Series: M4411B. GLP study Not published	Italy (30/12/92).

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 6.3	Kinkaid A and Sapiets A	1986a	PP321:- Residue Levels on Plums from Trials Carried Out in Canada During 1985. Jealott's Hill Research Station Report Series: M4202B. GLP study Not published	Austria (18/7/91), France (2/87), Italy (30/12/92).
AII 6.3	Kinkaid A and Sapiets A	1986b	PP321: - Residue Levels on Grass from Trials carried out in Germany during 1985. Jealott's Hill Research Station Report Series: M4232B. GLP study Not published	Denmark (26/4/89), Sweden (30/5/91).
AII 6.3	Massenot F	1996	*lambda*-Cyhalothrin: Residues in plums. SOPRA. Study nymber 94-S015 Not GLP study Not published	
AII 6.3	Massenot F and Culoto B	1985	Recherche de Residus de PP321 dans des Raisins. ICI Protection de l'Agriculture, Bernay Report Series: E 28-EP, E 29-EP, R 29-EP. Not GLP study Not published	France (9/5/86), Greece (2/87), Italy (30/12/92), Luxembourg (2/93).
AII 6.3	Massenot F and Culoto B	1987a	Recherche de Residus de *Lambda* cyhalothrine dans des Pommes. ICI Protection de l'Agriculture, Bernay Report S 55 FP. Not GLP study Not published	Austria (18/7/91), France (2/87), Italy (30/12/92).
AII 6.3	Massenot F and Culoto B	1987b	Recherche de Residus de *lambda* cyhalothrine dans des Poireaux. ICI Protection de l'Agriculture Report Bernay E 19 GP, S 04 GP. RIC1763. Not GLP study Not published	Belgium (23/2/94), France (3/88), Italy (30/12/92).
AII 6.3	Massenot F and Culoto B	1987c	Recherche de Residus de *Lambda* cyhalothrine dans des Artichauts. ICI Protection de l'Agriculture Report Bernay S 11 GP. RIC1765. Not GLP study Not published	France (3/88), Italy (30/12/92).
AII 6.3	Massenot F and Culoto B	1988a	Recherche de Residus de *Lambda* cyhalothrine dans des Fraises. ICI Protection de l'Agriculture Report Bernay S 03 GP. Not GLP study Not published	Austria (18/7/91), Denmark (8/89), Finland (7/7/93), France (3/88), Italy (30/12/92).

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AII 6.3	Massenot F and Culoto B	1988b	Recherche de Residus de ICIA0321 dans des Fraises. ICI Protection de l'Agriculture Report Bernay SE 042 HP. Not GLP study Not published	Finland (7/7/93), France (3/88), Italy (30/12/92).
AII 6.3	Massenot F and Culoto B	1988c	Recherche de Residus de *Lambda* cyhalothrine dans des Epinards. ICI Protection de l'Agriculture Report Series S03GP. RIC1766. Not GLP study Not published	France (3/88).
AII 6.3	Murnane D and Sapiets A	1987	PP321:- Residue Levels in Celery from a Trial carried out in Italy during 1986. Jealott's Hill Research Station Report Series: M4493B. GLP study Not published	France (3/88), Italy (30/12/92).
AII 6.3	Ruskin Y and Sapiets A	1986	PP321:- Residue Levels on Lentils from a Trial carried out in Italy during 1986. Jealott's Hill Research Station Report Series M4374B. GLP study Not published	Italy (30/12/92).
AII 6.3	Ruskin Y, Tyldesley and Sapiets A	1986	Residue Levels in Cereals from 1985 trials in Germany. ICI Plant Protection Products. Report Series: M4146B. Not GLP study Not published	
AII 6.3	Ryan J and Sapiets A	1993	*Lambda*-cyhalothrin: Residue Levels in Hops from Trials carried out in Germany during 1992. Jealott's Hill Research Station Report Series: RJ1484B. GLP study Not published	Belgium (17/3/94).
AII 6.3	Sapiets A	1984	PP321:- Residue Levels on Apricots from a 1984 Trial in Greece. Jealott's Hill Research Station Report Series: M3964B. GLP study Not published	Greece (2/87), Italy (20/5/87).
AII 6.3	Sapiets A	1985c	PP321:- Residue Levels in sugar and fodder beets from 1984 trials in Denmark. ICI Plant Protection Division Report Series: M4011B. Not GLP study Not published	Denmark, France (5/90), Italy (30/12/92).

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AII 6.3	Sapiets A	1985d	PP321:- Residue Levels in Wheat and Barley 1984 trials in France. ICI Plant Protection Products. Report Series: M3908B. Not GLP study Not published	
AII 6.3	Sapiets A	1985e	PP321:- Residue Levels on Apples from a 1984 Trial in Greece. Jealott's Hill Research Station Report Series: M3997B. GLP study Not published	Greece (2/87), Italy (30/12/92).
AII 6.3	Sapiets A	1985f	PP321:- Residue Levels in Stone Fruits from 1984 Trials in Canada. Jealott's Hill Research Station Report Series: M4004B. GLP study Not published	France (2/87).
AII 6.3	Sapiets A	1985g	PP321: - Residue Levels on Cabbage from 1984 Trials in the United Kingdom. Jealott's Hill Research Station Report Series: M3933B. GLP study Not published	Denmark (26/4/89), Finland (18/1/93), France (9/5/86), Italy (30/12/92), Sweden (30/5/91), UK (14/2/90).
AII 6.3	Sapiets A	1985h	PP321: Residue Levels in Potatoes from a 1984 trial in Greece. Jealott's Hill Research Station Report Series: M4027B. GLP study Not published	Greece (2/87), the Netherlands (5/2/94).
AII 6.3	Sapiets A	1986a	PP321: - Residue Trials on Pears from trials carried out in the United Kingdom during 1985. ICI Plant Protection Division Report Series: M4280B. Not GLP study Not published	Denmark.
AII 6.3	Sapiets A	1986b	PP321:- Residue Levels on Apples from Trials carried out in the United Kingdom During 1985. Jealott's Hill Research Station Report Series: M4279B. GLP study Not published	Austria (18/7/91), France (2/87).
AII 6.3	Sapiets A	1986c	PP321: Residue Levels on Cabbage from a 1985 Trial in the United Kingdom. Jealott's Hill Research Station Report Series: M4278B. GLP study Not published	Denmark (26/4/89), Sweden (30/5/91).

