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**EU-Beurteilungsbericht Metsulfuron-methyl
Rechtliche Regelungen der Europäischen Union
zu Pflanzenschutzmitteln und deren Wirkstoffen
Band D 8**

Review Report Metsulfuron-methyl
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 8

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Vorwort

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

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

Die Biologische Bundesanstalt stellt die Beurteilungsberichte als Berichte aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft als Band D in der Reihe "Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen" über den Saphir Verlag gegen Erstattung der Unkosten zur Verfügung. Das vorliegende 8. Heft dieser Reihe (Band D 8) 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 Metsulfuron-methyl war Frankreich 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)
68/2000	Band B: Verordnungen und Protokolle zur Wirkstoffprüfung (4. Auflage, Stand 01. Juli 2000)
	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 8th report belonging to this series (Volume D 8) 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 metsulfuron-methyl France 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)
68/2000	Volume B: Regulations and Protocols regarding the Evaluation of Active Substances (4 th Edition, date: 1 July 2000)
	Volume C: <i>In Progress</i>



RICHTLINIE 2000/49/EG DER KOMMISSION

vom 26. Juli 2000

zur Aufnahme eines Wirkstoffs (Metsulfuron-Methyl) in Anhang I der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln

DIE KOMMISSION DER EUROPÄISCHEN GEMEINSCHAFTEN —

gestützt auf den Vertrag zur Gründung der Europäischen Gemeinschaft,

gestützt auf die Richtlinie 91/414/EWG des Rates vom 15. Juli 1991 über das Inverkehrbringen von Pflanzenschutzmitteln⁽¹⁾, zuletzt geändert durch die Richtlinie 2000/10/EG der Kommission⁽²⁾, insbesondere auf Artikel 6 Absatz 1 und Artikel 8 Absatz 2 Unterabsatz 4,

in Erwägung nachstehender Gründe:

- (1) Mit der Verordnung (EWG) Nr. 3600/92 der Kommission⁽³⁾, zuletzt geändert durch die Verordnung (EG) Nr. 1972/1999⁽⁴⁾, wurden die Durchführungsbestimmungen für die erste Stufe des Arbeitsprogramms gemäß Artikel 8 Absatz 2 der Richtlinie 91/414/EWG (im Folgenden „die Richtlinie“ genannt) erlassen. Gemäß vorgenannter Verordnung wurde mit der Verordnung (EG) Nr. 933/94 der Kommission⁽⁵⁾, zuletzt geändert durch die Verordnung (EG) Nr. 2230/95⁽⁶⁾, die Liste der Wirkstoffe in Pflanzenschutzmitteln festgelegt, die im Hinblick auf ihre mögliche Aufnahme in Anhang I der Richtlinie zu bewerten sind.
- (2) Diese Wirkstoffe sollten in dem genannten Anhang I aufgenommen werden, wenn angenommen werden kann, dass sie keine schädlichen Auswirkungen auf die Gesundheit von Mensch und Tier oder auf das Grundwasser bzw. keine unannehmbaren Auswirkungen auf die Umwelt haben.
- (3) Eine solche Aufnahme sollte jeweils für einen Zeitraum von höchstens zehn Jahren gelten.
- (4) Gemäß Artikel 8 Absatz 2 stellen die Mitgliedstaaten nach der Aufnahme eines Wirkstoffs in Anhang I sicher, dass die Zulassungen von Pflanzenschutzmitteln, die einen Wirkstoff enthalten, innerhalb eines vorgeschriebenen Zeitraums erteilt, widerrufen bzw. geändert werden. In Artikel 4 Absatz 1 und Artikel 13 Absatz 1 der Richtlinie ist insbesondere festgelegt, daß ein Pflanzenschutzmittel nur zugelassen wird, wenn die Bedingungen in Zusammenhang mit der Aufnahme seiner Wirkstoffe in Anhang I sowie die einheitlichen Grundsätze gemäß Anhang VI auf der Grundlage von Unterlagen, die den Datenanforderungen nach Artikel 13 entsprechen, erfüllt sind.
- (5) Die Auswirkungen von Metsulfuron-Methyl auf die menschliche Gesundheit und auf die Umwelt wurden gemäß den Bestimmungen der Verordnung (EWG) Nr. 3600/92 für eine Reihe von vom Antragsteller vorgeschlagenen Anwendungen geprüft. In seiner Funktion als

berichterstattender Mitgliedstaat im Rahmen der Verordnung (EG) Nr. 933/94 hat Frankreich der Kommission am 25. Juni 1997 den betreffenden Bewertungsbericht übermittelt.

