Berichte

aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft

Reports

from the Federal Biological Research Centre for Agriculture and Forestry

Heft 69
2000

EU-Beurteilungsbericht Imazalil
Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen
Band D 6

Review Report Imazalil
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 6

Bearbeitet von
compiled by

Edelgard Adam
Axel Wilkening
Jutta Plekat

Abteilung für Pflanzenschutzmittel und Anwendungstechnik

Department of Plant Protection Products and Application Techniques

Herausgeber

Biologische Bundesanstalt für Land- und Forstwirtschaft
Braunschweig, Deutschland

Verlag
Eigenverlag

Vertrieb
Saphir-Verlag, Gutsstraße 15, D-38551 Ribbesbüttel
Telefon +49/(0) 53 74 / 65 76
Telefax +49/(0) 53 74 / 65 77

ISSN 0947-8809

Kontaktadresse
Edelgard Adam, Axel Wilkening
Biologische Bundesanstalt für Land- und Forstwirtschaft
Koordinierungsgruppe der Leitung der Abteilung für
Pflanzenschutzmittel und Anwendungstechnik
Messeweg 11/12
D-38104 Braunschweig

Telefon: +49/(0) 5 31 / 2 99-34 57, +49/(0) 5 31 / 2 99-34 54
Telefax: +49/(0) 5 31 / 2 99-30 03
E-Mail: e.adam@bba.de, a.wilkening@bba.de
Internet http://www.bba.de

Inhalt / Contents

Bereits erschienene Beurteilungsberichte / Already published Review Reports

Heft / Report	**Band / Volume** **Wirkstoff / Active Substance**	**Berichterstattender Mitgliedstaat** **Rapporteur Member State**
59/2000	D1: Fluroxypyr	Deutschland Germany
60/2000	D2: Azimsulfuron	Italien Italy
61/2000	D3: Kresoxim-methyl	Belgien Belgium
65/2000	D4: Azoxystrobin	Deutschland Germany
66/2000	D5: Spiroxamine	Deutschland Germany

Vorwort

Für neue Wirkstoffe werden die EU-Mitgliedstaaten in den Richtlinien zur Aufnahme der Wirkstoffe in Anhang I verpflichtet, den nach Abschluss aller Prüfungen erstellten Beurteilungsbericht (Review Report) mit allen Anlagen (mit Ausnahme von vertraulichen Informationen im Sinne von Artikel 14 der Richtlinie 91/414/EWG) allen Interessierten zur Verfügung zu stellen oder auf besonderen Antrag zugänglich zu machen. Für alte Wirkstoffe ergibt sich diese Verpflichtung für die Mitgliedstaaten bereits aus Artikel 7 Absatz 6 Unterabsatz 2 der Verordnung (EWG) Nr. 3600/92.

Die Mitgliedstaaten und die Europäische Kommission haben vereinbart, dass die Beurteilungsberichte, einschließlich der zum Teil sehr umfangreichen Hintergrunddokumente, vorzugsweise beim berichterstattenden Mitgliedstaat angefordert oder eingesehen werden sollen.

Die Biologische Bundesanstalt stellt die Beurteilungsberichte als Berichte aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft als Band D in der Reihe "Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen" über den Saphir Verlag gegen Erstattung der Unkosten zur Verfügung. Das vorliegende 6. Heft dieser Reihe (Band D 6) 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 Imazalil war Luxemburg 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)
36/97	Band B: Richtlinien, Verordnungen, Entscheidungen und Protokolle zur Wirkstoffprüfung (3. Auflage, Stand 01. November 1997)
	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 6th report belonging to this series (Volume D 6) 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 imazalil Luxembourg 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)
36/97	Volume B: Directives, Regulations, Decisions and Protocols regarding the Evaluation of Active Substances (3rd Edition, date: 1 November 1997)
	Volume C: *In Progress*

RICHTLINIE 97/73/EG DER KOMMISSION

vom 15. Dezember 1997

zur Aufnahme des Wirkstoffs Imazalil in Anhang I der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln

(Text von Bedeutung für den EWR)

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 97/57/EG (2), insbesondere auf Artikel 6 Absatz 1 und Artikel 8 Absatz 2 Unterabsatz 4,

in Erwägung nachstehender Gründe:

Die Verordnung (EWG) Nr. 3600/92 der Kommission (3), zuletzt geändert durch die Verordnung (EG) Nr. 1199/97 (4), enthält Durchführungsbestimmungen für die erste Stufe des Arbeitsprogramms nach Artikel 8 Absatz 2 der Richtlinie 91/414/EWG (nachstehend „die Richtlinie" genannt). Hierzu wurde in der Verordnung (EG) Nr. 933/94 der Kommission (5), zuletzt geändert durch die Verordnung (EG) Nr. 2230/95 (6), die Liste der Wirkstoffe von Pflanzenschutzmitteln aufgestellt, die im Hinblick auf ihre etwaige Aufnahme in Anhang I der Richtlinie zu bewerten sind.

Die Wirkstoffe sind in den Anhang I aufzunehmen, wenn angenommen werden kann, daß keine schädlichen Auswirkungen auf die Gesundheit von Mensch und Tier oder auf das Grundwasser bzw. keine unannehmbaren Auswirkungen auf die Umwelt zu erwarten sind.

Die Aufnahme in den Anhang sollte auf höchstens zehn Jahre befristet werden.

Nach Aufnahme eines Wirkstoffs in Anhangs I der betreffenden Richtlinie stellen die Mitgliedstaaten gemäß Artikel 8 Absatz 2 der Richtlinie sicher, daß die Zulassungen für den Wirkstoff enthaltenden Pflanzenschutzmittel in einem vorgeschriebenen Zeitraum erteilt, geändert bzw. entzogen werden. Insbesondere bestimmen Artikel 4 Absatz 1 und Artikel 13 Absatz 1 der Richtlinie, daß Pflanzenschutzmittel nur zugelassen werden, wenn nach Prüfung der Unterlagen gemäß Artikel 13 die Bedingungen für die Aufnahme des Wirkstoffs in Anhang I sowie die einheitlichen Grundsätze gemäß Anhang VI der Richtlinie erfüllt sind.

Für Imazalil wurden die Auswirkungen auf die menschliche Gesundheit und die Umwelt gemäß den Bestimmungen der Richtlinie (EWG) Nr. 3600/92 für bestimmte, von den beantragenden Stellen vorgeschlagene Anwendungen bewertet. Belgien hat für Luxemburg, dem berichterstattenden Mitgliedstaat nach der Verordnung (EG) Nr. 933/94, den betreffenden Bewertungsbericht am 15. Juli 1996 der Kommission vorgelegt.

