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EU-Beurteilungsbericht Azimsulfuron
Rechtliche Regelungen der Europäischen Union
zu Pflanzenschutzmitteln und deren Wirkstoffen
Band D 2

Review Report Azimsulfuron
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 2

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Inhalt / Contents

Vorwort / Preface

Richtlinie 2000/10/EG der Kommission

Directive 2000/10/EC of the Commission

Review Report

Summary Report of the Meeting of the Standing Committee on Plant Health held on 30 November 1999

Opinion of the Scientific Committee on Plants, 4 June 1999

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

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 2. Heft dieser Reihe (Band D 2) 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 Berichtersteller ist, ebenfalls beim Saphir Verlag gegen Erstattung der Unkosten bezogen werden. Für Azimsulfuron war Italien Berichtersteller.

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: <i>Wird zur Zeit bearbeitet</i>

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 2nd report belonging to this series (Volume D 2) 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 azimsulfuron Italy 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 (3 rd Edition, date: 1 November 1997)
36/97	Volume B: Directives, Regulations, Decisions and Protocols regarding the Evaluation of Active Substances (3 rd Edition, date: 1 November 1997)
	Volume C: <i>In Progress</i>

RICHTLINIE 1999/80/EG DER KOMMISSION

vom 28. Juli 1999

zur Aufnahme des Wirkstoffs Azimsulfuron 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 1999/1/EG der Kommission⁽²⁾, im folgenden „die Richtlinie“ genannt, insbesondere auf Artikel 6 Absatz 1,

in Erwägung nachstehender Gründe:

- (1) Die italienischen Behörden haben am 4. März 1996 gemäß Artikel 6 Absatz 2 der Richtlinie 91/414/EWG einen Antrag von DuPont de Nemours Italiana SpA, im folgenden „der Antragsteller“ genannt, auf Aufnahme des Wirkstoffs Azimsulfuron in Anhang I der Richtlinie erhalten.
- (2) Gemäß Artikel 6 Absatz 3 der Richtlinie hat die Kommission in ihrer Entscheidung 97/164/EG⁽³⁾ bestätigt, daß die für Azimsulfuron eingereichten Unterlagen grundsätzlich die an die Daten und Informationen gestellten Anforderungen des Anhangs II bzw. für ein Pflanzenschutzmittel, das diesen Wirkstoff enthält, diejenigen des Anhangs III der Richtlinie erfüllen.
- (3) Gemäß Artikel 5 Absatz 1 der Richtlinie ist ein Wirkstoff für einen Zeitraum von höchstens zehn Jahren in Anhang I aufzunehmen, wenn angenommen werden kann, daß keine schädlichen Auswirkungen auf die Gesundheit von Mensch und Tier oder auf das Grundwasser bzw. keine unannehmbaren Auswirkungen auf die Umwelt eintreten werden.
- (4) Die Auswirkungen von Azimsulfuron auf die menschliche Gesundheit und auf die Umwelt wurden gemäß Artikel 6 Absätze 2 und 4 der Richtlinie für die von dem Antragsteller vorgeschlagenen Anwendungen geprüft. In seiner Funktion als berichterstattender Mitgliedstaat hat Italien der Kommission am 22. Mai 1997 den betreffenden Bewertungsbericht übermittelt.
- (5) Der vorgelegte Bewertungsbericht wurde von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses für Pflanzenschutz geprüft. Diese Prüfung wurde am 2. Juli 1999 in Form des Prüfungsberichts der Kommission für Azimsulfuron abgeschlossen. Der Bericht muß möglicherweise unter Berücksichtigung technischer und wissenschaftlicher Entwicklungen aktualisiert werden. In diesem Fall sind auch die Bedingungen

für die Aufnahme von Azimsulfuron in Anhang I der Richtlinie 91/414/EWG gemäß deren Artikel 6 Absatz 1 zu ändern.

- (6) Die Unterlagen und die aus der Prüfung hervorgegangenen Informationen wurden auch dem Wissenschaftlichen Pflanzenausschuß zur Stellungnahme vorgelegt. Dieser Ausschuß hat seine Stellungnahme am 4. Februar 1999 abgegeben. Der Ausschuß stellte fest, daß potentielle Risiken für Wasserorganismen und Nichtziel-Landpflanzen bestehen. Deshalb müssen gegebenenfalls risikosenkende Maßnahmen getroffen werden⁽⁴⁾.
- (7) Die Bewertungen haben ergeben, daß davon ausgegangen werden kann, daß den betreffenden Wirkstoff enthaltende Pflanzenschutzmittel im allgemeinen die Anforderungen gemäß Artikel 5 Absatz 1 Buchstaben a) und b) und Absatz 3 der Richtlinie erfüllen, insbesondere hinsichtlich der geprüften Anwendungen. Daher muß der betreffende Wirkstoff in Anhang I aufgenommen werden, damit die Zulassung von Pflanzenschutzmitteln mit dem betreffenden Wirkstoff in allen Mitgliedstaaten gemäß den Bestimmungen der Richtlinie gewährt werden kann.
- (8) Nach der Aufnahme ist den Mitgliedstaaten eine angemessene Frist einzuräumen, um die Bestimmungen der Richtlinie 91/414/EWG über azimsulfuronhaltige Pflanzenschutzmittel umzusetzen und insbesondere innerhalb dieser Frist bereits bestehende vorläufige Zulassungen zu überprüfen bzw. vor Ablauf der Frist neue Zulassungen gemäß der Richtlinie zu erteilen. Für Pflanzenschutzmittel, die Azimsulfuron und andere in Anhang I aufgeführte Wirkstoffe enthalten, kann auch eine längere Frist erforderlich sein.
- (9) Es ist vorzuschreiben, daß die Mitgliedstaaten den endgültigen Prüfungsbericht (mit Ausnahme von vertraulichen Informationen im Sinne des Artikels 14 der Richtlinie) allen Betroffenen zur Einsicht zur Verfügung stellen oder zugänglich machen.
- (10) Der Prüfungsbericht ist erforderlich für die ordnungsgemäße Umsetzung bestimmter Teile der einheitlichen Grundsätze gemäß 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 der Richtlinie vorgelegt wurden.