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AII 6.3	Sapiets A	1987a	PP321: Residue Levels in Pears from Trials carried out in Greece during 1986. ICI Plant Protection Division Report Series: M4494B. Not GLP study Not published	Greece (5/87), Italy (30/12/92).
AII 6.3	Sapiets A	1987b	PP321:-Residue Levels in Blackcurrants from Trials carried out in the United Kingdom during 1986. Jealott's Hill Report Series: M4490B. Not GLP study Not published	Austria (18/7/91), Denmark (8/89), France (3/88), Italy (30/12/92).
AII 6.3	Sapiets A	1987c	PP321: Residue Levels on Eggplant (Aubergine) from a Trial carried out in Italy during 1986. Jealott's Hill Research Station Report Series: M4392B. GLP study Not published	Italy (30/12/92).
AII 6.3	Tummon OJ and Bonfanti F	1996a	Residue Levels in Pears from Trials carried out in Italy 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2103B. GLP study Not published	
AII 6.3	Tummon OJ and Bonfanti F	1996b	Residue Levels in Cherries from a Trial carried out in Italy during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2125B. GLP study Not published	
AII 6.3	Tummon OJ and Bonfanti F	1996c	Residue Levels in Courgettes from Trials carried out in Italy during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2126B. GLP study Not published	
AII 6.3	Tummon OJ and Bonfanti F	1996d	Residue Levels in Melons from Trials carried out in Italy during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2123B. GLP study Not published	
AII 6.3	Tummon OJ and Sapiets A	1987	PP321: Residue Levels on Strawberries from trials carried out in Canada during 1986. Jealott's Hill Research Station Report Series M4401B. Not GLP study Not published	Austria (18/7/91), France (3/88).

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AII 6.3	Tummon OJ and Sapiets A	1989	*Lambda* cyhalothrin:- Residue Levels in Hops from Trials carried out in France during 1987. Jealott's Hill Research Station Report Series: M4894B GLP study Not published	France (4/91).
AII 6.3	Tummon OJ, Taylor PS and Volpi E	1996	Residue Levels in Cauliflower from a Trial carried out in Italy during 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2044B. GLP study Not published	
AII 6.3	Tummon OJ, Volpi E and Bonfanti F	1996	Residue Levels in Peaches from a Trial carried out in Italy 1994. Zeneca Agrochemicals. Jealott's Hill Research Station. Report Series: RJ2104B. GLP study Not published	
AII 6.3	Tyldesley DJ and Sapiets A	1985a	PP321: Residue Levels in Field Peas from 1984 Trials in the United Kingdom. Jealott's Hill Research Station Report Series: M4089B. GLP study Not published	Belgium (23/2/94), Denmark (26/4/89), Finland (18/1/93), Italy (30/12/92), Sweden (30/5/91), UK (14/2/90).
AII 6.3	Yearsdon C and Sapiets A	1986a	PP321: - Residue Levels on Cherries from a 1985 Trial in Germany. Jealott's Hill Research Station Report Series: M4238B. GLP study Not published	Austria (18/7/91), France (2/87), Italy (30/12/92).
AII 6.3	Yearsdon C and Sapiets A	1986b	PP321: - Residue Levels in Plums from Trials carried out in Germany during 1985. Jealott's Hill Research Station Report Series: M4284B. GLP study Not published	Austria (18/7/91), Denmark (8/89), France (2/87), Italy (30/12/92), Sweden (27/12/94).
AII 6.3	Yearsdon C and Sapiets A	1986c	PP321: - Residue Levels on Peas from Trials carried out in Germany during 1985. Jealott's Hill Research Station Report Series: M4287B. GLP study Not published	Belgium (23/2/94), Denmark (26/4/89), Sweden (30/5/91).
AII 6.4	Eckstein CL and Francis PD	1992	*lambda*-Cyhalothrin (ICIA0321): Residue Levels of the Major Metabolites in Dairy Cows fed on a Diet containing the Insecticide. Western Research Center Report Series RR 92-028B. Not GLP study Not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 6.4	Sapiets A	1985i	PP321: Residue Transfer Study with Dairy Cows fed on a Diet containing the Insecticide. Jealott's Hill Research Station Report Series M3936B. GLP study Not published	Austria (18/7/91), Finland (18/1/93), France (6/91), Italy (30/12/92), the Netherlands (7/4/92), Sweden (30/5/91).
AII 6.4	Sapiets A	1986d	PP321: Residue Transfer Study with Laying Hens fed on a Diet containing the Insecticide. Jealott's Hill Research Station Report Series RJ0473B. GLP study Not published	
AII 6.5	Gillespie PS	1990	ICIA0321 (*lambda*-cyhalothrin) - Magnitude of the residue study in processed tomato products. Western Research Center, Richmond, California Report Series RR 90-419B. Not GLP study Not published	
AII 6.5	Grant CL and Francis PD	1991	ICIA0321 (*lambda*-cyhalothrin) - Magnitude of the residue study on processed field corn products. Western Research Center, Richmond, California Report Series RR 91-027B. Not GLP study Not published	
AII 6.5	McKay JC	1991a	*lambda*-Cyhalothrin (ICIA0321) -Magnitude of the residue study on processed wheat products. Western Research Center, Richmond, California Report Series RR 90-424B. GLP study Not published	
AII 6.5	McKay JC	1991b	Karate^{R} (*lambda*-cyhalothrin) - Magnitude of the residue study on processed sorghum products. Western Research Center, Richmond, California Report Series RR 90-426B. GLP study Not published	
AII 6.5	McKay JC	1991c	ICIA0321 (*lambda*-cyhalothrin) -Magnitude of the residue study on processed soybean products. Western Research Center, Richmond, California Report Series RR 91-048B. GLP study Not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 6.5	Neal J	1985	PP321 residues in the process fractions of cottonseed. ICI Americas Report Series TMU1805. Not GLP study Not published	