- (6) Der vorgenannte Bewertungsbericht wurde von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses für Pflanzenschutz geprüft. Diese Prüfung wurde am 16. Juni 2000 in Form des Prüfungsberichts der Kommission für Metsulfuron-Methyl abgeschlossen.
- (7) Die Unterlagen und die aus der Prüfung hervorgegangenen Informationen wurden auch dem Wissenschaftlichen Pflanzenausschuss zur Stellungnahme vorgelegt. In seiner Stellungnahme⁽⁷⁾ hat der Wissenschaftliche Pflanzenausschuss bestätigt, daß der Wirkstoff ohne unvertretbares Risiko verwendet werden kann. Die Mitgliedstaaten sollten jedoch die mögliche Auswaschung in das Grundwasser in besonders anfälligen Gebieten bewerten und Maßnahmen zur Risikobegrenzung treffen, um die Gewässer zu schützen.
- (8) Aufgrund der Bewertungen kann davon ausgegangen werden, daß den betreffenden Wirkstoff enthaltende Pflanzenschutzmittel im allgemeinen die Anforderungen gemäß Artikel 5 Absatz 1 Buchstaben a) und b) der Richtlinie, insbesondere hinsichtlich der geprüften Anwendungen, erfüllen. Der betreffende Wirkstoff sollte in Anhang I aufgenommen werden, damit in allen Mitgliedstaaten die etwaige Erteilung, Änderung bzw. Rücknahme der Zulassung von Metsulfuron-Methyl enthaltenden Pflanzenschutzmitteln gemäß der Richtlinie organisiert werden kann und weitere Verzögerungen vermieden werden.
- (9) Vor der Aufnahme ist eine angemessene Frist vorzusehen, um es den Mitgliedstaaten und interessierten Parteien zu ermöglichen, sich auf die sich daraus ergebenden neuen Anforderungen vorzubereiten. Nach der Aufnahme ist den Mitgliedstaaten eine angemessene Frist einzuräumen, um die Richtlinie umzusetzen und insbesondere bereits bestehende Zulassungen zu ändern oder zurückziehen bzw. neue Zulassungen gemäß den Bestimmungen der Richtlinie 91/414/EWG zu erteilen. Für die Einreichung und Bewertung der gemäß Anhang III für jedes Pflanzenschutzmittel vollständigen Unterlagen nach Maßgabe der einheitlichen Grundsätze von Anhang VI der Richtlinie ist ein längerer Zeitraum vorzusehen. Pflanzenschutzmittel, die mehrere Wirkstoffe enthalten, können jedoch auf der Grundlage der einheitlichen Grundsätze erst bewertet werden, wenn alle Wirkstoffe in Anhang I der Richtlinie aufgenommen sind.

⁽¹⁾ ABl. L 230 vom 19.8.1991, S. 1.⁽²⁾ ABl. L 57 vom 2.3.2000, S. 28.⁽³⁾ ABl. L 366 vom 15.12.1992, S. 10.⁽⁴⁾ ABl. L 244 vom 16.9.1999, S. 41.⁽⁵⁾ ABl. L 107 vom 28.4.1994, S. 8.⁽⁶⁾ ABl. L 225 vom 22.9.1995, S. 1.⁽⁷⁾ Wissenschaftlicher Pflanzenausschuss SCP/METSU/002-endg., 5. April 2000.

- (10) 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.
- (11) Der Prüfungsbericht ist erforderlich für die ordnungsgemäße Umsetzung bestimmter Teile der einheitlichen Grundsätze gemäß Anhang VI 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.
- (12) Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz —

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

Metsulfuron-Methyl 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 31. Dezember 2001 nachzukommen. Gemäß den Bestimmungen der Richtlinie 91/414/EWG ändern oder widerrufen sie innerhalb dieses Zeitraums erforderlichenfalls insbesondere bestehende Zulassungen für Pflanzenschutzmittel, die Metsulfuron-Methyl als Wirkstoff enthalten.