Der vorgelegte Bewertungsbericht wurde von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses für Pflanzenschutz geprüft. Als Ergebnis dieser am 11. Juli 1997 abgeschlossenen Prüfung hat die Kommission ihren Bericht für Imazalil gemäß Artikel 7 Absatz 6 der Verordnung (EWG) Nr. 3600/92 vorgelegt. Dieser Bericht ist von Zeit zu Zeit aufgrund des wissenschaftlich-technischen Fortschritts zu aktualisieren. Dabei müssen auch die Bedingungen für die Aufnahme von Imazalil in Anhang I der Richtlinie gemäß deren Artikel 6 Absatz 1 angepaßt werden.

Die Bewertungen haben ergeben, daß den betreffenden Wirkstoff enthaltende Pflanzenschutzmittel im allgemeinen die Anforderungen gemäß Artikel 5 Absatz 1 Buchstaben a) und b) der Richtlinie erfüllen, insbesondere hinsichtlich der geprüften Anwendungen. Daher sollte der betreffende Wirkstoff in Anhang I aufgenommen werden, damit sichergestellt ist, daß in allen Mitgliedstaaten die Erteilung, Änderung bzw. Entziehung der Zulassung von den betreffenden Wirkstoff enthaltenden Pflanzenschutzmitteln gemäß den Bestimmungen der Richtlinie geregelt werden kann und dies nicht weiter verzögert wird.

Vor der Aufnahme ist den Mitgliedstaaten und den Betroffenen eine angemessene Frist zur Vorbereitung auf die neuen Verhältnisse einzuräumen. Nach der Aufnahme ist den Mitgliedstaaten ein angemessener Zeitraum zur Durchführung insbesondere für die Überprüfung bestehender oder die Erteilung neuer Zulassungen gemäß den Bestimmungen der Richtlinie einzuräumen. Für die Vorlage und die Prüfung der kompletten Anhang-III-Unterlagen für jedes einzelne Pflanzenschutzmittel entsprechend den einheitlichen Grundsätzen gemäß Anhang VI der Richtlinie muß ein längerer Zeitraum vorgesehen werden. Für mehrere Wirkstoffe enthaltende Pflanzenschutzmittel kann die vollständige Bewertung anhand der einheitlichen Grundsätze jedoch erst durchgeführt werden, wenn alle betreffenden Wirkstoffe in Anhang I der Richtlinie aufgenommen sind.

(1) ABl. L 230 vom 19. 8. 1991, S. 1.
(2) ABl. L 265 vom 27. 9. 1997, S. 87.
(3) ABl. L 366 vom 15. 12. 1992, S. 10.
(4) ABl. L 170 vom 28. 6. 1997, S. 19.
(5) ABl. L 107 vom 28. 4. 1994, S. 8.
(6) ABl. L 225 vom 22. 9. 1995, S. 1.

Die Durchführungsfristen der vorliegenden Richtlinie greifen den für die Aufnahme anderer Wirkstoffe in Anhang I festzusetzenden Fristen nicht vor.

Der Prüfungsbericht ist erforderlich für die Umsetzung bestimmter Teile der einheitlichen Grundsätze in Anhang VI der Richtlinie durch die Mitgliedstaaten, soweit sich diese Grundsätze auf die Bewertung der Angaben nach Anhang II beziehen, die zwecks Aufnahme des Wirkstoffs in Anhang I vorgelegt wurden.

Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz —

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

Imazalil wird entsprechend dem Anhang dieser Richtlinie in den Anhang I der Richtlinie 91/414/EWG aufgenommen.

Artikel 2

(1) Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens 30. Juni 1999 [1] nachzukommen. Sie sind insbesondere befugt, die bestehenden Zulassungen von Pflanzenschutzmitteln, die den Wirkstoff Imazalil enthalten, innerhalb dieser Frist nach den Bestimmungen der Richtlinie 91/414/EWG erforderlichenfalls zu ändern oder zu entziehen.

Im Hinblick auf die Bewertung und Beschlußfassung nach den einheitlichen Grundsätzen in Anhang VI der Richtlinie 91/414/EWG anhand der in deren Anhang III vorgeschriebenen Unterlagen wird die obengenannte Frist jedoch verlängert

— für Pflanzenschutzmittel, die ausschließlich Imazalil enthalten und nicht für Blattspritzungen im Freiland bestimmt sind, auf vier Jahre ab Inkrafttreten dieser Richtlinie;

— für Pflanzenschutzmittel, die Imazalil und weitere, noch nicht in Anhang I aufgeführte Wirkstoffe enthalten und nicht für Blattspritzungen im Freiland bestimmt sind, auf vier Jahre ab Inkrafttreten der Richtlinie, durch die der letzte dieser Wirkstoffe in Anhang I aufgenommen wurde.

(2) Wenn die Mitgliedstaaten die Vorschriften nach Ziffer 1 erlassen, nehmen sie in diesen Vorschriften selbst oder durch einen Hinweis bei der amtlichen Veröffentlichung auf diese Richtlinie Bezug. Die Mitgliedstaaten regeln die Einzelheiten dieser Bezugnahme.

Artikel 3

Diese Richtlinie tritt am 1. Januar 1999 [2] in Kraft.

Artikel 4

Diese Richtlinie ist an alle Mitgliedstaaten gerichtet.

Brüssel, den 15. Dezember 1997

Für die Kommission

Franz FISCHLER

Mitglied der Kommission

[1] Grundsätzlich sechs Monate ab Inkrafttreten dieser Richtlinie.

[2] Grundsätzlich zwölf Monate ab Erlaß dieser Richtlinie

ANHANG

IMAZALIL

1. Identität

   (IUPAC-Nomenklatur): (±) -1-(β-allyloxy-2,4-dichlorophenylethyl)-imidazol

   oder

   (±) -allyl-1-(2,4-dichlorophenyl)-2-imidazol-1-ylethylether.