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 7.1.1.1.1 AII 7.1.1.1.2 AII 7.1.1.2.1	Bharti H, Bewick DW and White RD	1985	PP563 and PP321: Degradation in Soil. ICI Report Series RJ 0382B GLP study Not published	Submitted in all Member States except Belgium, France, Greece, Ireland, Luxembourg, the Netherlands, Portugal & Spain.
AII 7.1.1.1.2	Parker S and Leahey JP	1986	PP321: Photodegradation on a Soil Surface. ICI Report Series RJ 0537B GLP study Not published	Denmark, Germany (25/10/90), Sweden (30/5/91).
AII 7.1.1.2.2 AIII 9.1.1.2	Bewick DW, Bartlett DW and Hendley P	1986	PP321: Fate of Radiolabelled Material in Soil under Field Conditions. ICI Report Series RJ 0529B GLP study Not published	Austria (18/7/91), Germany (25/10/90), Italy (30/12/92).
AII 7.1.1.2.2 AIII 9.1.1.2	Burke S and Sapiets A	1990	*lambda*-Cyhalothrin: Soil Dissipation Studies (West Germany 1989). ICI Report Series RJ 0879B GLP study Not published	Germany (25/10/90).
AII 7.1.1.2.2 AIII 9.1.1.2	Fitzpatrick RD	1985	PP321 Dissipation in US Soils -1983. ICI Report Series TMU1809 Not GLP study Not published	
AII 7.1.2	Vickers JA and Bewick DW	1986	PP321: Adsorption and Desorption in Soil. ICI Report Series RJ 0535B GLP study Not published	Austria (18/7/91), Italy (30/12/92), the Netherlands.
AII 7.1.3.1 AIII 9.1.2.1	Clarke DM and Sapiets A	1993	*lambda*-Cyhalothrin: Leaching of Formulated Material in Soil Columns. ICI Report Series RJ 1447B GLP study Not published	
AII 7.1.3.2	Stevens JEB and Bewick DW	1985	PP563 and PP321: Leaching of PP563 and PP321 and their Degradation Products in Soil Columns. ICI Report Series RJ 0408B GLP study Not published	Submitted in all Member States except Belgium, France, Greece, Ireland, Luxembourg, Portugal & Spain.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 7.2 AII 8.2 AII 8.3	Maund SJ	1998	*Lambda*-cyhalothrin. Response of ZENECA to National Chemicals Inspectorate (KEMI) Appendix 3 to *Lambda*-cyhalothrin 5684/VI/97 rev 5 (September 1998). Zeneca Agrochemicals Report No. RAJ0003B. GLP not relevant Not published	
AII 7.2 AII 8.2 AIII 10.2.2	Farmer D, Coulson JM, Runnalls JK, Hill SE, McIndoe EC and Hill IR	1993	*lambda*-Cyhalothrin and Cypermethrin: Evaluation and Comparison of the Impact of Multiple Drift Applications on Aquatic Ecosystems (Experimental Ponds). ICI Report Series RJ 0571B GLP study (with deviations) Not published	
AII 7.2 AII 8.2 AIII 10.2.2	Kennedy JH, Cole JFH, Ekoniak P, Hadfield ST, Sadler JK, Francis PD, Moore M and Hill IR	1988	PP321: Evaluation of the Impact of the Run-off and Spray-frift on Aquatic Ecosystems, Using USA Experimental ponds (Mesocosms). ICI Plant Protection Division Report No. RJ0614B. GLP study Not published	
AII 7.2.1.2 AII 7.2.1.3.2	Hall JS and Leahey JP	1983	Cyhalothrin: Fate in River Water. ICI Report Series RJ 0320B Not GLP study Not published	Austria (18/7/91), Denmark, Finland (18/1/93), Germany (25/10/90), the Netherlands, Sweden (30/5/91).
AII 7.2.1.3.2	Hand LH and Mehta P	1998a	Lambda-cyhalothrin: Degradation in an Aquatic Microcosm. Zeneca Agrochemicals Report No. RJ2730B. GLP study Not published	
AII 7.2.1.3.2	Hand LH and Mehta P	1998b	Lambda-cyhalothrin: Metabolism in Aquatic Plants. Zeneca Agrochemicals Report No. RJ2626B. GLP study Not published	
AII 7.2.1.3.2	Hamer MJ and Goggin UM	1997	Lambda-cyhalothrin: Dissipation from water in a sediment-water system. Zeneca Agrochemicals Report No. RJ2369B. GLP study Not published	
AII 7.2.1.3.2	Kuet SF	1998	Lambda-Cyhalothrin: Adsorption and desorption in Aquatic Plants. Zeneca Agrochemicals Report No. RJ2716B. GLP study Not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 7.2.1.3.2	Marriott SH, Duley J, Hand L	1998	Lambda-cyhalothrin: Degradation in Water-sediment Systems Under Laboratory Conditions. Zeneca Agrochemicals Report No. RJ2640B. GLP study Not published	
AII 7.1.1.2.1	Chongtie S, Ericson J	1998	[^{14}C]R211133 (Ref.XV), a metabolite of LAMBDA-CYHALOTHRIN: Rate of degradation in soil under aerobic laboratory conditions (WRC-98-040B (WINo 32874). Zeneca Agrochemicals Report No. RR 98-019B GLP study Not published	Netherlands (25/9/98).
AII 7.1.2	Feeney E, Lane MCG	1998	Adsorption and desorption properties of compound XV (R211133), a soil degradate, in six soils. Zeneca Agrochemicals Report No. RJ2622B GLP study Not published	Netherlands (25/9/98).