(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 Pflanzenschutzmittel, die Metsulfuron-Methyl als einzigen Wirkstoff enthalten, auf vier Jahre nach dem Inkrafttreten dieser Richtlinie und
- für Pflanzenschutzmittel, die Metsulfuron-Methyl und einen anderen Wirkstoff enthalten, der in Anhang I der Richtlinie 91/414/EWG aufgenommen ist, auf vier Jahre ab dem Zeitpunkt des Inkrafttretens der Richtlinie über die Aufnahme des letzten dieser Wirkstoffe in Anhang I

verlängert.

(3) 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.

(4) Wenn die Mitgliedstaaten die Vorschriften gemäß Absatz 1 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. Juli 2001 in Kraft.

Artikel 4

Diese Richtlinie ist an die Mitgliedstaaten gerichtet.

Brüssel, den 26. Juli 2000

Für die Kommission

David BYRNE

Mitglied der Kommission

ANHANG

Metsulfuron-Methyl

1. Identität

Gebrauchliche Bezeichnung:	Metsulfuron-Methyl
IUPAC-Bezeichnung:	Methyl 2-(4-methoxy-6-methyl-1,3,5,-triazin-2-yl)carbamoylsulfamoyl)benzoat

2. Zu erfüllende Bedingungen:

- 2.1. Der hergestellte Wirkstoff muss eine Reinheit von mindestens 960 g/kg aufweisen.
 - 2.2. Nur Verwendungen als Herbizid dürfen zugelassen werden.
 - 2.3. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 16. Juni 2000 abgeschlossenen Prüfungsberichts über Metsulfuron-Methyl und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten:
 - dem Grundwasserschutz besondere Aufmerksamkeit widmen;
 - insbesondere die Auswirkungen auf Wasserorganismen berücksichtigen und sicherstellen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikobegrenzung enthalten.
 3. Aufnahme befristet bis: 30. Juni 2011.
-



COMMISSION DIRECTIVE 2000/49/EC

of 26 July 2000

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, as last amended by Commission Directive 2000/10/EC ⁽²⁾, and in particular Article 6(1) and the fourth subparagraph of Article 8(2) thereof,

Whereas:

- (1) Commission Regulation (EEC) No 3600/92 ⁽³⁾, as last amended by Regulation (EC) No 1972/1999 ⁽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'). Pursuant to that Regulation, Commission Regulation (EC) No 933/94 ⁽⁵⁾, as last amended by Regulation (EC) No 2230/95 ⁽⁶⁾, lays down the list of active substances of plant protection products to be assessed, with a view to their possible inclusion in Annex I to the Directive.
- (2) 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.
- (3) Such inclusions should be made for a period not exceeding 10 years.
- (4) Article 8(2) of the Directive provides that after inclusion of an active substance in its Annex I, Member States shall, within a prescribed period, grant, vary or withdraw, as appropriate, the authorisations of the plant protection products containing the active substance. In particular, Articles 4(1) and 13(1) of the Directive require that plant protection products are not authorised unless account is taken of the conditions associated with the inclusion of the active substance in Annex I and the uniform principles laid down in Annex VI on the basis of a dossier satisfying the data requirements laid down in its Article 13.
- (5) For metsulfuron-methyl 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. France, acting as designated rapporteur Member State

under Regulation (EC) No 933/94 submitted to the Commission on 25 June 1997 the relevant assessment report.

- (6) The said report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. This review was finalised on 16 June 2000 in the format of the Commission review report for metsulfuron-methyl.
- (7) The dossier and the information from the review have also been submitted to the Scientific Committee for Plants for consultation. The Scientific Committee for Plants in its opinion ⁽⁷⁾, confirmed that the substance can be used without unacceptable risk but noted that Member States should assess the leaching potential to groundwater in particularly vulnerable locations and should apply risk mitigation measures to protect the aquatic environment.
- (8) It appears 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. Therefore it is appropriate 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 authorisations of plant protection products containing metsulfuron-methyl can be organised in accordance with the provisions of the Directive.
- (9) Before inclusion, a reasonable deadline is necessary to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion. Moreover, after inclusion, a reasonable period is necessary for the Member States to implement the Directive and in particular to vary or withdraw, as appropriate, existing authorisations or grant new authorisations in accordance with the provisions of Directive 91/414/EEC. 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. 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 57, 2.3.2000, p. 28.⁽³⁾ OJ L 366, 15.12.1992, p. 10.⁽⁴⁾ OJ L 244, 16.9.1999, p. 41.⁽⁵⁾ OJ L 107, 28.4.1994, p. 8.⁽⁶⁾ OJ L 225, 22.9.1995, p. 1.⁽⁷⁾ Scientific Committee for Plants SCP/METSU/002-final, 5 April 2000.