⁽¹⁾ ABL L 230 vom 19.8.1991, S. 1.⁽²⁾ ABL L 21 vom 28.1.1999, S. 21.⁽³⁾ ABL L 64 vom 5.3.1997, S. 17.⁽⁴⁾ Stellungnahme des Wissenschaftlichen Pflanzenausschusses über die Aufnahme von Azimsulfuron in Anhang I der Richtlinie 91/414/EWG über das Inverkehrbringen von Pflanzenschutzmitteln (SCP/AZIM/002-endg. 24.2.1999).

(11) . Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz vom 2. Juli 1999 —

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

Azimsulfuron wird hiermit gemäß dem Anhang der vorliegenden Richtlinie als Wirkstoff in Anhang I der Richtlinie 91/414/EWG aufgenommen.

Artikel 2

(1) Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens 1. April 2000 nachzukommen.

(2) Hinsichtlich der Bewertung und Zulassung gemäß den einheitlichen Grundsätzen von Anhang VI der Richtlinie 91/414/EWG jedoch wird der in Absatz 1 festgesetzte Zeitraum auf der Grundlage von Unterlagen, die die Anforderungen von Anhang III derselben Richtlinie erfüllen, für die bestehenden vorläufigen Zulassungen von Azimsulfuron enthaltenden Pflanzenschutzmitteln bis zum 1. April 2001 verlängert.

(3) Bei Pflanzenschutzmitteln, die Azimsulfuron zusammen mit einem anderen in Anhang I der Richtlinie 91/414/EWG aufgeführten Wirkstoff enthalten, wird die Frist gemäß Absatz 1 jedoch so weit verlängert, als die Vorschriften der Richtlinie

über die Aufnahme dieses anderen Wirkstoffs in den genannten Anhang I eine längere Umsetzungsfrist vorsehen.

(4) Die Mitgliedstaaten stellen den Prüfungsbericht (mit Ausnahme von vertraulichen Informationen im Sinne von Artikel 14 der Richtlinie 91/414/EWG) allen Betroffenen zur Einsicht zur Verfügung oder machen ihn gegebenenfalls auf besonderen Antrag zugänglich.

(5) Wenn die Mitgliedstaaten diese Vorschriften erlassen, nehmen sie in den 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. Oktober 1999 in Kraft.

Artikel 4

Diese Richtlinie ist an alle Mitgliedstaaten gerichtet.

Brüssel, den 28. Juli 1999

Für die Kommission

Franz FISCHLER

Mitglied der Kommission

ANHANG

AZIMSULFURON

1. Identität
(IUPAC)1-(4,6-Dimethoxyypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-pyrazol-5-ylsulfonyl]-harnstoff
 2. Zu erfüllende Bedingungen
 - 2.1 Der Wirkstoff muß eine Reinheit von mindestens 980 g/kg technischem Erzeugnis aufweisen.
 - 2.2 Nur Verwendungen als Herbizid dürfen zugelassen werden.
 - 2.3 Aviotechnische Ausbringungen dürfen nicht zugelassen werden.
 - 2.4 Die Mitgliedstaaten müssen besonders auf die Auswirkungen auf Wasserorganismen und Nichtziel-Landpflanzen achten und dafür sorgen, daß die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Senkung des Risikos umfassen (zum Beispiel im Reisanbau eine Mindestwartezeit vor Ableiten des Wassers).
 - 2.5 Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlußfolgerungen des vom Ständigen Ausschuß für Pflanzenschutz am 2. Juli 1999 abgeschlossenen Prüfungsberichts über Azimsulfuron und insbesondere dessen Anlagen I und II zu berücksichtigen.
 3. Aufnahme befristet bis 1. Oktober 2009.
-

COMMISSION DIRECTIVE 1999/80/EC

of 28 July 1999

including an active substance (azimsulfuron) 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 Commission Directive 1999/1/EC ⁽²⁾, hereafter referred to as the Directive, and in particular Article 6(1),

- (1) Whereas in accordance with Article 6(2) of Directive 91/414/EEC Italy received on 4 March 1996 an application from Du Pont de Nemours Italiana SpA, hereafter referred to as the applicant, for the inclusion of the active substance azimsulfuron in Annex I to the Directive;
- (2) Whereas in accordance with the provisions of Article 6(3) of the Directive the Commission confirmed in its Decision 97/164/EC ⁽³⁾ of 17 February 1997 that the dossier submitted for azimsulfuron could be considered as satisfying, in principle, the data and information requirements of Annex II and for a plant protection product containing this active substance, of Annex III to the Directive;
- (3) Whereas, in accordance with Article 5(1) of the Directive, an active substance should be included for a period not exceeding 10 years in Annex I 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;
- (4) Whereas for azimsulfuron, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of the Directive, for the uses proposed by the applicant; whereas Italy acting as nominated rapporteur Member State, has submitted to the Commission on 22 May 1997 the assessment report concerned;
- (5) 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 finalised on 2 July 1999 in the format of the Commission review report for azimsulfuron; whereas it may be necessary to update this report to take account of technical and scientific developments; whereas in such case the conditions for the inclusion of azimsul-

furon in Annex I to Directive 91/414/EEC will also need to be amended pursuant to Article 6(1) of that Directive;

- (6) Whereas the dossier and the information from the review have also been submitted to the Scientific Committee on Plants for opinion; whereas this Committee has given its opinion on 4 February 1999; whereas this Committee identified potential risks to aquatic organisms and terrestrial non-target plants, whereas therefore appropriate risk mitigation measures must be taken ⁽⁴⁾;
- (7) Whereas 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),(b) and (3) 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 authorisations of plant protection products containing the active substance concerned can be granted in accordance with the provisions of the said Directive;
- (8) Whereas after inclusion a reasonable period is necessary to permit Member States to implement the provisions of Directive 91/414/EEC on plant protection products containing azimsulfuron and in particular to review, within this period, existing provisional authorisations or to grant, by the end of this period at the latest, new authorisations in accordance with the provisions of the Directive; whereas a longer period may also be required for plant protection products containing azimsulfuron and other active substances included in Annex I;
- (9) Whereas it is appropriate to provide that the finalised review report (except for confidential information in the meaning of Article 14 of the Directive) is kept available or made available by the Member States for consultation by any interested parties;
- (10) 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 of the Directive;

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.⁽²⁾ OJ L 21, 28.1.1999, p. 21.⁽³⁾ OJ L 64, 5.3.1997, p. 17.⁽⁴⁾ Opinion of the Scientific Committee on Plants regarding the inclusion of azimsulfuron in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market (SCP/AZIM/002-Final 24/02/1999)

(11) Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health delivered on 2 July 1999,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Azimsulfuron 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, at the latest by 1 April 2000.