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 8.1.1	Roberts NL, Fairley C	1984	The acute oral toxicity (LD_{50}) of PP321 to the mallard duck. Huntingdon Research Centre Report No. ICI438 BT/831011. CTL/C/1240. GLP study Not published	Submitted in all Member States except Greece, Ireland, Luxembourg & Portugal.
AII 8.1.2	Roberts NL, Fairley C, Anderson A and Dawe IS	1985	The subacute dietary toxicity of PP321 to the bobwhite quail. Huntingdon Research Centre Report No. ISN 45BT/841287. CTL/C/1358. GLP study Not published	Austria (18/7/91), Denmark, Finland (18/1/93), Germany (19/4/89), Italy (30/12/92), Sweden (30/5/91), UK (14/2/90).
AII 8.1.3	Beavers JB, Hoxter KA and Jaber MJ	1989	PP321: A one-generation reproduction study with the mallard (*Anas platyrhynchos*). Wildlife International Report No: 123-143. GLP study Not published	Germany (25/10/90).
AII 8.1.3	Gorder GW	1990	Measurement of PP321 Levels in Feed Used in a One-Generation Reproduction Study with the Mallard (*Anas platyrhynchos*). Western Research Center Report No. 89-242. RR 89-059B GLP study Not published	
AII 8.2.1	Hill RW	1984a	PP321 : Determination of acute toxicity to rainbow trout (*Salmo gairdneri*). Brixham Laboratory Report BL/B/2405. GLP study Not published	Submitted in all Member States except Greece, Ireland, Luxembourg & Portugal.
AII 8.2.1	Hill RW	1984b	PP321: Determination of acute toxicity to bluegill sunfish (*Lepomis macrochirus*). Brixham Laboratory Report BL/B/2406. GLP study Not published	Submitted in all Member States except Belgium, Greece, Ireland, Luxembourg, Portugal & Spain.
AII 8.2.1	Hill RW	1984c	PP890: Determination of the acute toxicity to rainbow trout (*Salmo gairdneri*). Brixham Laboratory Report No. BL/B/2457. GLP study Not published	Germany, the Netherlands.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 8.2.1	Hill R and Young BE	1981a	Determination of the acute toxicity of 3-Phenoxybenzoic acid to Rainbow trout (*Salmo gairdneri*). ICI Brixham Laboratory report No. BL/B/2038. Not GLP study Not published	Germany, the Netherlands.
AII 8.2.1	Hill R and Young BE	1981b	Determination of the acute toxicity of 3-Phenoxybenzoic acid to Bluegill sunfish (*Lepomis macrochirus*). ICI Brixham Laboratory Report No. BL/B/2086. Not GLP study Not published	Germany, the Netherlands.
AII 8.2.1	Tapp JF and Caunter JE	1987	PP890: Determination of the acute toxicity to bluegill sunfish (*Lepomis macrochirus*). Brixham Laboratory Report No. BL/B/3029. GLP study Not published	Germany, the Netherlands.
AII 8.2.2.1	Hill RW, Caunter JE and Cumming RI	1985	PP321: Determination of the chronic toxicity to sheepshead minnow (*Cyprinodon variegatus*) embryos and larvae. Brixham Laboratory Report No. BL/B/2677. GLP study Not published	France (2/87), Germany (25/10/90).
AII 8.2.3	Hamer MJ and Hill IR	1985	Cyhalothrin : The accumulation of cyhalothrin and its degradation products by channel catfish and *Daphnia magna* in a soil/water system. ZENECA Agrochemicals Report No. RJ0427B. GLP study Not published	Denmark, Finland (18/1/93), Germany (25/10/90), Sweden (30/5/91).
AII 8.2.3	Yamauchi F	1984	PP563 (Cyhalothrin) : Accumulation in fish (carp) in a flow-through water system. MITES Report No. 58-367. RIC2139. GLP study Not published	Germany (25/10/90).
AII 8.2.4	Everett CJ, Hamer MJ and Hill IR	1983	3-Phenoxybenzoic acid: Toxicity to first instar *Daphnia magna* (II). ICI Plant Protection Division report No. RJ0318B. Not GLP study Not published	Germany, the Netherlands.
AII 8.2.4	Farrelly E, Hamer M J and Hill IR	1984	PP321 : Toxicity to first instar *Daphnia magna*. Jealott's Hill Research Station Report No RJ0359B. GLP study Not published	Submitted in all Member States except Greece, Ireland, Luxembourg, Portugal & Spain.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 8.2.4	Goggin UM, Hamer MJ	1998	Lambda-Cyhalothrin. Acute toxicity of short-term exposures to *Gammarus pulex*. Zeneca Agrochemicals Report No. RJ2542B. GLP study Not published	
AII 8.2.4	Hamer MJ and Goggin UM	1998a	Lambda-cyhalothrin: Acute toxicity to different life-stages of *Gammarus pulex*. Zeneca Agrochemicals Report No. RJ2483B. GLP study Not published	
AII 8.2.4	Hamer MJ and Goggin UM	1998b	Lambda-cyhalothrin: Acute toxicity to *Gammarus pulex* in a sediment-water system. Zeneca Agrochemicals Report No. RJ2484B. GLP study Not published	
AII 8.2.4	Yamauchi F and Shigeoka T	1984	PP-563 ("Cyhalothrin acid"): Acute toxicity to *Daphnia magna*. Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences (MITES) Report No. 58-367. GLP study Not published	Germany, the Netherlands.
AII 8.2.5	Farrelly E and Hamer MJ	1989	PP321 : *Daphnia magna* life-cycle study using a flow-through system. Jealott's Hill Research Station Report No RJ0764B. GLP study Not published	Germany, the Netherlands.
AII 8.2.5	Kedwards TJ	1998a	A Stage-Structured Ecological Model of the Freshwater Amphipod *Gammarus pulex* (L.). Zeneca Agrochemicals Report No. TMJ4047B. GLP not relevant Not published	
AII 8.2.5	Kedwards TJ	1998b	Lambda-cyhalothrin: Ecological modelling of effects on and recovery of *Gammarus pulex* (L.) populatons. Zeneca Agrochemicals Report No. TMJ4155B. GLP not relevant Not published	
AII 8.2.6	Thompson RS and Williams TD	1985	PP321 : Toxicity to the green alga *Selenastrum capricornutum*. Brixham Laboratory Report No BL/B/2584. GLP study Not published	Denmark, Finland (18/1/93), Germany (19/4/89), the Netherlands, Sweden (30/5/91).

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 8.2.7	Hamer M and Gentle W	1997	Lambda-cyhalothrin: Sediment Toxicity Test with *Chironomus riparius*. Zeneca Agrochemicals Report No. RJ2227B. GLP study Not published	
AII 8.2.7	Hamer MJ and Rapley JH	1997	Lambda-cyhalothrin: BBA Toxicity Test with Sediment-dwelling *Chironomus riparius*. Zeneca Agrochemicals Report No. RJ2234B. GLP study Not published	
AII 8.2.7	Muller K, Hamer MJ, Goggin U and Lane MCG	1995	Lambda-Cyhalothrin: Bioavailability and Bioconcentration by *Chironomus riparius* in in Water-only and Sediment/Water Systems. Zeneca Agrochemicals Study No. RJ1933B. GLP study Not published	
AII 8.3.1 AIII 10.4.1	Gough HJ, Collins IG, Everett CJ and Wilkinson W	1984	PP321: Acute Contact and Oral Toxicity to Honey Bees (*Apis mellifera*). Jealott's Hill Research Station Report No. RJ0390B. GLP study Not published	Submitted in all Member States except Germany, Greece, Ireland, Luxembourg, Portugal & Spain.
AII 8.3.1 AIII 10.4.4	Gough HJ, Collins IG and Wilkinson W	1985	PP321: Field Test of Toxicity to Honey Bees (*Apis mellifera*) on Flowering Oilseed Rape (*Brassica napus*). Jealott's Hill Research Station Report No. RJ0413B. GLP study Not published	Submitted in all Member States except Germany, Greece, Ireland, Luxembourg, Portugal & Spain.
AII 8.3.1 AIII 10.4.5	Gough HJ, Collins IG and Wilkinson W	1986	PP321: Effects on Honey Bees (*Apis mellifera*) Foraging on Simulated Honeydew on Winter Wheat, 1985. Jealott's Hill Research Station Report No. RJ0464B. GLP study Not published	Greece (2/87), Italy (30/12/92), the Netherlands, Sweden (30/5/91).
AII 8.3.1 AIII 10.4.4	Nengel S	1999	Assessment of Side Effects of Karate WG on the Honey Bee (*Apis mellifera* L.) in the Field Following Application during Bee-Flight in Spain. Report code: 98139/S1-BFEU/C. GLP study Not published	
AII 8.3.2 AIII 10.5.1	Busschers M and Farrelly LC	1994a	*Lambda*-cyhalothrin: Laboratory Test on the Effects of 3 Different Formulations on predatory Lycosid Spiders (Lycosidae, Araneae). Jealott's Hill Research Station Report No. RJ1580B. GLP study Not published	