- (10) 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.
- (11) 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.
- (12) 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

Metsulfuron-methyl 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 31 December 2001. In particular they shall, in accordance with the provisions of Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing metsulfuron-methyl as an active substance within such period.

2. However, with regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the

requirements of Annex III thereto, the period laid down in the first paragraph is extended:

- for plant protection products containing metsulfuron-methyl as the only active substance to four years from the entry into force of this Directive,
- for plant protection products containing metsulfuron-methyl together with another active substance which is in Annex I to Directive 91/414/EEC, to four years from the entry into force of such Directive as shall include the last of those substances in Annex I.

3. 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.

4. 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 July 2001.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 July 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX

Metsulfuron-methyl

1. Identity:

Common name:

Metsulfuron-methyl

IUPAC name:

Methyl 2-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl) benzoate

2. Particular conditions to be fulfilled:

2.1. The active substance as manufactured shall have a minimum purity of 960 g/kg.

2.2. Only uses as herbicide may be authorised.

2.3. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on metsulfuron-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 16 June 2000 shall be taken into account. In this overall assessment Member States:

— must pay particular attention to the protection of groundwater,

— must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.

3. Expiry date of the inclusion: 30 June 2011.





EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH & CONSUMER PROTECTION
Directorate E - Public, animal and plant health
Unit E1 Legislation relating to crop products and animal nutrition

Metsulfuron-methyl

7593/VI/97-final

14 August 2000

FINAL

Review report for the active substance **metsulfuron-methyl**

Finalised in the Standing Committee on Plant Health at its meeting on 16 June 2000
in view of the inclusion of metsulfuron-methyl 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 metsulfuron-methyl, 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 3600/92¹ laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1972/99², has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Metsulfuron-methyl 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, Du Pont De Nemours on 23 July 1993 and Barclay Chemicals on 27 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance metsulfuron-methyl 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 933/94³, as last amended by Regulation (EC) No

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 244, 16.9.1999, p. 41.

³ OJ No L 107, 28.04.1994, p.8.

2230/95⁴, designated France as rapporteur Member State to carry out the assessment of metsulfuron-methyl on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for metsulfuron-methyl this deadline was 31 October 1995.

Only Du Pont De Nemours submitted a dossier to the rapporteur Member State which was considered as complete. No information has been submitted by third parties.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, France submitted on 25 June 1997 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of metsulfuron-methyl 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 metsulfuron-methyl from Du Pont De Nemours, on 18 July 1997.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States as well as to Du Pont De Nemours being the main data submitter, on 16 July 1997.

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

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

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, from September 1997 to January 1998.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 17 March 1998 for comments and further clarification.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on Plant Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from December 1998 to September 1999, and was finalised in the meeting of the Standing Committee on 16 June 2000.

⁴ OJ No L 225, 22.09.1995, p.1.

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

These documents were also submitted to the Scientific Committee for Plants for separate consultation. The report of this Committee was formally adopted on 17 March 2000 (SCP/METSU/002- Final/05 April 2 000⁵).

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 Commission Directive 00/49/EC⁶ of 26 July 2000 concerning the inclusion of metsulfuron-methyl in Annex I to Directive 91/414/EEC, and to assist the Member States in their decision-making on individual plant protection products containing metsulfuron-methyl. Such decisions have to take in accordance with the provisions of that Directive, and in particular with 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 metsulfuron-methyl 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

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

⁶ OJ No L 197, 8.8.2000, p32

implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each metsulfuron-methyl containing plant protection product for which Member States will grant or review the authorisation.

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

- herbicide for use on cereals and flax/linseed.

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

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is less than 1 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

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

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and Physical/chemical properties

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

The active substance shall comply with the specifications given in Appendix I of this report.

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

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints as identified during the re-evaluation process are set out under point 1 above. These endpoints are listed in Appendix II.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing metsulfuron-methyl

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

- Aquatic organisms: Member States must carefully consider the risk to aquatic plants and algae if this active substance is applied directly adjacent to surface waters. The exposure input from drain flow with respect to local conditions should also be considered. Where appropriate, risk mitigation measures (e.g. buffer zones) should be applied.
- Leaching to groundwater: Particular attention should be given to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil (e.g. soils with high pH values) and/or extreme climatic conditions.

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 metsulfuron-methyl in Annex I under the current inclusion conditions.