2. However, 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 period laid down in the first paragraph is extended for existing provisional authorisations of plant protection products containing azimsulfuron to 1 April 2001.

3. However for plant protection products containing azimsulfuron together with another active substance which is in Annex I to Directive 91/414/EEC, the period referred to in paragraph 1 is extended to the extent that a longer imple-

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

5. When Member States adopt the measures, 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 laid down by the Member States.

Article 3

This Directive shall enter into force on 1 October 1999.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 28 July 1999.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX

AZIMSULFURON

1. Identity
(IUPAC) 1-(4,6-dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-pyrazol-5-ylsulfonyl]-urea
 2. Particular conditions to be fulfilled:
 - 2.1. The active substance shall have a minimum purity of 980 g/kg technical product.
 - 2.2. Only uses as herbicide may be authorised.
 - 2.3. Aerial applications may not be authorised.
 - 2.4. 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 (for example, in rice cultivation minimum holding periods for water prior to discharge).
 - 2.5. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on azimsulfuron, and in particular the Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 2 July 1999 shall be taken into account.
 3. Expiry date of the inclusion: 1 October 2009.
-

FINAL

Review report for the active substance **azimsulfuron**

Finalised in the Standing Committee on Plant Health at its meeting on XX/XX/XX in view of the inclusion of azimsulfuron in Annex I of Directive 91/414/EEC.

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance azimsulfuron, made in the context of the work provided for in Articles 5 and 6 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.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, Italian authorities received on 4 March 1996 an application from Du Pont De Nemours, hereafter referred as the applicant, for the inclusion of the active substance azimsulfuron in Annex I to the Directive. Italian authorities indicated to the Commission on 31 July 1996 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6 (2), a dossier on azimsulfuron was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on Plant Health in the meeting of the working group 'legislation' thereof on 11 October 1996, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 97/164/EC¹ of 17 February 1997 that these requirements were satisfied.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that Italy would, as rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or

¹ OJ No L 64, 05.03.1997, p.17

non-inclusion and any conditions relating thereto, to the Commission as soon as possible and at the latest within a period of one year.

Italy submitted to the Commission on 22 May 1997 the report of its detailed scientific examination, hereafter referred to as the draft report, including, as required, a recommendation concerning the possible inclusion of azimsulfuron in Annex I to the Directive.

On receipt of the draft report, the Commission forwarded it for consultation to all the Member States as well as to Du Pont De Nemours being the applicant on 18 June 1997.

The Commission organised further an intensive consultation of specialised scientific experts from a representative number of Member States, to review the rapporteur Member States' 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 1997 to January 1998.

The report of the peer review (i.e. full peer review report) was circulated, for further consultation, to Member States and the applicant on 30 July 1997.

The dossier, draft report and the full peer review report (i.e. full report) including in particular an outline resume of the remaining technical questions, 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 1998 to July 1999, and was finalised in the meeting of the Standing Committee on 2 July 1999.

These documents were also submitted to the Scientific Committee for Plants for a separate consultation. The report of this Committee was formally adopted on 4 February 1999 (SCP/AZIM/002- Final²).

The present azimsulfuron review report contains the conclusions of this final examination; given the importance of the rapporteur Member States' assessment report, the full peer review 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 Opinion of the Scientific Committee on Plants regarding the inclusion of azimsulfuron in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market (SCP/AZIM/002-Final 24/02/1999)

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 1999/80/99 EEC concerning the inclusion of azimsulfuron in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing azimsulfuron 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 parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the 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 the applicant.

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 possession of 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 azimsulfuron 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 azimsulfuron 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 applicant:

-herbicide for rice cultivation (aerial applications excluded)

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.

4. Specific conclusions which are highlighted in this evaluation

4.1 Residues of azimsulfuron in foodstuffs

The review has established that the residues arising from the proposed uses, consequent on application of good plant protection practices, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI) for a 60 kg adult is 0.01 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This intake value reflects the current use pattern for this active substance.

4.2 Exposure of operators, workers and bystanders

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

4.3 Ecotoxicology

The review has concluded that under the proposed and supported conditions of uses there are no unacceptable effects on the environment, as required in Article 4 (1)(b)(iv) and (v) of Council Directive 91/414/EEC, provided that certain conditions of use are taken into account as detailed in section 7 of this report.

5. Identity and Physical/chemical properties

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

The active substance shall have a minimum purity of 980 g/kg technical product.

The review has established that for the active substance notified by the applicant (Du Pont De Nemours), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

6. 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 evaluation process are listed in Appendix II.

7. 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 azimsulfuron.

On the basis of the proposed and supported uses, the following particular issue has been identified, which require particular attention by the Member States and which is highlighted at the level of the Annex I inclusion for this active substance.

- impact on aquatic organisms and terrestrial non - target plants

Member States must pay particular attention to the risks to aquatic organisms and terrestrial non target plants. Appropriate risk mitigation measures should be applied by the Member States when granting or reviewing existing authorisations.

8. List of studies to be generated

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

9. Information on studies with claimed data protection

For information of any interested parties, appendix III gives information about the studies for which the applicant has claimed data protection and which are not present in the original dossier neither mentioned in the draft report. 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.