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AII 8.3.2 AIII 10.5.1	Busschers M and Farrelly LC	1994b	*Lambda*-cyhalothrin: Laboratory Test on the Effects of 3 Different Formulations on the Carabid Beetle *Poecilus cupreus*. Jealott's Hill Research Station Report No. RJ1579B. GLP study Not published	
AII 8.3.2 AIII 10.5.1	Deprez C and McMullin LC	1993	*Lambda*-cyhalothrin: Investigation into the Toxicity of a 5% WG Formulation to the Larvae of the Hoverfly *Episyrphus balteatus* De Geer. Jealott's Hill Research Station Report No. RJ1399B. GLP study Not published	Italy (30/12/92).
AII 8.3.2 AIII 10.5.1	Everett CJ and Cole JFH	1993a	*Lambda*-cyhalothrin: Laboratory Test on the Effects on the Ground Beetle *Pterostichus melanarius*. Jealott's Hill Research Station Report No. RJ1327B. GLP study Not published	
AII 8.3.2 AIII 10.5.1	Everett CJ and Cole JFH	1993b	*Lambda*-cyhalothrin: Laboratory Test on the Effects on Lycosid spiders. Jealott's Hill Research Station Report No. RJ1329B. GLP study Not published	
AII 8.3.2 AIII 10.5.2	McMullin LC, Everett CJ, White JS and Brown RA	1991	*Lambda*-cyhalothrin : Effects of a summer application to cereals on the beneficial arthropod fauna. Jealott's Hill Research Station Report No. RJ0956B. GLP study Not published	Italy (30/12/92).
AII 8.3.2 AIII 10.5.2	McMullin LC, Everett CJ, Canning L and Brown RA	1992	*Lambda*-cyhalothrin: The Effects of a Summer Application on the Beneficial Arthropod Fauna in Cereals Using Three Different Spray Rates. Jealott's Hill Research Station Report No. RJ1250B. GLP study Not published	Austria (18/7/91), Germany (25/10/90).
AII 8.3.2 AIII 10.5.2	Pilling ED	1995	Lambda-cyhalothrin: A Study of the Effects on Natural Enemies of Rice Insect pests in the Philippines. Zeneca Agrochemicals Study No. TMJ3453B. Not GLP study Not published	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 8.3.2 AIII 10.5.1	Solomon MG and Fitzgerald JD	1989	Laboratory Determination of LC_{50} for PP321 against *Panonychus ulmi* and *Typhlodromus pyri*. Undertaken for ICI Agrochemicals. AFRC Institute of Horticultural Research Not GLP study Not published	Germany (25/10/90), Italy (30/12/92).
AII 8.3.2	White JS, Boersma AHR and Brown RA	1989	PP321: Laboratory LD_{50} Test on the Aphid Pest *Rhopalosiphum padi* and a Range of its Enemies. Jealott's Hill Research Station Report No. RJ0686B. GLP study Not published	Austria (18/7/91), Germany (25/10/90), Italy (30/12/92).
AII 8.3.2 AIII 10.5.2	White JS and Brown RA	1992	Lambda-cyhalothrin: Effects of application in soybean on the principal target pests and their key natural enemies. ICI Agrochemicals Report No. TMJ2969A. Not GLP study Not published	
AII 8.3.2 AIII 10.5.2	White JS, Everett CJ, Jackson DJ and Brown RA	1989	PP321 : Effects of autumn application to cereals on the beneficial arthropod fauna. Jealott's Hill Research Station Report No. RJ0728B. GLP study Not published	Austria (18/7/91), Germany (25/10/90).
AII 8.3.3	Yearsdon HA, Coulson JM and Edwards PJ	1993	*Lambda*-cyhalothrin: Toxicity to the Earthworm *Eisenia foetida*. Jealott's Hill Research Station Report No. TMJ3062B. Not GLP study Not published	
AII 8.3.4	Aze CJ, Tarry AR and Lewis FJ	1990	PP321: Studies on Microorganisms and their Activities in Soil. Jealott's Hill Research Station Report No. RJ0853B. GLP study Not published	Germany (25/10/90).
AII 8.3.5	Rea D, Mannion SK, Martin EA and Hill IR	1989	PP321 : Effects on the Plants in the Weed Science and Plant Growth Regulator Screens of the Biological Group. ICI Agrochemicals unpublished Report No. RJ0565B. GLP study Not published	Germany (25/10/90).

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 8.3.5	Rea D, Palk MS, Spinney MA and Hill IR	1990	PP321 : Effects on the Plant Pathogens and Invertebrate Pests in the Plant Pathology and Entomology Screens of the Biological Group. ICI Agrochemicals unpublished Report No. RJ0549B. GLP study Not published	

EXTRACT OF SUMMARY REPORT OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH HELD ON 19 OCTOBER 2000 IN BRUSSELS

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

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Examination and possible vote on a Draft Commission Directive concerning the consolidation of Annex I and the inclusion of lambda-cyhalothrin in Annex I to Council Directive 91/414/EEC
(Directive Sanco/2481/2000 rev.9; Review Report 7572/VI/97-rev.6).

The Commission presented the Review Report on lambda-cyhalothrin in document 7572/VI/97-rev. 6. The Committee took note of the Review Report.

The following declarations were made:

Spain: "The Spanish delegation does not agree to the methodology used to set the acute Reference Dose. The acute Reference Dose should be set on the basis of acute studies and not on short term studies, as it was done in this case. If taking into account studies of 6 weeks, 3 months or 2 years to establish the acute Reference Dose for the consumer risk assessment, it is necessary also to take into account average diet intakes of 6 weeks, 3 months or 2 years in order to be coherent, and not only the diet of one day."

This declaration was supported by Greece.

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 if 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).

The Commission subsequently presented the draft Commission Directive concerning the consolidation of Annex I to Directive 91/414/EEC and the inclusion of lambda-cyhalothrin.

Vote : unanimous favourable opinion.

The substance is an existing active substance used as an insecticide.

...

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/LAMBDA/002- Final
29 February 2000

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

(Opinion expressed by the Scientific Committee on Plants, 28 January 2000)

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

Terms of Reference

(1) Can the Committee comment on the appropriate dietary risk assessment to be used?
(2) Can it be confirmed that the proposed risk mitigation measures for aquatic organisms would avoid unacceptable risk for the aquatic environment?
(3) Can it be confirmed that the proposed risk mitigation measures are adequate to protect non-target arthropods and honey bees?