2. Insbesondere zu erfüllende Bedingungen:

2.1. Die Reinheit des die Produktion verlassenden Wirkstoffs muß der entsprechenden FAO-Spezifikation genügen.

2.2. Nur Anwendungen als Fungizid dürfen zugelassen werden.

2.3. 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 Risikoanalyse dem zulassenden Mitgliedstaat gegenüber nachgewiesen wurde, daß das Austreten der Behandlungslösung kein unannehmbares Risiko für die Umwelt, insbesondere für Wasserlebewesen, mit sich bringt;

— Nacherntebehandlung von Kartoffeln darf nur zugelassen werden, wenn bei der Risikoanalyse dem zulassenden Mitgliedstaat gegenüber nachgewiesen wurde, daß das Austreten von Verarbeitungsabfällen von behandelten Kartoffeln kein unannehmbares Risiko für die Umwelt, insbesondere für Wasserlebewesen, mit sich bringt;

— Blattspritzungen im Freiland dürfen nur zugelassen werden, wenn bei der Risikoanalyse dem zulassenden Mitgliedstaat gegenüber nachgewiesen wurde, daß die Anwendung kein unannehmbares Risiko für die Gesundheit von Mensch und Tier sowie für die Umwelt mit sich bringt.

2.4. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlußfolgerungen des vom Ständigen Ausschuß für Pflanzenschutz am 11. Juli 1997 abgeschlossenen Imazalil-Prüfungsberichts der Kommission, insbesondere dessen Anlagen I und II zu berücksichtigen.

3. Zeitpunkt des Ablaufs der Aufnahme: 31. Dezember 2008.

COMMISSION DIRECTIVE 97/73/EC

of 15 December 1997

including an active substance (imazalil) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market

(Text with EEA relevance)

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 Directive 97/57/EC (2), and in particular Article 6 (1) and the fourth subparagraph of Article 8 (2) thereof,

Whereas Commission Regulation (EEC) No 3600/92 (3), as last amended by Regulation (EC) No 1199/97 (4), has 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'); whereas, pursuant to that Regulation, Commission Regulation (EC) No 933/94 (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;

Whereas those active substances should be included in that Annex when it may be expected that there will not be any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment;

Whereas such inclusion should be made for a period not exceeding 10 years;

Whereas the Directive, at Article 8 (2), provides that after inclusion of an active substance in Annex I to the Directive, Member States shall, within a prescribed period, grant, vary or withdraw, as appropriate, the authorizations of the plant protection products containing the active substance; whereas, in particular, Articles 4 (1) and 13 (1) of the Directive require that plant protection products are not authorized 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 Annex VI on the basis of a dossier satisfying the data requirements laid down in Article 13;

Whereas for imazalil 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 number of uses proposed by the notifiers; whereas Belgium, acting on behalf of Luxembourg as designated rapporteur Member State pursuant to Regulation (EC) No 933/94, has submitted to the Commission on 15 July 1996 the relevant assessment report;

Whereas the submitted report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health; whereas this review has been finalized on 11 July 1997 in the format of the Commission review report for imazalil, in accordance with the provisions of Article 7 (6) of Regulation (EEC) No 3600/92; whereas it may be necessary to update this report from time to time to take into account technical and scientific developments; whereas in such case the conditions for the inclusion of imazalil in Annex I to Directive 91/414/EEC will also need to be amended pursuant to Article 6 (1) of that Directive;

Whereas it has appeared from the assessments 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; whereas therefore it is necessary to include the active substance concerned in Annex I, in order to ensure that, in all Member States, the granting, varying or withdrawing, as appropriate, of the authorizations of plant protection products containing the active substance concerned can be organized in accordance with the provisions of the Directive, and to ensure that this activity is not further delayed;

Whereas before inclusion a reasonable deadline is necessary to permit Member States and the interested parties to prepare themselves to the new requirements which will result from the inclusion; whereas moreover after inclusion a reasonable period is necessary for the Member States to implement the Directive and in particular to vary or withdraw, as appropriate, existing authorizations or grant new authorizations in accordance with the provisions of Directive 91/414/EEC; whereas a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product in accordance with the uniform principles laid down in Annex VI to the Directive; whereas, however, 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;

(1) OJ L 230, 19. 8. 1991, p. 1.
(2) OJ L 265, 27. 9. 1997, p. 87.
(3) OJ L 366, 15. 12. 1992, p. 10.
(4) OJ L 170, 28. 6. 1997, p. 19.
(5) OJ L 107, 28. 4. 1994, p. 8.
(6) OJ L 225, 22. 9. 1995, p. 1.

Whereas the periods laid down for implementation of this Directive do not prejudice the periods which will be established for the inclusion of other active substances in Annex I to the Directive;

Whereas the review report is required for the proper implementation by the Member States of several sections of the uniform principles laid down in Annex VI to the Directive, where these principles refer to the evaluation of the Annex II data which were submitted for the purpose of the inclusion of the active substance in Annex I to the Directive;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Imazalil is hereby designated as an active substance in Annex I to Directive 91/414/EEC, as set out in the Annex hereto.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive, not later than 30 June 1999 (1); in particular they shall, in accordance with the provisions of Directive 91/414/EEC, where necessary, vary or withdraw existing authorizations for plant protection products containing imazalil as active substance within such period.

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 subparagraph is extended:

— for plant protection products containing only imazalil, and not intended for outdoor foliar uses, to four years from the entry into force of this Directive,

— 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. When Member States adopt the provisions referred to in paragraph 1, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive shall enter into force on 1 January 1999 (2).

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 15 December 1997.

For the Commission

Franz FISCHLER

Member of the Commission

(1) In principle six months from the date of entry into force of the present Directive.

(2) In principle 12 months from the date of adoption of the present Directive.

ANNEX

IMAZALIL

1. Identity:

   (Iupac name) (±) -1-(β-allyloxy-2,4-dichlorophenylethyl) imidazole

   or

   (±) -allyl 1-(2,4-dichlorophenyl)-2-imidazol-1-ylethyl ether

2. Particular conditions to be fulfilled:

2.1. Purity of the active substance as manufactured shall satisfy the specification established by FAO for this active substance.

2.2. Only uses as fungicide may be authorized.

2.3. For the following uses the following particular conditions apply:

- post harvest fruit, vegetable and potato treatments may only be authorized when an appropriate decontamination system is available or a risk assessment has demonstrated to the authorizing 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 authorized when a risk assessment has demonstrated to the authorizing 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 authorized when a risk assessment has demonstrated to the authorizing Member State that the use has no unacceptable effects on human and animal health and the environment.

2.4. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on imazalil, and in particular Appendixes I and II thereof, as finalized in the Standing Committee on Plant Health on 11 July 1997 shall be taken into account.

3. Expiry date of the inclusion: 31 December 2008.

FINAL

Review report for the active substance imazalil.