The notifier is producing confirmatory data on the environmental fate and behaviour of certain break-down products of metsulfuron-methyl in soil, which will allow Member States to make a refined assessment of leaching potential to groundwater in the context of national authorisations.

8. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the time this review report was prepared but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

9. Updating of this review report

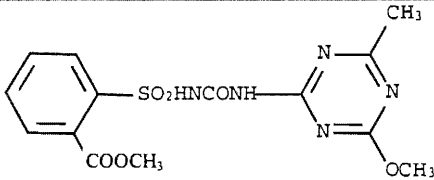
The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC.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

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

APPENDIX I

Identity, physical and chemical properties

Metsulfuron-methyl

Common name (ISO)	Metsulfuron methyl
Chemical name (IUPAC)	Methyl 2-(4-methoxy-6-methyl-1,3,5,-triazin-2-yl)carbamoylsulfamoyl) benzoate
Chemical name (CA)	Methyl 2[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]benzoate
CIPAC No	not available
CAS No	74223-64-6
EEC No	441
FAO SPECIFICATION	960g/kg (1997)
Minimum purity of the active substance as manufactured (g/kg)	960g/kg
Molecular formula	C ₁₄ H ₁₅ N ₅ O ₆ S
Molecular mass	381,4
Structural formula	

Melting point	162 °C (97.4% purity)
Boiling point	no information
Appearance	off white solid
Relative density	1.447 (97.4% purity)
Vapour pressure	1.1 10 ⁻¹⁰ Pa at 20 °C 3.3 10 ⁻¹⁰ Pa at 25 °C (99.4% purity)
Henry's law constant	2,3 10 ⁻¹⁰ Pa m ³ mol ⁻¹ at pH 5 4.5 10 ⁻¹¹ Pa m ³ mol ⁻¹ at pH 7 (99.4% purity)
Solubility in water	pH 5: 548 mg/l at 25 °C pH 7: 2,79 g/l at 25 °C pH 9: 213 g/l at 25 °C
Solubility in organic solvents (at 20 °C)	(25 °C; 97.4% purity) N hexane 0.000584g/l acetone 37 g/l dichloromethane 132 g/l methanol 7.63 g/l acetonitrile 25.9 g/l ethyl acetate 11.1 g/l toluene 1.24 g/l
Partition co-efficient (log P_{OW})	pH 7: log Pow= -1.7 at 25°C
Hydrolytic stability (DT₅₀)	pH 5: DT50 22 d at 25 °C (radiolabelled purity 99.4%) pH 7: DT 50 > 30 d at 25 °C pH 9: DT 50 >30 d at 25 °C No degradation
Dissociation constant	pKa = 3.75
Quantum yield of direct phototrans- formation in water at λ > 290nm	No measurable photodegradation in water Very slightly absorption occurs at λ>290nm due to the fact that at 290nm very slightly absorption due to the large peak at 234 nm
Flammability	Not flammable (purity 99.1 %)
Explosive properties	Not explosive (purity 99.1 %)
UV/VIS absorption (max.)	254 nm maximum (99.4% pure)
Photostability (DT₅₀) in water	(radiolabelled; 99.4% pure) pH 5, pH 7 and pH 9 no degradation

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

Rate and extent of absorption:	>80 % within 48 h
Distribution:	uniformly distributed
Potential for accumulation:	no potential for accumulation
Rate and extent of excretion:	100 % excreted, 71 - 95 % urine, 5 - 13 % faeces within 72 h
Toxicologically significant compounds:	parent compound
Metabolism in animals:	15 % metabolised by hydroxylation, oxidation and demethylation

Acute toxicity

Rat LD ₅₀ oral:	> 5000 mg/kg bw
Rat LD ₅₀ dermal:	> 2000 mg/kg bw
Rat LC ₅₀ inhalation:	> 5.0 mg/l
Skin irritation:	non irritant
Eye irritation:	Non irritant
Sensitization:	non sensitising (Buehler)

Short term toxicity

Target / critical effect:	body weight and liver
Lowest relevant oral NOAEL:	1000 ppm (68 mg/kg bw/d) 90 d rat
Lowest relevant dermal NOAEL:	> 2000 mg/kg bw/d, 21 d dermal rabbit
Lowest relevant inhalation NOAEL:	Inhalation: not required

Genotoxicity

no genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect:	body weight and liver.
Lowest relevant NOAEL:	500 ppm (22 mg/kg bw/d) rat carcinogenicity study.
Carcinogenicity:	no carcinogenic potential.