Background

Lambda-cyhalothrin is an existing active substance in the context of Directive 91/414/EEC[1] concerning the placing of plant protection products on the market and is one of the active substances covered by the first stage of the work programme provided for under the Directive.

To answer the questions the Committee had access to documentation comprising a Monograph prepared by Sweden as Rapporteur Member State (RMS) and further information from the ECCO[2] Peer Review programme.

Lambda-cyhalothrin is a synthetic pyrethroid insecticide and is effective against harmful organisms via contact and stomach action.

Plant protection products with lambda-cyhalothrin as an active substance are authorised for use in agriculture, horticulture, hops, viticulture, stored grain and forestry.

Question 1

Can the Committee comment on the appropriate dietary risk assessment to be used?

Opinion

Lambda-cyhalothrin belongs to the group of pyrethroids containing an α-cyano-group which are known to be potentially neurotoxic. In addition to a long-term dietary intake risk assessment, as routinely carried out for plant protection products, *lambda*-cyhalothrin should also undergo a short-term acute dietary risk assessment due to its potential neurotoxicity properties.

An Acute Reference Dose (ARfD) would be needed for this reason. For guidance on establishing an ARfD, the Committee refers the reader to the "Opinion of the Scientific

[1] OJ No L230, 19.8.91, p. 1
[2] European Community Co-ordination

Committee on Plants on the general criteria for setting acute reference doses for plant protection products", expressed on 28 January 2000. In addition, attention is drawn to the "Report of the International Conference on Pesticide Residues Variability and Acute Dietary Assessment", 1-3 December 1998, York, and the JMPR Report 1998 (FAO PLANT PRODUCTION AND PROTECTION PAPER 148).

Question 2

Can it be confirmed that the proposed risk mitigation measures for aquatic organisms would avoid unacceptable risk for the aquatic environment?

OPINION

The Committee is of the opinion that the recommended buffer zones, based on a combination of laboratory and higher-tier mesocosm studies, are scientifically justifiable. It is recommended that the comprehensive set of buffer values recommended by the RMS be used for guidance purposes.

The Committee emphasises that whereas the recommended buffer zones provide a useful starting point for defining risk mitigation measures, they must be re-evaluated by each Member State with respect to local conditions and specific use scenarios of *lambda*-cyhalothrin. All of the recommended buffer zones are based on the German Spray Drift Model (Ganzelmeier et al. 1995), but local agronomic practices and aquatic ecosystems may vary considerably from the conditions under which this model has been derived, and therefore local variations should be taken into consideration when determining risk reduction measures at a Member State level. Given the very steep exposure-response curve for aquatic species, it is essential that the buffer zones, once adjusted for local conditions, be strictly enforced in practice.

Scientific Background on Which the Opinion is Based

The risk mitigation measures proposed to avoid unacceptable risk for the aquatic environment refer specifically to buffer zones. The conclusion of the evaluation group was that risk mitigation measures can be defined at the Member State level and that safe uses of *lambda*-cyhalothrin have been demonstrated. The RMS suggested that inclusion in Annex I should not require specific buffer zones but that risk reduction measures must be undertaken by individual Member States in order to protect aquatic life. It was concluded that no extra risk reduction measures were needed to protect sediment-dwellers.

Guidance on buffer zone distances was provided by both the RMS and the Notifier (Table 1). Exposure estimates for all of the buffer zone calculations were based on the German Spray Drift Model (Ganzelmeier et al. 1995). The RMS_{lab} values shown in Table 1(from Table 12 in Appendix 3-Rev. 1 to *lambda*-cyhalothrin doc. 5684/VI/97-Rev. 8) were based on TWA[3] PEC^4_{SW} estimates, that assumed a DT^5_{50} value of 11 h, and acute toxicity for *Daphnia* (0.36

[3] Time weighted average
[4] Predicted environmental concentration in surface water
[5] Period required for 50% dissipation

µg/l= 48 h EC^{6}_{50}) and fish (0.21 µg/l =96 h LC^{7}_{50}). The buffer zone was set at a distance at which TER[8] exceeded 100. The $RMS_{mesocosm}$ values (from Table 13 in Appendix 3-Rev. 1 to *lambda*-cyhalothrin doc. 5684/VI/97-Rev. 8) assumed a LOEC[9] of 0.17 g as/ha, estimated from Mesocosm Study I, and drift values calculated as in Ganzelmeier et al. (1995). The buffer zones were set so that the g as/ha from drift did not exceed the LOEC. The RMS recommended values take both the laboratory and mesocosm estimates into account and provide the final recommendation by RMS. For comparison, the Notifier's recommendations (from Table 15 in Appendix 3-Rev. 1 to *lambda*-cyhalothrin doc. 5684/VI/97-Rev. 8) are based on calculated TERs using laboratory toxicity data for *Daphnia* and fish, and TWA PEC_{SW} values that assumed a DT_{50} of 3 h.

Table 1. Summary of buffer zones for *lambda*-cyhalothrin proposed by the RMS and Notifier. The buffer zones are in units of meters. The RMS calculated buffer zones on the basis of both laboratory (column 3) and mesocosm (column 4) studies, and on the basis of these derived their recommended values (column 5). The Notifier's recommendations are shown in column 6.

Crop	Appl. rate g as/ha	RMS_{lab}	$RMS_{mesocosm}$	RMS Recommended	Notifier Recommended
Field crops	7.5	10	≥ 3	3-5	3
	20		≥ 5	5-10	10
	15-30	20			5-10
	30		≥ 10	10-20	
Fruit crops	5-10		≥ 20	20-30	
	10-15	50			
	20-30	> 50			
	30		> 30	> 30	> 30
Grapes & cane fruit	5	20			
	5-10		≥ 10	10-20	
	17.5-26	> 50	≥ 20	20-30	20
	10-125			> 50	
Hops	20-125	> 50			
	Up to 44		≥50		> 50
	75-125		> 50		> 50
Hand-held sprayer (forestry)	10	20	≥ 10	20-30	
	25	> 50	≥ 20	20-30	20
Flowers & potatoes (high frequency)	7.5 and 15		20	20	

[6] Median effective concentration
[7] Lethal concentration , median
[8] Toxicity exposure ratio
[9] Lowest observable effect concentration

The Committee agrees that due to the rapid dissipation of *lambda*-cyhalothrin, chronic exposure of water column organisms is unlikely, and TERs based on 48 h and 96 h effects on *Daphnia* and fish, respectively, are the relevant effect endpoints to use in the risk assessment. TERs based on 48 h TWA PEC_{SW} and *Daphnia* toxicity versus 96 h TWA PEC_{SW} and fish toxicity gave very similar cut-off values (i.e. distances at which TER > 100 for different uses; Tables 9 & 10 of Appendix 3-Rev. 1). Although *lambda*-cyhalothrin adsorbs rapidly to sediment, risk assessment for chironomids indicated that buffer zones used to protect water column organisms would prevent unacceptable risk to sediment dwellers as well.