10. Updating of this review report

The technical information in this report may require periodic updating 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 azimsulfuron in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

Azimsulfuron

Common name (ISO)	azimsulfuron
Chemical name (IUPAC)	1-(4,6-dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-pyrazol-5-ylsulfonyl]-urea
Chemical name (CA)	N-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-1H-pyrazole-5-sulfonamide
CIPAC No	584
CAS No	120162-55-2
EEC No	New compound: not yet available
FAO SPECIFICATION	New compound: not yet available
Minimum purity	Minimum purity of a.s. as manufactured 980g/kg
Molecular formula	C ₁₃ H ₁₆ N ₁₀ O ₅ S
Molecular mass	424.40
Structural formula	

Melting point	170 °C (443 °K) (purified compound > 99%)
Boiling point	azimsulfuron melted into a clear colourless liquid. Boiling point was not measured.
Appearance	White powdered solid with sharp odour similar to phenol (purified compound = 99.62%).
Temperature of decomposition	Begins to decompose at 180°C
Relative density	At 20 °C the relative density is 1.12 ± 0.046 (RSD = 4.1%) (purified compound = 99.62%).
Vapour pressure	4×10^{-9} Pa (25°C) (purity 99.62%)
Henry's law constant	pH 5 = 8×10^{-9} Pa m ³ mol ⁻¹ pH 7 = 5×10^{-10} Pa m ³ mol ⁻¹ pH 9 = 9×10^{-11} Pa m ³ mol ⁻¹
Solubility in water	pH 5 = 72.3 mg/l at 20 °C pH 7 = 1050 mg/l at 20 °C pH 9 = 6536 mg/l at 20 °C (purity >99.64%)
Solubility in organic solvents (at 20 °C)	At 25 °C with purified compound 99.62%: Acetone 26.4 g/l Methanol 2.1 g/l Acetonitrile 13.9 g/l Methylene chloride 65.9 g/l Etylacetate 13.0 g/l Toluene 1.8 g/l Hexane < 0.2 g/l
Partition coefficient (log P_{ow})	pH 5 = 4.43 at 25 °C pH 7 = 0.043 at 25 °C pH 9 = 0.008 at 25 °C
Hydrolytic stability (DT₅₀)	(radiolabelled; 97.4% pure) pH 5 = 89 d at 26 °C pH 7 = 124 d at 26 °C pH 9 = 132 d at 26 °C
Dissociation constant	pka = 3.6 (99.62% pure)
UV/VIS absorption (max.)	232 nm (acid conditions) (>99.7% pure) 236 nm (basic conditions) No max >290nm
Quantum yield of direct photo-transformation in water at >290nm	9×10^{-4}
Flammability	Not flammable
Explosive properties	Not explosive
Photostability (DT₅₀)	pH 5 DT ₅₀ = 103 d at 20 °C pH 7 DT ₅₀ = 164 d at 20 °C pH 9 DT ₅₀ = 225 d at 20 °C
Surface tension	68.1×10^{-3} nm at 23.7°C-purity 99.7%

APPENDIX II**ENDPOINTS AND RELATED INFORMATION****Azimsulfuron****1 Toxicology and metabolism****Absorption, distribution, excretion and metabolism in mammals**

Rate and extent of absorption:	High bio-availability 90-95 % in 48 h
Distribution:	Uniformly distributed
Potential for accumulation:	No potential for accumulation, Tissue residues < 0.7 % after 72 h
Rate and extent of excretion:	Urine 73-80 %, faeces 18-24 % within 48 h
Toxicologically significant compounds:	Parent compound
Metabolism in animals	Approximately 30 % metabolised by o- demethylation, hydroxylation, conjugation and hydrolysis

Acute toxicity

Rat LD ₅₀ oral:	> 5000 mg/kg bw
Rat LD ₅₀ dermal:	> 2000 mg/kg bw
Rat LC ₅₀ inhalation:	> 5.94 mg/l
Skin irritation:	Non irritant
Eye irritation:	Non irritant
Sensitisation:	Non sensitiser (M&K)

Short term toxicity

Target / critical effect:	Liver, pancreas, spleen, lymph-nodes, bone marrow and testes
Lowest relevant NOAEL:	Oral: 750 ppm (17.8 mg/kg bw/d) 1 year dog study Dermal: not submitted Inhalation: not required

Genotoxicity

no genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect:	Body weight, pancreas, testes
Lowest relevant NOAEL:	1000 ppm (34.3 mg/kg bw/d) 2 year rat study
Carcinogenicity:	No carcinogenic potential

Reproductive toxicity

Reproduction:	Increased perinatal mortality and reduced pup weights at parental toxic doses
Developmental toxicity:	Foetal weight changes and variations at maternally toxic doses
Lowest relevant reproductive NOAEL	76 mg/kg bw/day (rat)

Lowest relevant developmental NOAEL	200 mg/kg bw/day (rat)
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Delayed neurotoxicity

No relevant effects

Other toxicological studies

Mechanistic studies in the rat - show the mechanism of pancreatic effects not relevant to human risk assessment
Studies using metabolites - confirms that the parent is the toxicological significant compound

Medical data

Currently limited as azimsulfuron is a new active substance

Summary

ADI:	0.1 mg/kg bw; 2 generation rat (parental NOEL); AF: 100
AOEL:	0.2 mg/kg bw; 1 year dog study; AF: 100
ARfD (acute reference dose)	Not allocated (Not necessary)

Dermal absorption

10 %*

* default value based on physical/chemical properties

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

Pyrimidine -label treated soils:
flooded soil: 2 % after 84 d
upland soil: 2 - 13 % after 84 d
10,2 % after 270 d
No ¹⁴CO₂ was released from any of Pyrazole -label treated soils and sterilised soils. No volatile organics were released from any experiment groups

non-extractable residues:

73 - 86 % after 84 d in flooded non sterilised soil
24 - 37 % after 84 d in flooded sterilised soil
34 - 46 % after 84 d in non sterilised upland soil
36 - 42% after 270 d in non sterilised upland soil
27.7 - 41.2 % after 120 d in non sterilised upland soil

relevant metabolites above 10 % of applied active substance: name and/or code
% of applied (range and maximum)

Degradation pathways: oxidative desmethylation, oxidative ring cleavage, hydrolysis, incorporation to humic materials, mineralization to ¹⁴CO₂

A8342, 1-methyl-4-(2-methyl-2*H*-tetrazol-5-yl)-1*H*-pyrazole-5-sulfonamide;
J290, 2-amino-4,6-dimethoxypyrimidine
JJ999, N-[(4-hydroxy-6-methoxypyrimidin-2-yl)aminocarbonyl]-1-methyl-4-(2-methyl-2*H*-tetrazol-5-yl)-1*H*-pyrazole-5-sulfonamide
KQ962 N-[[{(aminoiminomethyl)amino]carbonyl]-1-methyl-4-(2-methyl-2*H*-tetrazol-5-yl)-1*H*-pyrazole-5-sulfonamide

Definition:

flooded soil: 1 cm of water above the soil

upland soil: 45 - 60 % of the maximum water-holding capacity of the soil

In flooded non sterilised soil: metabolites < 10 %

In upland soil:

Japan soils - at day 84:

A8342: 14 - 28 %; J290: 8 - 23 %; KQ962: 13 %.

USA soil - at day 270

JJ999: 15.5 % and then declined to less than 10 %

by the end of the study; KQ962: < 8.2 %; A8342: 18 % after 30 and 34 % after 270 d.

In flooded condition, typical scenario for this substance, no relevant metabolites are expected.

Supplemental studies

Anaerobic:

Cleavage of the sulfonylurea bridge gave A8342 (2 - 15 %) and J290 (0.6 - 6 %) from [pyrazole-4-¹⁴C]azimsulfuron and [pyrimidine-2-¹⁴C]azimsulfuron, respectively. Demethylation of a pyrimidine ring methoxy gave JJ999 (0.3 - 9 %) and H9235(2-amino-6-methoxy-4-pyrimidinol;1-7%)
Bound residues reached about 32 % at 91 d and 48 % at 162 d

Soil photolysis:

Azimsulfuron is applied to a layer of water in rice paddies and not directly to soil. Water photodegradation is more relevant.

Remarks:

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Rate of degradation

Laboratory studies:

DT₅₀lab (20 °C, aerobic):

DT ₅₀ lab:			
(25 °C, aerobic):			
<u>Experiment Group</u>	<u>days</u>	<u>n</u>	<u>r²</u>
Non-sterilised/Flooded-Japan	23-26	7	0.976
Sterilised/Flooded-Japan	76-90	7	0.842
Non-sterilised/Upland-Japan	24-33	7	bi-exp.
USA	21-22	4-11	bi-exp.
Japan: pH = 5.55, 5.92. USA: pH = 6.1			
(20°C, aerobic)			
<u>Experiment Group</u>	<u>days</u>	<u>n</u>	<u>r²</u>
Italian soil-upland (pH 5.8, 6.9)	18-26	11	bi-exp.
Spanish soil-upland (pH 8.1)	98-134	11	bi-exp.

DT₅₀lab (20 °C, aerobic):DT₉₀lab (20 °C, aerobic):

DT ₉₀ lab			
(25°C, aerobic):			
<u>Experiment Group</u>	<u>days</u>		
Non-sterilised/Flooded - Japan	78 - 85		
Sterilised/Flooded - Japan	260 - 298		
Non-sterilised/Upland - Japan	148 - 196		
USA	178-213		
(20°C, aerobic)			
<u>Experiment Group</u>	<u>days</u>		
Italian soil	60-116		
Spanish soil	>120		
No data.			
DT ₅₀ lab (25°C, anaerobic):			
	<u>days</u>	<u>n</u>	<u>r²</u>
flooded soil:	77-82	7	0.894

DT₅₀lab (10°C, aerobic):DT₅₀lab (20°C, anaerobic):

**Field studies
(country or region):**DT_{50f} from soil dissipation studies:

A field dissipation study has been performed in Italy in two typical rice paddy fields: S. Angelo Lomellina (Pavia) and Morano sul Po (Alessandria). Samples of water and soil have been collected 3 hours after the application and 1, 2, 5, 7, 7.5, 8, 8.5, 14 d after the application.

DT_{50f}: 3 days in the water phase for static paddies (first order kinetic).

No significant residues of azimsulfuron were found in the soil samples from both locations (one sample per test contains 1.0 and 1.4 µg/kg azimsulfuron residues respectively). The limit of detection was 1 ppb for soil and 0.1 ppb for water.

Japan - outdoor lysimeters have been performed in a concrete lysimeter 1m x 1m x 1m filled with 20 cm of coarse gravel in the bottom, followed by 20 cm of sand and filled with clay loam or light clay. 5 cm of water were kept on the surface to simulate rice paddy.

The study cannot be considered a lysimeter study for the evaluation of leaching (it is not representative of a real paddy field soil) but can add information to field dissipation.

DT_{50f} 2.38 - 2.34 days for the two soils in the water phase (first order kinetic).

DT_{90f} from soil dissipation studies:

DT_{90f}: 8-10 days in the water phase for static paddies (Italian field study).

Soil accumulation studies:

It is unlikely that residues of azimsulfuron or its degradates will accumulate in soil:

From laboratory studies in both upland (moist) and flooded soils, the DT₉₀ was less than 1 year and dissipation in the field is expected to be faster than in the laboratory. Field residue studies showed no azimsulfuron residues in the soil.

Azimsulfuron has to be applied only once per season.

Soil residue studies:

Field residue studies showed no azimsulfuron residues in the soil.

Remarks:

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

Degradation rate is increased by low pH values, so DT50s are lower in acidic conditions.