Reproductive toxicity

Target / critical effect - Reproduction:	decrease in litter size at parental toxic doses
Lowest relevant reproductive NOAEL:	500 ppm (34 mg/kg bw/d) two generation oral rat
Target / critical effect - Developmental toxicity:	no teratogenic potential
Lowest relevant developmental NOAEL:	25 mg/kg bw/d (maternal), 700 mg/kg bw/d (developmental) in rabbit.

Delayed neurotoxicity

no study required

Other toxicological studies

none

Medical data

no concern

Summary

	Value	Study	Safety factor
ADI:	0.22 mg/kg bw/d	2 year oral rat	100
AOEL systemic:	0.7 mg/kg bw/d	90 day oral rat	100
AOEL inhalation:	Not required		
AOEL dermal:	20 mg/kg bw/d	21 day dermal rabbit	100
ARfD:	Not allocated -Not necessary		

Dermal absorption

10 % (default figure)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

32 % (phenyl, 112 d, 1 soil)
11.4% (triazine, 90d, 1soil)
10 % (triazine amine, 1 soil) - 38 % (65 w)

Non-extractable residues:

12 - 25 % (phenyl, 98 d, 3 soils)
17.6% (triazine, 90d, 1soil)
6 % (triazine amine, 1 soil) - 10 % (65 w)

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

4 soils
IN-D5803 : Ester Sulfonamide
max. 17 % (4w), < 4 % (24 w)
IN-D5119 : Acid sulfonamide
< 10 % (16 %, 24 w, 1 soil)
IN-B5685 : Phenylurea, max. 17 % (14 w)
IN-00581 : Saccharin
max. 47 % (8 w), < 33 % (14 w)
1 soil
IN-A4098 : Triazine amine, max. 33 % (12 w)
IN-NC148 : carbamoyl guanidine, max 16% (12 w), <3% (52w)
IN-B5067 : O-desmethyl metsulfuron, max 11% (10 days), <2% (52w)

Supplemental studies

Anaerobic:

No data

Soil photolysis:

Moist soil (phenyl-¹⁴C) : slow degradation
Dry soil (triazine-¹⁴C) : DT50 = 10 d
5 unidentified degradates
No significant effect of light

Remarks:

None.

Rate of degradation

Laboratory studies:

DT₅₀lab (20 °C, aerobic):

Metsulfuron
22°C, aerobic 23 - 29 d (2 soils)
25° C, aerobic 20 -51 d (mean, 31.6d, 7 soils)
25° C, sterile 61 - 405 d (7 soils)
Triazine amine
25° C, aerobic 210 d (1 soil)
Other metabolites : no DT50 value provided. Saccharin is persistent ; ester sulfonamide is not persistent (DT50<< 1 month ; O-desmethyl metsulfuron methyl and carbamoyl guanidine are less persistent than saccharin.

DT₉₀lab (20 °C, aerobic):

22°C, aerobic 76 - 98 (2 soils)
25° C, aerobic 94 -320 d (mean 182d, 7 soils)
25° C, sterile 203 – 1344 (7 soils)

DT₅₀lab (10°C, aerobic):

no data

DT₅₀lab (20°C, anaerobic):

no data

Field studies (USA, Canada):

DT_{50f} from soil dissipation studies:

DT _{50f} : (metsulfuron)
US sites 4 - 15 d (mean 10 d, 4 soils)
Canadian and US sites
- fall 41 - 100 d (mean 60 d, 4 soils)
- spring 7 - 71 d (mean 25.9 d, 8 soils)
metabolites :
IN-00581 (saccharin) 51 – 156 d (mean 109 d, 4 US sites)
Other : no DT50 value provided ; ester sulfonamide and phenylurea are not persistent (<10%) ; acid sulfonamid is less persistent than saccharin

DT_{90f} from soil dissipation studies:

DT _{90f} : (metsulfuron)
US sites 30 - 141 d (n = 4)
Canadian and US sites
- fall 164 - 423 d (n = 4)
- spring 57 - 301 (713) d (n = 8)

Soil accumulation studies:

Residue (US and canadian sites)
- Metsulfuron, 0.8 - 12 % (1 year)

Soil residue studies:

- Ac. Sulfonamide, max. 29 % (8 w), 1 - 16 % (26 w)
 - Saccharin, max. 32 % (4w), < 3 % (26 w)
 - Triazine amine, estimated < 4.5 µg/kg
 - Others, < 10 % no tendency to accumulate

No specific study. See above results from field dissipation studies.