The RMS buffer zones assume up to 4 applications/season for all uses with the exception of flowers and potatoes for which more frequent applications are assumed. The buffer zones recommended by RMS are similar to those recommended by the notifier with the exception of the frequent uses (up to 18 applications with an interval of 7 days) on flowers and potatoes, for which the RMS recommends more stringent measures.

Despite disagreement between RMS and the notifier as to whether a DT_{50} of 3 (microcosm study) or 11 (water-sediment study) hours be used to calculate TWA PEC_{SW} values and as to whether the effects seen in Mesocosm Study I at the lower treatment level should be considered as ecologically relevant, the buffer distances recommended by the different approaches are very similar.

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Question 3

Can it be confirmed that the proposed risk mitigation measures are adequate to protect honey bees and other non-target arthropods?

OPINION

No risk mitigation measures for honey bees or other non-target arthropods were proposed. In the absence of specific risk mitigation measures the data show that the intended uses of *lambda*-cyhalothrin pose an unacceptable risk to non-target arthropods under Annex VI criteria of Directive 91/414/EEC.

The SCP believes that if risk mitigation measures can be implemented, then there are indeed conditions under which the use of lambda-cyhalothrin will not pose an unacceptable risk to honey bees and other non-target arthropods. Specific risk mitigation measures that should be considered for honey bees include: (a) the control of the timing of application (time of day and season) with respect to (i) honey bee activity and (ii) flowering of the crop, and (b) restrictions on spraying close to hives. Specific risk mitigation measures that should be considered for other non-target arthropods include restrictions on the number of applications per season, restrictions on spraying close to field margins, selection of appropriate application techniques to minimise spray drift, and limits on the extent of application.

The SCP is generally satisfied that the use of *lambda*-cyhalothrin will not pose an unacceptable risk to honey bees if it is applied at application rates of 20g as /ha or less and the above risk mitigation measures can be implemented. However, since application rates are approximately 30g as /ha in fruit crops and vines and these crops are regularly visited by honey bees, the Committee recommends that a further risk assessment be conducted to determine the likely effects of *lambda*-cyhalothrin in these systems.

Beneficial arthropods were monitored in European arable crops during field trials involving application rates of 5.0-10 g as/ha. Some species showed no effect after applications of the active substance, but populations of other species were significantly reduced, taking approximately 3-5 weeks to recover. In these trials, recovery over this time period must have arisen largely through immigration. The SCP suggests that in principle, it is entirely appropriate to take natural recolonisation from off-crop habitats into account in the risk assessment process. However, initial population effects were observed. Furthermore, given the nature of the recovery, the permanent viability of source populations will depend on the usage pattern of the compound. Thus, there remains a need for specific risk reduction measures (see above).

There are two main patterns of use in which it was particularly difficult to assess risk to non-target arthropods: (a) applications to cereals at concentrations of approximately 20g/ha (well above field rates employed in European field trials) and, (b) applications to citrus, pome fruits and vines. The SCP recommends that further risk assessments for these intended uses should be conducted.

1. Scientific background on which the opinion is based

1.1 Honey bees

1.1.1 Review of available ecotoxicity data

Laboratory assays

- The estimated mean 24 hr LD50[10] for worker bees after contact exposure was between 51 and 95 ng as/bee, depending on formulation. The estimated mean 24 hr LD50 for oral administration was somewhat higher (between 965 and 570 ng as/bee).

Greenhouse tunnel trials

- A greenhouse study was conducted, in which individual colonies of honeybees were enclosed and observed in tunnels containing treated winter wheat. Treatment levels (7.5g as /ha and 15 g as /ha *lambda*-cyhalothrin) were somewhat less than the critical Good Agricultural Practice (GAP) proposed for cereals in some regions (20 g as/ha), but the close confinement can often result in longer periods of exposure than equivalent field trials. Overall, mortality rates did not differ significantly between treatments. There was some evidence of foraging inhibition lasting up to 3 days in treatments, and abnormal locomotive behaviour was also observed.

Field trials

- A field study was conducted in plots of flowering winter rape. The application rate (10 g as / ha) was again less than the critical GAP for this crop in some regions (20-30 g as / ha). The mortality rate did not differ significantly between *lambda*-cyhalothrin treated and controls (2 replicate plots of each, 5 bee colonies plot), while foraging was significantly depressed for a short while after application. There were also no observed effects on egg-laying or brood development.

- Given this data, ECCO 3 considered application rates up to and including 15 g *lambda*-cyhalothrin /ha to be safe and acceptable with respect to honey bees. To support application rates > 15g as/ha, higher tier bee data (e.g. semi field/field data) would be required. The notifier has since responded by providing provisional details (subject to audit by Quality Assurance) of a trial conducted in a number of fields of oil seed rape using application rates that included 20 and 25 g as / ha (another trial was also commissioned, but there was insufficient bee activity). Although more than twice the number of bee deaths were recorded in high dose treatments compared to controls on the day of application and the following day, in the medium-term (≥ approximately 2 days following application) the daily numbers of bee deaths recorded fell to levels that were comparable to pre-treatment levels.

[10] Lethal dose 50%

1.1.2 Importance and adequacy of risk mitigation measures

Given the high sensitivity of bees reported under laboratory conditions, risk mitigation measures should be implemented before safe use can be confirmed. No specific risk mitigation measures for honey bees have so far been proposed that the notifier wishes to support in the context of Annex 1. However, appropriate measures that should be considered include : (a) the control of the timing of application (time of day and season) with respect to (i) honey bee activity and (ii) flowering of the crop, and (b) restrictions on spraying close to hives.

The SCP supports the RMS opinion that, if the above risk mitigation measures are implemented, then applications up to 20-25 g as/ha would not pose an unacceptable risk to honey bees. However, this preliminary interpretation needs to be reviewed when the final report on the field trial in oil seed rape is made available.

The SCP notes that a reliable risk assessment for honey bees is difficult under some of the application scenarios listed by the notifier. These cases merit more detailed consideration. In particular, the SCP notes that no study has been conducted to evaluate the effects of application rates of *lambda*-cyhalothrin of the order of 30 g as / ha or higher. Yet the critical good agricultural practice application rate of *lambda*-cyhalothrin is 30 g as / ha for citrus, pome fruit and stone fruit in several southern European countries. Since these crops are likely to be regularly visited by bees, the Committee is of the opinion that a further risk assessment of on-crop effects in fruit crops and vines should be required (see also section 2.2.2).