Finalised in the Standing Committee on Plant Health at its meeting on 11/07/1997 in view of the inclusion of imazalil 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 imazalil, 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) n° 1199/97[2], has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Imazalil 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, Sanachem Pharmaceutica via ACI International on 30 July 1993, Janssen Pharmaceutica on 27 July 1993, Farma Lepori on 28 July, B.V Luxan on 15 July 1993 and Makhteshim Agan on 20 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance imazalil 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) n° 2230/95[4], designated Luxembourg as rapporteur Member State to carry out the assessment of imazalil on the basis of the dossiers submitted by the notifiers. In the same Regulation the Commission specified furthermore the deadline for the notifiers and third parties with regard to the submission to the rapporteur Member States of the dossiers and further information ; for imazalil this deadline was 30 April 1995.

Janssen Pharmaceutica, Makhteshim Agan and Sanachem Pharmaceutica via ACI International submitted each a dossier to the rapporteur Member State. Janssen Pharmaceutica was the main

---

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

2 O.J. No. L170, 28.6.1997, p.19

3 O.J. No. L 107, 28.4.1994, p. 8.

4 OJ No L 225, 22.9.1995, p.1.

data submitter, with a dossier which did not contain substantial data gaps, taking into account the supported uses. Makhteshim and Sanachem Pharmaceutica via ACI International did not submit complete dossiers. Information has furthermore been submitted by third parties, including the European Federation of Agricultural Workers, the Pesticide Action Network, the European Environmental Bureau and the Comité Regional Phyto (Université Catholique de Louvain, Belgium).

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Belgium acting on behalf of Luxembourg submitted on 15 July 1996 to the Commission the report of its examination, based in particular on the dossier of the main data submitter, hereafter referred to as the monograph, including, as required, a recommendation concerning the possible inclusion of imazalil 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 imazalil from Janssen Pharmaceutica, on 30th August 1996.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the monograph to all the Member States as well as to Janssen Pharmaceutica being the main submitter of the required data, on 24 June 1996.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the monograph 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 Pesticides Safety Directorate (PSD) in York from September to November 1996.

The report of the peer review was circulated, for further consultation, to Member States and the main submitter on 19 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 monograph, the peer review report and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on Plant Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from April to June 1997, and was finalised in the meeting of the Standing Committee on 11/07/97.

The present review report contains the conclusions of this final examination ; given the importance of the monograph, the peer review report (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.

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 97/73/EC[5] concerning the inclusion of imazalil in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing imazalil 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 imazalil will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4 (1) and the Uniform Principles laid down in Annex VI of Directive 91/414/EEC, for each imazalil containing plant protection product for which Member States will grant or review the authorisation.

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

- seed dressing of cereals ;
- foliar applications under glass ;
- wound healing treatment ;
- post harvest application to fruit,melons and potatoes.

---

[5] OJ.L 353 , 24/12/1997 P.26-28

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

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Estimated Maximum Daily Intake (excluding water and products of animal origin) for a 60kg adult is 28% of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

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

Given the results of the evaluation of the information submitted on fate and behaviour and ecotoxicology, particular conditions have been provided for as explained in section 6 of this report, which need on short term attention from the Member States when granting new authorisations or varying existing authorisations.

4. Identity and Physical/chemical properties.

The main identity and the physical/chemical properties of imazalil 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 (Janssen Pharmaceutica), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, Belgium, acting on behalf of the rapporteur Member State, is also satisfied, on the basis of the information currently available, that the substances notified by the other data submitters (Makhteshim Agan and Sanachem Pharmaceutica) do not, in the meaning of Article 13(2) and (5) of the Directive, differ significantly in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main notifier.

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.

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term (within 18 months at the latest) attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate :

- post harvest fruit,vegetable and potato treatments can only be authorised when an appropriate decontamination system is available or unless a risk assessment has demonstrated that the discharge of the treatment solution does not have an unacceptable risk to the environment and in particular aquatic organisms ;

- post harvest treatment of potatoes can only be authorised provided that a risk assessment has demonstrated that the discharge of the processing waste from treated potatoes does not have an unacceptable risk to aquatic organisms.

At the time of the finalisation of this review report, no sufficient data were submitted to perform in all detail the risk assessment for the outdoor foliar uses of imazalil containing plant protection products. Therefore it is necessary to provide that authorisations for such uses may only be delivered 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.

7. List of studies to be generated.

No further studies were identified which were at this stage considered necessary in relation to the inclusion of imazalil 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 (i) the fate of imazalil in the soil at 10°C, where the submitted information is insufficient to permit extrapolation and (ii) for refining the estimation of the dermal absorption. Also if an application is made for outdoor foliar uses, the applicant will submit the appropriate additional data to allow the Member State to perform the risk assessment in accordance with the Uniform Principles of Annex VI.

8. Information on studies with claimed data protection.

For information of any interested parties, appendix III lists the 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. This list 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.

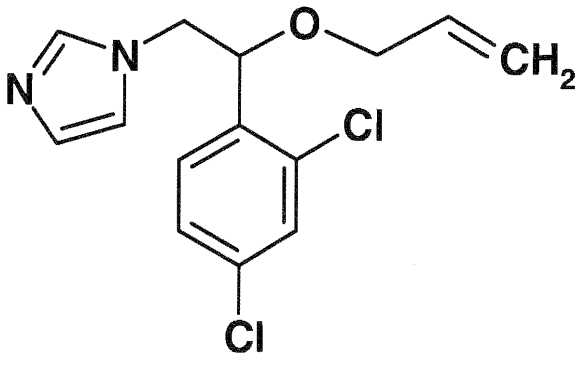
9. Updating of this review report.