Adsorption/desorption K_{OC} / K_{OM} :

<u>Azimsulfuron</u>					
<u>Soil</u>	K_d	K_{OC}			
Clay	1.36	80			
Silty clay	1.38	86			
Sandy loam	0.81	61			
Silt loam	1.50	79			
<u>Metabolites</u>					
<u>Type</u>	<u>K_{OC}</u>				
	<u>JJ999</u>	<u>KQ962</u>	<u>A8342</u>	<u>J290</u>	
Clay	34	51	142	111	
Silty clay	40	57	120	113	
Sandy loam	29	28	48	91	
Silt loam	28	37	90	95	
<i>Average</i>	33	43	100	103	
Type	pH	%OC	%Sand	%Silt	%Clay
Clay	8.1	1.7	11	36	53
Silty clay	8.1	1.6	9	46	45
Sandy loam	5.8	1.4	55	34	11
Silt loam	6.9	1.9	33	62	5

There is a positive correlation between K_d and either the soil pH ($r^2=0,63$) and cation exchange capacity (CEC, $r^2=0,94$). There is no correlation with OC ($r^2=0.26$).

Mobility**Laboratory studies:**

- Column leaching:
- Aged residue leaching:

No data submitted

Sufficient information was obtained from the previous studies to obviate the need for aged residue column leaching

Field studies:

Lysimeter/Field leaching studies:

Lysimeter studies and field leaching studies are not relevant to the proposed use of azimsulfuron. Rice paddies have an underlying impermeable layer to facilitate flooding and minimise vertical percolation of water.

Remarks:

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2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation :

pH 5. DT₅₀: 89 d at 26 °C
pH 7. DT₅₀: 124 d at 26 °C
pH 9. DT₅₀: 132 d at 26 °C

Photolytic degradation:

pH 5: DT₅₀: 103 d at 20 °C
Relevant metabolites: A8342 (12 %) and J290 (10.6 %)
pH 7: DT₅₀: 164 d at 20 °C
Relevant metabolites: A8342 (8.4 %) and J290 (11.6 %)
pH 9: DT₅₀: 225 d at 20 °C
Relevant metabolites: A8342 (9.8 %) and J290 (10.4 %)

Photodegradation in natural river water (pH=7)

Type	DT ₅₀
sterile	12.2 d
nonsterile	12.0 d

After about 12 d of photolysis:

approximately 50 % of ¹⁴C was present as azimsulfuron, 41 % (pyrazole-label) or 32 % (pyrimidine-label) as sulfonylurea bridge-intact products, of which 5 % (pyrazole) or 4% (pyrimidine) were KQ962, while cleavage of the bridge gave 9 % as A8342 (pyrazole) and about 2 % as J290 (pyrimidine). CO₂ accounted for about 0.3 %.

Degradation probably due to photooxidation and photosensitisation.

Photolytic degradation:

A study was conducted to determinate the reaction of azimsulfuron with hydroxyl radicals in water. Degradation was observed after addition of H₂O₂ to buffer solution and exposure to artificial light at 35 °C. No degradation was observed in the dark control.

Biological degradation

Ready biological degradability:

Water/sediment study:

Azimsulfuron is not readily biodegradable.			
First order kinetic model was used to determine half-lives (DT ₅₀) and DT ₉₀ in water and sediment.			
<u>Azimsulfuron</u>	<u>DT₅₀</u>	<u>DT₉₀</u>	<u>r²</u>
pond (water)	44.5 d	148 d	0.957
pond (water/sediment)	112 d	373 d	0.985
moving water (water)	54.1 d	180 d	0.954
moving water (water/sediment)	145 d	483 d	0.973

Accumulation in water and/or sediment:

Azimsulfuron	Water	Sediment		
Pond (60 d)	27-28%	33-42.7%		
Pond (100d)	15-23%	28-29%		
Moving water (60 d)	32-34%	27-44%		
Moving water (100 d)	19-26%	25-34%		
Major degradation products in water / sediment systems were A8342, J290, and JJ999.				
<u>% Applied Radioactivity After 60 days</u>				
	<u>Pond</u>		<u>Moving water</u>	
	Water	Sediment	Water	Sediment
A8342	6.3	6.3	7.6	18
J290	0.9	1.9	1.1	0.9
JJ999	3.2	2.1	2.7	2.2
<u>% Applied Radioactivity After 100 days</u>				
	<u>Pond</u>		<u>Moving water</u>	
	Water	Sediment	Water	Sediment
A8342	12.5	11.6	8.7	18.8
J290	0.7	0.9	3	3.5
JJ999	4.5	2.5	6.8	3.8

Degradation in the saturated zone

Azimsulfuron was rapidly decomposed; major metabolic and/or degradation products were A8342-J290-JJ999-KQ962-14CO₂ and bound residues. Degradation pathways were : oxidative desmethylation, oxidative ring cleavage, hydrolisis, incorporation to humic materials and mineralization to 14CO₂.

Remarks:

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2.3 Fate and behaviour in air

Volatility

Vapour pressure:

4×10^{-9} Pa (25 °C, purity 99.62 %)

Henry's law constant:

pH 5: 8×10^{-9} Pa m ³ mol ⁻¹
pH 7: 5×10^{-10} Pa m ³ mol ⁻¹
pH 9: 9×10^{-11} Pa m ³ mol ⁻¹

Photolytic degradation

Direct photolysis in air:

203 cm ³ /molecule-sec

Photochemical oxidative degradation in air
(DT₅₀):

0.632 hours

Volatilisation:

From plant surfaces: 2.7% in 24 hours.