1.2. Other arthropods

1.2.1 Review of available ecotoxicity data

Laboratory assays

- The notifier has provided details of a large number of laboratory tests to evaluate the toxicity of *lambda-cyhalothrin* to both beneficial non-target arthropods and pests. These tests cover ground beetles (*Trechus quadristriatus*, *Pterosticus melanarius*, *Poecilus cupreus*), a predatory hoverfly (*Episyrphus baleatus*), a parasitic wasp (*Aphidius urzbeckistanicus*), lycosid spiders (*Pardosa* sp.), 4 species of linyphiid spider and a predatory mite (*Typhlodromus*), as well as several pest species (the aphids *Rhopalosiphum padi* and *Sitobion avenae* and the herbivorous mite *Panonychus ulmi*).

- In several tests, nominal concentrations fell in the range of 6.25-9.0 g as / ha which is less than the critical GAP application rate for a number of crops. Overall, while aphids appeared highly sensitive to *lambda*-cyhalothrin, it was also highly toxic to both linyphiid and lycosid spiders, as well as mites. Significant mortality and reductions in mobility were also recorded in the other tests (e.g. beetles), although in these tests the rate of mortality did not exceed 30%.

Field trials

- The notifier also provided details of three intensive field studies conducted in winter wheat crops in Berkshire, UK. Additional details were also sent to the RMS at a later

date (along with details of a soyabean study in Brazil, a rice study in the Phillipines and a cotton study in the USA). In one of the Berkshire trials *lambda*-cyhalothrin was applied at 5 g as /ha to replicated plots (> 4ha in size) in November on consecutive years, while in the other Berkshire trials the chemical was applied to plots (> 1ha) at a rate of 7.1 g as/ha (trial 1) and 5, 7.5 or 10 g as/ha (trial 2) in June. A number of other chemicals were also applied to the experimental fields both before and during the surveys. In these experiments, some species of polyphagous predators (Carabidae, Staphylinidae and Araneae) showed significant reductions in population size compared to controls, which persisted on average for 4-5 weeks in the November trials and 3-4 weeks in the June trials.

- In these trials the observed recovery over this time period can only have arisen through immigration of predators from untreated fields and field margins, rather than through reproduction.

1.2.2 Importance and adequacy of risk mitigation measures

The RMS suggests that, while beneficials appear to be maintained in arable crops, a mean recovery rate of 4-5 weeks as observed in the European field highlights the need for risk reduction measures. The SCP agrees with this interpretation: the data show that the intended uses of *lambda*-cyhalothrin pose an unacceptable risk to non-target arthropods under Annex VI criteria, unless specific risk mitigation measures can be implemented. So far, no specific risk mitigation measures for arthropods have been proposed that the notifier wishes to support through Annex 1. In the following paragraphs the SCP expands on why it considers risk mitigation to be important even in the light of the observed recovery, and the same reasoning is used to identify some appropriate mitigation measures.

The observation of population recovery through immigration from unsprayed sources raises a fundamental issue: should it be incorporated into the risk assessment process, and if so how? Furthermore, if recovery is considered, what risk mitigation measures should be implemented to ensure that recovery can take place via this process? Immigration is a natural ecological process, and as such, the SCP feels that it is appropriate to consider it in the context of a risk assessment. Indeed, it would often be impractical to attempt to rule it out as a factor in field trials. However, it is important to recognise that the actual rates of immigration of arthropods into treated areas are likely to be highly dependent on the sizes and proximities of suitable source populations. Thus, repeated applications of the chemical may eventually deplete the sizes of the source populations through continued attrition (Sherratt & Jepson 1993). Similarly, the rates of recovery of arthropod populations within the treated crop will depend on the actual sizes of populations that were lost after treatment. Thus, if sprays are applied extensively, then large populations are likely to be affected and the subsequent rate of recovery is likely to be low. This reasoning is supported by experimental data which show that the rate of recovery will depend on the area of crop sprayed (e.g. Jepson & Thacker 1990; Thomas *et al.* 1990). Another important caveat is that the rate of recovery of arthropods in the treated area will depend not just on the frequency and extent of application of the pesticide in question, but on the suitability of the surrounding habitats for arthropods, and the toxicities and patterns of use of other pesticides.

Whenever initial population reductions are observed in the field, then this should raise cause for concern. Furthermore, whenever immigration is seen as an important factor in the

recovery process, then it is likely that the usage pattern of the compound will have a correspondingly high influence on long-term viability of affected populations in the treated area. Therefore, in such cases, the SCP feels that it is necessary to implement risk mitigation measures. One appropriate measure is to restrict spraying close to any off-crop areas that are likely to support significant populations of beneficial arthropods. Such a restriction might also involve selection of appropriate application techniques to minimise spray drift. While it is also recognised that repeated or extensive applications of the compound may affect the ability of beneficial arthropod populations to recover, there are currently no agreed guidelines with which to set quantitative limits on these parameters. Given the uncertainty, the SCP recommends that selection of appropriate upper levels of frequency and extent of application should be based on a consideration of the conditions under which field trials were conducted.

As far as we can assess, the majority of critical GAP scenarios provide a considerable interval outside a short period of spraying activity to enable recovery, if it occurs at approximately the observed rates. The likely effects of *lambda*-cyhalothrin and the subsequent recovery of beneficial arthropods under certain GAPs are however difficult to gauge. In particular, the SCP notes that the critical GAP for cereals in Italy and France involves 2 applications 15 days apart at twice the maximum application rate (20 g as / ha) used in the European field studies. While beneficial arthropod populations will probably show the same pattern and begin to recover several weeks after the second spray (as indicated by several of the notifiers' trials outside the EU), it is clearly more difficult to assess the risk to beneficial arthropods under these particular conditions, and further work to assess risk under these conditions is recommended. As with the honey bees, high application rates of *lambda*-cyhalothrin to citrus, pome fruits and vines pose risks to terrestrial non-target arthropods which are difficult to ascertain. The Committee therefore feels that it is appropriate to : (a) restrict the general use of *lambda*-cyhalothrin in these crops and/or (b) initiate reliable monitoring programmes, until further assessments are conducted.

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ACKNOWLEDGEMENTS

The Committee wishes to acknowledge the contribution of the following working groups that prepared the initial draft opinion:

Toxicology: Professor M. Maroni (Chairman), and Committee Members Dr. M.-P. Delcour-Firquet, Dr. R. Hans, Dr. O. Meyer, Prof. A. Silva Fernandes, Dr. G. Speijers

Environmental Assessment: Professor A Hardy (Chairman), and Committee Members Mr H. Koepp, Dr. H. G. Nolting, Professor A. Silva Fernandes and Dr. T. Sherratt and invited experts Dr. V. Forbes, Dr. J. Boesten, Dr. A. Carter.

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