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 Imazalil in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

IMAZALIL

Common name (ISO)	Imazalil
Chemical name (IUPAC)	(±)-1-(β-allyloxy-2,4-dichlorophenylethyl)imidazole or (±)-allyl 1-(2,4-dichlorophenyl)-2-imidazol-1-ylethyl ether
Chemical name (CA)	(±)-1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)-1*H*--imidazole
CIPAC No	335
CAS No	73790-28-0, 35554-44-0(unstated stereochemistry)
EEC No	2526150
FAO SPECIFICATION	The material shall consist of imazalil together with related manufacturing impurities and shall be a slightly yellow to brown crystalline mass, free from visible extraneous matter and added modifying agents. The imazalil content shall be declared (not less than 975g/kg) and, when determined, the content obtained shall not differ from that declared by ±25g/kg.
Molecular formula	$C_{14}H_{14}Cl_2N_2O$
Molecular mass	297.18
Structural formula	

Physical-chemical properties continued

Melting point	51.5°C

Boiling point	319°C
Appearance	crystalline mass slightly yellow to brown
Relative density	1.348 g/ml (density at 26°C)
Vapour pressure	1.58 x 10-4 Pa at 25°C
Henry's law constant	2.615 x 10^{-4} Pa m^3 . mol $^{-1}$ at 25°C
Solubility in water	pH 4.9: 1.0g/l at 30°C
	pH 7.6: 0.18g/l at 30°C
	pH 10: 1.8mg/l at 30°C
Solubility in organic solvents (at 25°C)	methanol : >500g/l at room temperature
	ethyl acetate : >500g/l, at room temperature
	hexane: 52.1 g/l at room temperature
Partition co-efficient (log POW)	3.82 at 23°C
Hydrolytic stability (DT50)	pH 5: > 60 days
	pH 7: > 60 days
	pH 9: > 60 days
Dissociation constant	pKa:6.53
UV/VIS absorption (max.)	270nm
Photostability (DT 50)	18.15 hours in water

APPENDIX II

ENDPOINTS AND RELATED INFORMATION

IMAZALIL

1. Toxicology and metabolism.

Absorption, distribution, excretion and metabolism in mammals (Annex II 5.1)

Rate and extent of absorption:	Oral, 24 hours, 63 - 117%, rats
Distribution:	Liver, kidney, intestine (organs involved in metabolism and excretion of compound)
Potential for accumulation:	None
Rate and extent of excretion:	24 hours, +85%.
Toxicologically significant compounds	Parent compound
Metabolism	>99% metabolized

Acute toxicity

Rat LD_{50} oral	227 - 371 mg/kg bw
Rat LD_{50} dermal	>2000 mg/kg bw
Rat LC_{50} inhalation	1.84 mg/l air
Skin irritation	Non irritant
Eye irritation	Severe eye irritant
Sensitization	Not sensitizer

Short term toxicity

Target / critical effect	Liver/reduction in bodyweight
Lowest relevant NOAEL	2.5mg/kg bw/day. 1 year dog study.

Genotoxicity	No genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect	Liver/several effects noted*
Lowest relevant NOAEL	3.6 mg/kg bw/day. 30 month oral rat study.
Carcinogenicity	No carcinogenic potential.

Reproductive toxicity

Reproduction	NOAEL parental toxicity = 5 mg/kg bw/day, **NOAEL pups = 20mg/kg bw/day.** 2 generation rat study
Developmental toxicity	**Negative**

Delayed neurotoxicity	Not relevant*
Other toxicological studies	Not relevant*
Medical data	Reported in background document A

Summary

ADI	0.025 mg/kg bw/day. 1 year dog study, AF=100.
AOEL	0.05 mg/kg bw/day (systemic), 6 month oral toxicity in rat,on the basis of AF=100.**
Dermal absorption	10 % estimation (default value as no data was submitted)

* detailed explanations are given in the background documents, in connection with the precise data requirements as defined in Annex II of directive 91/414/EEC.

** represents the best possible estimation according to the currently available methodology, which is however not yet completely harmonised.

Fate and behaviour in soil

Route of degradation

aerobic:

mineralization after 100 days:	9 % after 115 days
non-extractable residues after 100 days:	16.6 % after 115 days
relevant metabolites above 10 % of applied active substance: name and/or code % of applied (range and maximum)	None
Supplemental studies:	Not relevant*
anaerobic:	Not relevant*
soil photolysis:	Not required*
Remarks:	No particular remarks

Rate of degradation:

Laboratory studies

DT50lab (25°C, aerobic):	80 days
DT90lab (25°C, aerobic):	> 1 year
DT50lab (10°C, aerobic):	May have to be confirmed (see point 6 review report)
DT50lab(20°C, anaerobic):	Not relevant*

Field studies
(country or region)

DT_{50f} from soil dissipation studies: DT_{90f} from soil dissipation studies:	4 - 5 days (DE) 54 - 68 days (DE)
Soil accumulation studies:	Not relevant*
Soil residue studies:	Not relevant*
Remarks: e.g. effect of soil pH on degradation rate	No particular remarks

Adsorption/desorption:

K_{oc} / K_{OM}	K_{oc}=2080 - 8150 mg/l (12 soils)

Mobility:

Laboratory studies:

-Column leaching	Average penetration < 5 cm, no residues in leachate
-Aged residue leaching	Average penetration < 2 cm, no residues in leachate

Field studies:

Lysimeter/Field leaching studies:	Not relevant*
Remarks:	No particular remarks

Fate and behaviour in water

Abiotic degradation:

Hydrolytic degradation:	No hydrolysis between pH 5 - 9
Photolytic degradation:	DT_{50} in river water = 18.15 hour

Biological degradation:

Ready biological degradability:	Not relevant*
Water/sediment study:	Rapid dissipation from water phase into sediment
Accumulation in water and/or sediment	

Degradation in the saturated zone:

	Not relevant*
Remarks:	No particular remarks

Fate and behaviour in air

Volatility:

Vapour pressure:	see Appendix I
Henry's law constant:	see Appendix I

Photolytic degradation:

Direct photolysis in air	No particular remarks
Photochemical oxidative degradation in air: DT50	DT_{50}=1.8 hours
Remarks:	No particular remarks

3. Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals	LD_{50} in female rats = 227mg as/kg bw
Acute toxicity to birds:	LD_{50} in japanese quail = 510 mg as/kg bw, single dose
Dietary toxicity to birds:	LC_{50} in mallard duck > 5620 mg/kg food, 5 day study
Reproductive toxicity to birds:	NOEC in mallard duck = 250 mg/kg food, 22 week study
Short term oral toxicity to mammals	NOAEL in female rats = 11.3 mg/kg bw/day

Aquatic Organisms

Acute toxicity fish	LC_{50} rainbow trout = 1.48 mg/l, 96 hours study
Bioaccumulation fish	BCF rainbow trout = 48.7 - 63.8
Acute toxicity invertebrate	EC_{50} *Daphnia magna* = 3.5 mg/l, 48 hours study
Acute toxicity algae	EC_{50} = 0.87 mg/l
Chronic toxicity sediment dwelling organism	NOEC *Chironomus* = 165.4 mg/kg sediment

Honeybees

Acute oral toxicity	LD_{50} = 35.1 µg/bee, 48 hours
Acute contact toxicity	LD_{50} = 39 µg/bee, 48 hours