From soil: 12.9% in 24 hours

Remarks:

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3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals	LD50: > 5000 mg/kg bw (rat)
Acute toxicity to birds:	LD50: > 2250 mg/kg bw (both northern bobwhite and mallard duck)
Dietary toxicity to birds:	LC50: > 5620 mg/kg (both northern bobwhite and mallard duck)
Reproductive toxicity to birds:	Not performed
Short term oral toxicity to mammals.	Mouse : 300 ppm (40.62 mg/kg bw/day) male and 3000 ppm (469.9 mg/kg bw/day) female. and 3000(f) mg/kg/food Rat : 1250 ppm (75.3 and 82.4 mg/kg bw/day for male and female respectively

Aquatic Organisms

Acute toxicity fish:	LC50 (96 h, <i>O. mykiss</i>): 154 mg/l
Long-term toxicity fish:	NOEC (90 d, ELS, <i>Oncorhynchus mykiss</i>): 6.3 mg/l
Bio-accumulation fish:	Not tested since Azimsulfuron is very water soluble (1.05 g/l at pH 7) and log Kow is very low (-1.4 at pH 7) and DT90 from field study in water phase is 10 days.
Acute toxicity invertebrate:	EC50 (48 h, <i>Daphnia magna</i>): 941 mg/l
Chronic toxicity invertebrate:	NOEC (21 d, <i>D. magna</i>): 5.4 mg/l
Acute toxicity of a.s. to algae:	EC50 (120 h, <i>S. capricornutum</i>): 0.012 mg/l
Acute toxicity of preparation to algae	NOEC (120h, <i>S.capricornufum</i> 0.003 mg/l
Acute toxicity aquatic plant:	EC50 (14 d, <i>Lemna gibba</i>): 0.0008 mg/l
Chronic toxicity sediment dwelling organism:	Not tested since: azimsulfuron Koc<100 ; DT50 and DT90 are 3 days and 10 days respectively ; Azimsulfuron was of low toxicity to <i>Daphnia</i> , <i>Neocaridina</i> (shrimp) and <i>Corbicula</i> (mollusc), so acute and long term TERs were extremely high, ranging from 43000 to 730000.

Metabolite IN-A8342 (main metabolite in water/sediment study)

Acute toxicity algae:	EC50 (72h, <i>S.capricornutum</i>):>1 mg/l
Long-term toxicity aquatic plants	EC50 (14d, <i>Lemna gibba</i>): >1mg/l

Honeybees

Acute oral toxicity:

LD50: > 400 µg GULLIVER/bee (200 µg as/bee) ⁽¹⁾
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Acute contact toxicity:

LD50: > 25 µg as/bee

⁽¹⁾ The LD50/bee value derived from the study with the formulated product was used for the calculation of QHO since the dietary toxicity study performed with the active substance did not supply the LD50/bee value.

Other arthropod species*Typhlodromus pyri*

Reduction beneficial capacity: 2.1 % effect on 1 d-protonymphs (0.027 g a.s. /ha GULLIVER)

Poecilus cupreus

Reduction beneficial capacity: - 8.2 % effect on 2-10 w old animals (0.032 g a.s. /ha GULLIVER)

Chrysoperla carnea

Reduction beneficial capacity: - 5.7 % effect on 2-3 d old larvae (0.030 g a.s. /ha GULLIVER)

Aphidius rhopalosiphi

Reduction beneficial capacity: 22.6% effect on 10 imagines (mortality) and 10 females (fertility) (0.029 g a.s. /ha GULLIVER)

Earthworms

Acute toxicity:

LC50: > 1000 mg as/kg soil
NOEC: < 1000 mg as/kg soil

Reproductive toxicity:

Not tested since : DT50 and DT90 values from field study were 3 days and 10 days respectively and azimsulfuron is applied as a single application per year.

Soil micro-organisms

Nitrogen mineralization:

effect < 5% (GULLIVER)

Carbon mineralization:

effect < 5% (GULLIVER)

Appendix III

AZIMSULFURON

The following studies were submitted after the peer review examination and were not cited in the monograph:-

Guideline	Author	Title	Date of submission	GLP
		AMR 4471-97 Surface tension of azimsulfuron		
		AMR 3163-94 Shelf life stability of DPX-A8974 50% water dispersible granular herbicide formulations		
		AMR-4230-96 Determination of azimsulfuron residues in water and paddy soil by HPLC/UV (method validation) including amendment to final report		
		AMR-4569-97 Analytical enforcement method for the determination of azimsulfuron in air by adsorption on C18 cartridges and RP-HPLC/UV		
		AMR-4581-97 Analytical method for the determination of azimsulfuron (DPX-A8974) in whole milk, eggs and animal tissues (beef and poultry muscle) by HPLC		
		HLO 1997-00102 DPX-A8974 technical mouse bone marrow micronucleus assay		
		AMR-3804-96 Field dissipation of azimsulfuron in a representative rice field following treatment with gulliver herbicide in Italy season 1996 analysis by LC/UV		
		AMR-4751-97 IN-A8342 (metabolite of azimsulfuron) Influence on growth and growth rate on the green elgae <i>Selenastrum capricornutum</i>		
		AMR-4765-97 IN-A8342 (metabolite of azimsulfuron) Influence on growth and reproduction of aquatic weed <i>Lemna gibba</i>		
		AMR-5040-98 Spectra of azimsulfuron		
		AMR-1724-90 Supplement n.1 April 24, 1998: Photodegradation of Pyrimidine-2-14C DPXA8947 and Pyrazole-4-14C DPXA8974 in water conducted in simulated sunlight: quantum efficiency for degradation of azimsulfuron in water		
		AMR-5173-98 Atmospheric oxidation rates for azimsulfuron		
		AMR-5055-98 Shelf life stability of azimsulfuron 50% water dispersible granular herbicidal formulation.		

**SHORT REPORT
OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH
HELD ON 2 July 1999**

Extract

President : G. Del Bino

All Member States were present

Examination and possible opinion on a Draft Commission Directive concerning the inclusion of azimsulfuron in Annex I to Council Directive 91/414/EEC (doc 7591/VI/97 rev. 4 Review Report ; doc 6900/VI/98 rev. 4 Draft Directive).

The Commission confirmed its declaration made on May 12, 1999 in the context of the inclusion decision for Spiroxamine.

The Commission consequently presented the draft Commission Directive concerning the inclusion of azimsulfuron in Annex I to Council Directive 91/414/EEC.

Vote: favourable opinion by qualified majority (79 votes) with one MS (ES) voting against the Directive.