Other arthropod species

Coccinella septempunctata	E (mort) = 0 %, 14 days of exposition
Coccinella septempunctata	E (fecund) = 24.4 %, 14 days reproduction period
Poecilus cupreus	E (mort) = 0 %, 14 days exposition
Encarsia formosa	E (mort) = 0 %, 7 days, concentration 30 g as/100 l water
Encarsia formosa	E (parasitization) = 0 %, 7 days, concentration 30 g as/100 l water

Earthworms

Acute toxicity	LC_{50} = 541 mg/kg soil
Reproductive toxicity:	Not relevant*

Soil micro-organisms

Nitrogen mineralization	No effect at 1mg/kg soil
Carbon mineralization:	No effect at 1mg/kg soil

APPENDIX III

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])

Author	Title of study	Date requirement covered by the study([1])	Reports[2] on previous use in granting national authori-zations
D. Cleeren A. Ruts J. Bracke	R23979. Ultraviolet absorption; Generated and submitted by: Janssen Pharmaceutica NV. Company file No: SP-NMR 84-38. Date March 10, 1995	Annex IIA 2.5.1 UV spectrum	
J. van Thienen, J. Dockx	Physico-chemical properties of imazalil technical: Flammability (contact with water) Generated and submitted by: Janssen Pharmaceutica NV. Company file No: STL41. Date February 2, 1995	Annex II A 2.11.1. Flammability	
J. v Helvoirt	On the explosive properties of imazalil ZR 023979 Generated by NOTOX B. V. Submitted by: Janssen Pharmaceutica NV. Company file No: NOTOX.Project 139894. Date February 21, 1995	Annex IIA 2.13. Explosive properties. A statement which can be protected.	
J. v Helvoirt	Determination of the surface tension of an aqueous solution of imazalil. ZR 023979	Annex II A 2.14. Surface tension.	

[1] List based on a detailed analysis from Belgium in its letter of 07/04/97 (background document C)

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

	Generated by NOTOX B. V. Submitted by: Janssen Pharmaceutica NV. Company file No: NOTOX.Project 139804. Date February 21, 1995		
J. v Helvoirt	Determination of the oxidizing properties of imazalil. ZR 023979 Generated by NOTOX B. V. Submitted by: Janssen Pharmaceutica NV. Company file No: NOTOX.Project 139905. Date February 21, 1995	Annex 2.15. Oxidizing properties	
M. De Smet, J. mateusen	Validation: -Method Validation of the purity-and stability-indicating $(GC)^2$ assay method ST-GC 91-22 for imazalil (R023979). -Reference: report ST-GC 93-35 (Purity-and Stability-indicating $(GC)^2$ assay method for imazalil (R023979), October 25, 1993), which is an update from report ST-GC 91-22 Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : ST-QA 91-14 Date : June 19, 1991	Annex II A 4.1.1 This study corresponds to data requirement II A 4.1.3 ir relation to the method under II A	
M. De Smet, J. mateusen	Validation: Method validation of the purity-and stability-indicating $(GC)^2$ method ST-GC 91-9 for imazalil (R023979). (report ST-GC 91-9 was updated by report ST-GC 93-36) Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : ST-QA 91-11 Date : March 27, 1991		
M. De Smet, S. Niljsmans	Method:Purity-and stability-indicating $(GC)^2$ method for imazalil (R023979) Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : ST-GC 93-36 Date : October 25, 1993	Annex II A 4.1.2; This method corresponds to data requirement II A 4.1.2 abd also the validation of the method in accordance with II A 4.1.3	
P. Heylen P. Van Nyen J. Mateusen M. De Smet	Method validation of the purity-and stability-indicating $(GC)^2$ method ST-GC 91-9 for imazalil (R023979) with regard	Annex II A 4.1.2. Comments by the Beligium authorities can	

	to the compound R091856 Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : ST-QA 93-8 Date : May 17, 1993	be found in document C.	
A. Garnier	A validated gas chromatographic method for the determination of total regulable residues of imazalil on cucurbits (melons) Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : AGR 15 Date : October 22, 1992	Annex II A 4.2.1	
T. Ligtvoet, M. Nuyts	A validated gas chromatographic method for the determination of total regulable residues of imazalil on bananas Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : 56 Date : August 10, 1992	Annex II A 4.2.1	
T. Ligtvoet, M. Nuyts	A validated gas chromatographic method for the determination of imazalil-related residues on cereals (grain) Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : 58 Date : December 10, 1992	Annex II A 4.2.1	
F. Van Rompaey, R. Woesten-borghs	GC-ECD determination of imazalil and its metabolite in soil Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : R023979/009 Date : December 10, 1993	Annex A 4.2.2	
Mannens,G.,Van Leemput,L. and Heykants, J.	General metabolism of imazalil in the rat Generated by: Janssen Pharmaceutica N.V Submitted by: Janssen Pharmaceutica N.V. Company file n°: R 23979/FK1116 Date:1993	Annex A 5.1	
Meuldermans, W., and Heykants,J.	the metabolic fate of imazalil on banana plants Generated by: Janssen	Annex 5.1	

	Pharmaceutica N.V Submitted by: Janssen Pharmaceutica N.V Company file n°: R 23979/21 Date:1980		
O'Connor, J.	Imazalil:distribution and metabolism in spring wheat Generated by: Life Science Research Ltd.,UK Submitted by: Janssen Pharmaceutica N.V. Company file n°:R23979/ENV187 Date:1993	Annex 5.1. Comments by the Beligium authorities can be found in document C.	
Van Gompel, J.,Vanparys, Ph and Van Cauteren,H.	In vitro mammalian gene mutation assay Generated by: Janssen Pharmaceutica N.V. Submitted by: Janssen Pharmaceutica N.V. Company file n°:3470 Date:1995	Annex 5.4.1; The study is a test for gene mutation in mammalian cells provided for under II A 5.4.1	
Verstraeten ,A., Vandenberghe , J., Lampo, A., Coussement, W. and Van Cauteren, H.	Carcinogenicity study on Imazalil technical grade in Swiss mice when administered through the diet for 2 years Generated by: Janssen Pharmaceutica N.V. Submitted by: Janssen Pharmaceutica N.V. Company file:1999 Date: 1993		DE: The study has been submitted on 28/2/96 in a national authorisa-tion
Dirkx,P., Lampo ,A., Vandenberghe, J., Coussement ,W. and Van Cauteren, H.	2-Generation reproduction study in imazalil technical grade with 1 litter per generation in wistar rats, when orally administered through the diet.. Generated by: Janssen Pharmaceutica N.V. Submitted by: Janssen Pharmaceutica N.V Company file n°:2337 Date:1992	Annex II A 5.6.1.	NL: The study has been submitted on 22 October 1993 in a national application;
J O' Connor	Imazalil : Distribution and metabolism in spring wheat. Generated by : Life Science Research Ltd., UK Submitted by : Janssen Pharmaceutica N.V. Company file No. : R 23979/ENV187 Date : January 8, 1993	Annex 6.1.5. Comments from Begium can be found in document C	
W. Meuldermans J. Heykants	The metabolic fate of imazalil on banana plants Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : R 23979/21	Annex II A 6.3.1	

	Date : May 1980		
W. Meuldermans J. Heykants	he metabolic fate of imazalil on banana plants. Addendum 1 : Translocation into sleeved bunches Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : R 23979/25 Date : May 1981	Annex II A 6.3.1	
A. Van Dijk	14C-Imazalil: Distribution, degradation, metabolism and excretion after repeated oral administration to a lactating goat. Generated by : RCC Umweltchemie AG, CH Submitted by : Janssen Pharmaceutica N.V. Company file No. :R 23979/FK1206 and R 23979/FK1346 Date : July 22, 1992 and June 30, 1993	Annex II A 6.2.1	
G. Mannens L. Van Leemput J. Heykants	A study on milk and tissue metabolites of imazalil in a lactating goat after repeated oral administration at 10 mg/kg/day Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : R 23979/FK1346 Date : June 30, 1993	Annex II A 6.2.1	
D. Hallifax	Imazalil : Distribution, metabolism (nature of the residue) and excretion study in the laying hen. Generated by : Pharmaco LSR, UK Submitted by : Janssen Pharmaceutica N.V. Company file No. : 93/JST006/0615 Date : December 1993	Annex II A 6.2.2	
A. Garnier J. Van Gestel B. Duytschaever	Analysis of imazalil -derived residues in bananas Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Date : August 1991	Annex II A 6.3	
L. Gensens J. Van Gestel B. Duytschaever	Imazalil residues in tomatoes after foliar spray against powdery mildew (greenhouse trial) Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen	Annex II A 6.3.	

	Pharmaceutica N.V. Date : September 1995 a		
L. Gensens J. Van Gestel B. Duytschaever	Imazalil residues in tomatoes after foliar spray against powdery mildew (greenhouse trial) Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Date : September 1995 b	Annex II A 6.3	
W.R. Goodwine B. Duytschaever	Imazalil and R 14821 residue levels in processing fractions of lemons, oranges and grapes fruits resulting from post-harvest treatment with Fungaflor 500 EC. Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : AGR 8 Date : August 19, 1992	Annex II A 6.5.2.1	
L. Van Leemput	Soil dissipation of imazalil under field conditions in Goch-Nierswalde, Germany, following a single application of Fungaflor 200 EC at 1000 g a.i./ha. Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : R 23979/ENV202/GN Date : March 17, 1995	Annex II A 7.1.1.2.2	
L. Van Leemput	Soil dissipation of imazalil under field conditions in Meissner-Vockerode, Germany, following a single application of Fungaflor 200 EC at 1000 g a.i./ha. Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : R 23979/ENV202/MV Date : March 17, 1995	Annex II A 7.1.1.2.2	
L. Van Leemput	Soil dissipation of imazalil under field conditions in Obernburg, Germany, following a single application of Fungaflor 200 EC at 1000 g a.i./ha. Generated by : Janssen Pharmaceutica N.V.	Annex II A 7.1.1.2.2	

	Submitted by : Janssen Pharmaceutica N.V. Company file No. : R 23979/ENV202/OB Date : March 17, 1995		
G. Teuns	Reproduction study in Mallard Ducks Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : 2288 Date : September 4, 1991	Annex II A 8.1.3	
I. Van Ginneken D. Weytjens	The effect of imazalil (R023979) on the growth of the unicellular green alga *Selenastrum capricornutum* Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : AASc/0034 Date : March 27, 1996	Annex II A 8.2.6	
Wyness L.E.	Imazalil : Chronic sediment toxicity test using an infaunal insect *Chironomus riparius* Generated by : Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Date : 1996	Annex 8.2.7; As the as is likely to partition to aquatic sediments the study can be considered necessary.	
J. Lacy N. Hamon D.C. Twinn	Imazalil (R 023979) Laboratory determination of direct contact toxicity to adult honeybees, *Apis mellifera L.* by Potter Tower application. Estimation of the LC50. Generated by : May & Baker Ltd., UK Submitted by : Janssen Pharmaceutica N.V. Company file No. : AgR/JL/NH/DCT/207 Date: September 1986	Annex II A 8.3.1	AU: The study has been submitted on 24 march 1992 in a national application.
M. Peeters	On the influence of repeated dosages of imazalil on the operation of a sewage treatment plant. Generated by: Janssen Pharmaceutica N.V. Submitted by : Janssen Pharmaceutica N.V. Company file No. : none Date: February 1980	Annex II A 8.7	

EUROPEAN COMMISSION
DIRECTORATE-GENERAL VI
AGRICULTURE
Public, animal and plant health
VI.B.II.1 Legislation relating to crop products and animal nutrition

8887/VI/97

SUMMARY REPORT OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH HELD ON 2 DECEMBER 1997

1. **Examination and possible opinion on a draft Commission Directive amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market in order to include imazalil in Annex I (Doc. 1635/VI/97 - Rev.15).**

The Commission presented the draft Commission Directive as finalised in document 1635/VI/97, rev. 15. Some minor amendments were read out to the Committee.

In order to clarify several issues that were discussed in the Working Group "Legislation" the following declarations were made :

"1. Member States and the Commission understand that the directive is an appropriate legal instrument for deciding on inclusion of active substances in Annex I of Directive 91/414/EEC in accordance with the provisions of Articles 6 and 8 (2) of the Directive.

2. On request from the Irish delegation, the Commission indicates that, in its opinion, the date of decision referred to in Article 13(3)(d) is the date of entry into force of the directive including the active substance in Annex I.

3. On request from the French delegation, the Commission indicates that, in its opinion, it results from Article 4(6)(a) and 13 of Directive 91/414/EEC, that the authorisations of products containing an existing active substance included in Annex I must be withdrawn when the data requirements laid down in article 13 of the Directive are not satisfied.