A CHECCHI LANG
Director



EUROPEAN COMMISSION
DIRECTORATE-GENERAL XXIV
CONSUMER POLICY AND CONSUMER HEALTH PROTECTION
Scientific Health Opinions
Management of scientific committees I

SCIENTIFIC COMMITTEE ON PLANTS

**SCP/AZIM/002-Final
24 February 1999**

**OPINION OF THE
SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE INCLUSION OF
AZIMSULFURON IN ANNEX 1 TO DIRECTIVE 91/414/EEC CONCERNING
THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET
(SCP/AZIM/002-Final)**

(Opinion expressed by the SCP on 4 February 1999)

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TERMS OF REFERENCE

The draft Commission Directive proposing the inclusion of azimsulfuron in Annex 1 to Directive 91/414/EEC had been referred to the Scientific Committee on Plants for consultation with the following questions:

1. Are the male reproductive effects seen in the 2-generation rat study of relevance for health and the environment?
2. Having regard to the intrinsic aquatic ecotoxicological properties of azimsulfuron, the Committee is requested to evaluate the risk to the environment which could occur from its uses.

BACKGROUND

The draft Commission Directive for the inclusion of azimsulfuron in Annex 1 to Directive 91/414/EEC concerning the placing of plant protection products on the market was submitted to the Committee for opinion. The Committee had been supplied with documentation comprising a dossier provided by du Pont de Nemours and Company, a monograph prepared by the Italian authorities, a review report prepared by the Commission services of the Directorate General for Agriculture and the Recommendations of the ECCO Peer Review Programme.

Azimsulfuron is a sulfonylurea herbicide used to control a wide range of monocotyledonous and dicotyledonous weeds in rice culture. It acts on sensitive species by inhibition of the enzyme acetolactate synthase which leads to the cessation of cell division. It is absorbed mainly through the leaves and to a lesser extent by the roots and is translocated in plants via the xylem and phloem. It is applied post-emergence at a maximum application rate of 25 g active substance / ha per growing season.

OPINION OF THE COMMITTEE

The Committee would like to draw the Commission's attention to the fact that in preparing its opinion, it has been necessary to re-evaluate original studies in order to clarify inconsistencies between the monograph and the review report regarding important data. Particular attention is drawn to the difficulty in establishing the relevance of Italian field studies on the fate and distribution in paddy field water which were poorly reported in the documentation. The Committee is of the opinion that this situation does not contribute to the necessary transparency required of the evaluative procedure nor to the efficient use of resources. The effectiveness of the SCP's intervention is highly dependent it being supplied with high quality reliable documentation. Accordingly, the Committee requests that in future it is supplied with documentation of an appropriate quality in order to discharge its responsibility.

Question 1

Are the male reproductive effects seen in the 2-generation rat study of relevance for health and the environment?

It is the Committee's opinion that since the mammalian reproductive effects of azimsulfuron were first detectable at concentrations equal to or above those causing systemic toxicity, it is unlikely that reproductive effects would occur in man through use of this product, except when human exposure is so high so as to cause systemic toxicity.

In the two-generation reproduction in rats (1) the NOECs¹ for systemic toxicity were 125 ppm for F0 and F1 parents and 1000 ppm for F0 and F1 pups. NOECs for reproductive toxicity for F0 and F1 parents were 1000 ppm for both. There were no detectable effects on fertility or gestation indices, length of gestation, number of implantations or delivered pups in any treatment group. In the highest treatment (i.e., 8000 ppm) hypertrophy of the pancreas occurred and the mean number of epididymal sperm in F1 males was significantly lower than the control value, but there was no detectable effect on testes weight. In a separate study (2) examining testicular effects of azimsulfuron in rats, plasma estradiol levels were significantly depressed in a 30,000 ppm exposure group giving a NOAEL² estimated at 300 ppm. The NOAEL for estradiol depression was above the NOAEL which was based on pancreas weight, hypertrophy and the acinar cell labelling index.

Regarding the ecotoxicological significance of possible endocrine modulation, the applicant referred to two chronic studies performed on rainbow trout (3) that no evidence of possible endocrine modulation was found in these studies and therefore possible adverse effects on endocrine modulation do not appear to be relevant for azimsulfuron. The Committee is aware of ongoing international activities to develop a harmonised testing and assessment scheme regarding endocrine disruptive effects in the environment (i.e., the OECD EDTA working group, in conjunction with the US-EPA EDSTAC group). Although the Committee notes that the end-points measured in the two mentioned studies are not specific for determining endocrine modulation per se, it is of the opinion that endocrine modulation is very unlikely to occur with azimsulfuron in the environment.

¹ No observed effect concentration

² No observed adverse effect level

Question 2

Having regard to the intrinsic aquatic ecotoxicological properties of azimsulfuron, the Committee is requested to evaluate the risk to the environment which could occur from its uses.

The Committee accepts that azimsulfuron is likely to degrade under field conditions within 3 (DT₅₀³) to 10 (DT₉₀) days. Partitioning into the sediment can be expected to be low. Initial concentrations in paddy water are expected to be 25 - 33 µg/l which will be reduced to approximately 10 µg/l after 5 days and 5 µg/l after 7 days, respectively (when water will be discharged into irrigation ditches and/or other surface waters). Those levels are close to or within the range of effect concentrations for algae (NOEC < 8.1 µg/l) and *Lemna* (NOEC 0.46 µg/l, with 14-day EC₅₀s⁴ of 0.8 - 0.93 µg/l; but effects reversible after the end of the exposure). The severity of effects to algae and mainly aquatic plants will therefore depend on (and be manageable by appropriate choice of)

- the length of the holding period
- the dilution at the time of application and in the receiving water bodies.

It is suggested that risk management might take account of these factors.

With regard to terrestrial non-target plants, it can be concluded from efficacy screening data that there is a risk of phytotoxic effects from spray drift directly adjacent (1-2 m) to the treated paddies. Appropriate care needs to be taken to protect non-target plants and adjacent crops from spray drift or treated water.

³ Disappearance time for 50/90% of compound

⁴ Effective concentration 50%

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