4. The Commission declares that it will organise at regular intervals a forum discussion between Member States on any issues they may raise with regard

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: Loi 84 1/12.
Telephone: direct line (+32-2)295.59.51, exchange 299.11.11. Fax: 296.59.63.
Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.

to the practical implementation of the data protection provisions in Directive 91/414/EEC."

It was reminded that the flexibility for the data to be submitted for national authorisations can find a solution in the introduction to Annex III.

A recital clarifies that the periods laid down for the implementation of this Directive do not prejudice decisions in this respect for other active substances.

Germany made the following declaration :

"Germany interprets Article 4 (6) and Article 13 in relation to the transitional measures in Article 8 (2) of Council Directive 91/414/EEC in such a way that they apply when an application for an authorisation is submitted and not when existing authorisations are re-evaluated. Germany is of the opinion that Article 13 does not constitute a legal basis for the withdrawal of existing authorisations of products containing imazalil."

The Committee gave a favourable opinion on the draft by unanimity.

2. Other business

None.

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

Heft 47, 1998: Zuständigkeiten bei der Prüfung und Zulassung von Pflanzenschutzmitteln und bei der EU-Wirkstoffprüfung. (Stand: September 1998). Bearbeitet von Edelgard Adam, 59 S.

Heft 48, 1999: Tropischer und Subtropischer Pflanzenbau. Seine Entwicklung als Teil der Landbauwissenschaften – am Beispiel der Kagera-Region in Tansania/Ostafrika – eine Kurzdarstellung der tansanischen Landwirtschaft. Dr. Heinrich Brammeier, 82 S.

Heft 49, 1999: Art und Menge der in der Bundesrepublik Deutschland abgegebenen und der exportierten Wirkstoffe in Pflanzenschutzmitteln (1987 – 1997). Ergebnisse aus dem Meldeverfahren nach § 19 des Pflanzenschutzgesetzes. Bearbeitet von Dr. Hans-Hermann Schmidt, Dr. Achim Holzmann, Edeltraut Alisch, 77 S.

Heft 50, 1999: Pflanzenschutzmittel im ökologischen Landbau – Probleme und Lösungsansätze. Erstes Fachgespräch am 18. Juni 1998 in Kleinmachnow - Pflanzenstärkungsmittel – Elektronenbehandlung - . Bearbeitet von Dr. Holger Beer und Dr. Marga Jahn, 76 S.

Heft 51, 1999: Wirkstoffdatenblätter zur arbeitsmedizinischen Vorsorgeuntersuchung - Pflanzenschutzmittel - . 2. Folge, Stand: Dezember 1998. Bearbeitet von Dr. Hans-Hermann Schmidt, Dr. Eberhard Hoernicke, Dr. Marion Fathi, Dr. Rudolf Pfeil, 239 S.

Heft 52, 1999: Liste der zugelassenen Pflanzenschutzmittel (Stand: 1. Januar 1999). Bearbeitet von Dr. Achim Holzmann und Andreas Spinti, 63 S.

Heft 53, 1999: Pflanzenschutz im ökologischen Landbau – Probleme und Lösungsansätze. Zweites Fachgespräch am 5. November 1998 in Darmstadt. Die Anwendung kupferhaltiger Pflanzenschutzmittel, ihre Auswirkungen auf den Naturhaushalt und Erörterung der Möglichkeiten, unerwünschte Auswirkungen zu begrenzen. Bearbeitet von Dr. Marga Jahn und Dr. Holger Beer, 85 S.

Heft 54, 1999: Verzeichnis der Wirkstoffe in zugelassenen Pflanzenschutzmitteln (ehemals Merkblatt Nr. 20). Stand: Juli 1999. Bearbeitet von Dr. Walter Dobrat, 265 S.

Heft 55, 2000: Liste der zugelassenen Pflanzenschutzmittel (Stand: 1. Januar 2000). Bearbeitet von Dr. Achim Holzmann, 88 S.

Heft 56, 2000: Einführung in die Biometrie unter Berücksichtigung der Software SAS. Teil 4: Korrelationsanalyse, Regressionsanalyse und Kovarianzanalyse. Zur Nutzung von SAS/INSIGHT® und der Analyst Application. Bearbeitet von Dr. Eckart Moll, 94 S.

Heft 57, 2000: Synopsis of Testing Plant Protection Equipment in the Federal Republic of Germany. Published on the Occasion of the 50th.Anniversary of Testing Plant Protection Equipment at the Federal Biological Research Centre for Agriculture and Forestry in Braunschweig. Bearbeitet von Siegfried Rietz, 214 S.

Heft 58, 2000: Aufgaben der Biologischen Bundesanstalt für Land- und Forstwirtschaft als selbständige Bundesoberbehörde. Stand: März 2000. Dr. Gerhard Gündermann, 21 S.

Heft 59, 2000: EU-Beurteilungsbericht Fluroxypyr. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 1. Bearbeitet von Dr. Achim Holzmann und Jutta Plekat, getr. Zählung.

Heft 60, 2000: EU-Beurteilungsbericht Azimsulfuron. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 2. Bearbeitet von Dr. Achim Holzmann und Jutta Plekat, getr. Zählung.

Heft 61, 2000: EU-Beurteilungsbericht Kresoxim-methyl. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 3. Bearbeitet von Herbert Köpp und Jutta Plekat, getr. Zählung.

Heft 62, 2000: Wirkstoffdatenblätter zur arbeitsmedizinischen Vorsorgeuntersuchung - Pflanzenschutzmittel - . 3. Folge, Stand: Dezember 1999. Bearbeitet von Dr. Hans-Hermann Schmidt, Dr. Eberhard Hoernicke, Dr. Marion Fathi, Dr. Rudolf Pfeil, 224 S.

Heft 63, 2000: Biodiversität in der Biologischen Bundesanstalt für Land- und Forstwirtschaft (BBA). Bearbeitet von Prof. Dr. Fred Klingauf, Dr. Heinrich Brammeier, Dr. Wolfgang Burgermeister und Dr. Holger Beer, 507 S.

Heft 64, 2000: Zuständigkeiten bei der Prüfung und Zulassung von Pflanzenschutzmitteln und bei der EU-Wirkstoffprüfung. Stand: Juni 2000. Bearbeitet von Edelgard Adam, 59 S.

Heft 65, 2000: EU-Beurteilungsbericht Azoxystrobin. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 4. Bearbeitet von Herbert Köpp und Jutta Plekat, getr. Zählung.

Heft 66, 2000: EU-Beurteilungsbericht Spiroxamine. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 5. Bearbeitet von Herbert Köpp und Jutta Plekat, getr. Zählung.