Remarks:

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

None.

Adsorption/desorptionK_f / K_{oc}:Metsulfuron methylK_{oc} = 4 - 60 (180) ml/g (mean 39.5)K_f = 0.05 - 4.9 ml/g

12 soils, OC = 0.2 - 11 %, pH = 5.4 - 7.7

SaccharinK_{oc} = 5.7-10.6 (mean 8.9)K_d = 0.033 - 0.27

4 soils, OC = 0.58 - 2.55 %, pH = 6.7 - 7.7

triazine amineK_{oc} = 46-226 (mean 155)K_f 0.26-6.8

4 soils, OC = 0,46 -3,02%, pH 5.3-6.3

see above K_f or K_d valuesK_d:

No

pH dependence:

Mobility**Laboratory studies:**

- Column leaching:

Phenyl-¹⁴C

- 4 soils, leachates (250 mm) > 87 %

- Aged residue leaching:

2 soils, Phenyl-¹⁴C, 30 d, greenhouse

leachates (250 mm): 54 - 76 %

- saccharin (38 - 46 %)

- sulfonamide (19 %, one soil)

Field studies:

Lysimeter/Field leaching studies:

loam soil at Kjettslinge, sandy soil and clay soil at Bulstofta (Sweden), 4 - 8 g as / ha (May).

Duration 7 m

- metsulfuron in drainage water < 22 ng/l
(for high dose)
- no data for soil residues and metabolites

Remarks:

None.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation :

pH 5 , 25° C, DT50 = 22 days
metabolites = transient sulfonamide, saccharin and probably triazine amine which is stable at all pH
pH 7 , 25° C, stable
pH 9 , 25° C, stable

Relevant metabolites

Sulfonamide (IN-D5803) max. 25 %, saccharin (IN-00581) max. 35 %, triazine amine (IN-A4098) max. not determined but estimated to be about 50 %, at pH 5 only

Photolytic degradation:

Light has no effect on degradation of metsulfuron methyl in water

Relevant metabolites:

No relevant metabolite

Biological degradation

Readily biodegradable:

No data

Water/sediment study:

DT₅₀ water:

DT50 water: 81 - 148 d

DT₉₀ water:

DT90 water: 269 - 491 d

DT₅₀ whole system:

DT50 whole system: 105 - 175 d (mean 140 d)

DT₉₀ whole system:

DT90 whole system: 357 - 588 d

Mineralization 3% (91d)

Bound Residues 7% (91d)

max. 22 % (2w) in sediment

Distribution in water/sediment systems (active substance)

Distribution in water/sediment systems (metabolites)

Metabolites: bis-O-demethyl metsulfuron methyl: max. 25 % (13 w) in water and max. 8 % (8 - 13 w) in sediment

Accumulation in water and/or sediment:

See above for distribution in water and sediment
For yearly application at 8 g/ha, spray drift (4 %) at 1 m and DT50 of 148 d (water) and 175 d (sediment), max. concentration would be 0.13 µg/l in water and 0.13 µg/kg in sediment.

Degradation in the saturated zone

No data, not required

Remarks:

None.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

1.1×10^{-10} Pa at 20 °C

Henry's law constant:

4.5×10^{-11} Pa m ³ mol ⁻¹ at pH 7

Photolytic degradation

Direct photolysis in air:

No data

Photochemical oxidative degradation in air (DT₅₀):

49,79 hours

Volatilisation

No data

Remarks:

None.

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals

LD50 (rats) > 5 000 mg/kg
NOAEL (90 d, rats) = 100 ppm

Long term oral toxicity to mammals:

NOAEL (90 d, rat) = 100 ppm

Acute toxicity to birds:

LD50 (mallard duck) > 2 510 mg/kg

Dietary toxicity to birds:

LC50 (bobwhite quail) > 5 620 ppm
LC50 (mallard duck) > 5 620 ppm

Reproductive toxicity to birds:

NOEC = 1 000 ppm

Aquatic Organisms

Active substance:

Acute toxicity fish:

LC50 (96 h) > 150 mg/l

Chronic toxicity fish:

NOEC (21 d) = 68 mg/l

Bioaccumulation fish:

log P _{ow} = - 1,7 (pH 7.0) whole fish: < 1

Acute toxicity invertebrate:

EC50 (48 h, <i>D. magna</i>) > 150 mg/l
--

Chronic toxicity invertebrate:

NOEC (21 d, daphnids) = 150 mg/l

Acute toxicity algae:

EC _b 50 (72 h, <i>S. capricornutum</i>) = 0.045 mg/l
--

Acute toxicity (aquatic plants):

EC50 (<i>L. gibba</i>) = 0.00036 mg/l

Chronic toxicity sediment dwelling organism:

not required

Preparation (WG 20%):

Acute toxicity fish:

LC50 (trout, 96 h) > 1 000 mg/l

Acute toxicity invertebrate:

EC50 (daphnids) > 1 000 mg/l

Metabolites:

Acute toxicity fish:

LC50 (trout) = 981 mg IN-JX909/l

Acute toxicity invertebrate:

EC50 (daphnids) = 971 mg IN-JX909/l

Acute toxicity algae:

EC50 (<i>S. capricornutum</i>) = 64 mg IN-JX909/l

Acute toxicity (aquatic plants)

EC50 (<i>L. gibba</i>) = 30 mg IN-JX909/l

EC50 (<i>L. gibba</i>) > 10 mg IN-A4098/l

Honeybees

Acute oral toxicity:

LD50 > 44.3 microg a.s./bee

Acute contact toxicity:

LD50 > 25 microg a.s./bee

Other arthropod species

Chrysoperla carnea

E (beneficial effect) = - 3.5 % (WG 20%)

Typhlodromus pyri

E (beneficial effect) = - 1.2 % (WG 20%)

Poecilus cupreus

E (mortality) = 3.5 % (WG 20%)

E (prey consumption) = 3%

Aleochara bilineata

E (beneficial effect) < 30 % (WG 20%)

Aphidius rhopalosiphi

E (beneficial effect) = 19.3 % (WG 20%)

Earthworms

Acute toxicity:

LC50 > 1 000 mg a.s./kg dry soil

Metabolites

LC50 > 1 000 mg IN-A4098/kg dry soil

LC50 > 1 mg IN-00581/kg dry soil

LC50 > 1 mg IN-B5067/kg dry soil

LC50 > 1 mg IN-NC148/kg dry soil

Reproductive toxicity:

No data submitted

Soil micro-organisms

Nitrogen mineralization:

0.2 mg a.s./kg: No effect

Carbon mineralization:

0.2 mg a.s./kg: No effect

Appendix III

METSULFURON-METHYL

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 inclusion¹.

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information

B.4 Proposals for classification and labelling

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 2.1.1	Cooke, LA	1998	Melting Point of Metsulfuron Methyl. DuPont Agricultural Products. AMR 5004-98. GLP or GEP: yes Published: no	
All 2.2.	Huntley, K Edgar, L	1998	Determination of Density of Metsulfuron Methyl. ABC Laboratories. AMR 5133-98. GLP or GEP: yes Published: no	
All 2.3	Barefoot	1991	Henry's Law Constant of Metsulfuron-Methyl. AMR 1964-91. GLP or GEP: no Published: no	FR : 11 June 1997
All 2.3.1	Schmuckler, M	1998	Vapor Pressure of Metsulfuron Methyl. DuPont Agricultural Products. GLP or GEP: no Published: no	

¹ List based on a detailed analysis from France in its submission of XX/XX/XX (background document C).

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 2.5	Anonymous	no date	Analytical Standards Files, METS/PRO 2. DuPont Agricultural Products, E.I. du Pont de Nemours and Company, DuPont Agricultural Products, Wilmington, Delaware 19880-0402, U.S.A. GLP or GEP: no Published: no	FR : 11 June 1997
All 2.6	Barefoot, A.C., Cooke, L.A.	1990	"Water Solubility of DPX-T6376 Using Continuous Sample Agitation". DuPont Agricultural Products Report No. AMR 1661-90. E. I. du Pont de Nemours and Company, DuPont Agricultural Products, Wilmington, Delaware 19880-0402, U.S.A. GLP or GEP: yes Published: no	FR : 11 June 1997
All 2.7	Cooke, LA	1998	The Solubility of Metsulfuron Methyl in Organic Solvents. DuPont Agricultural Products. AMR 5042-98. GLP or GEP: yes Published: no	
All 2.8	Cooke, LA	1998	The Octanol/Water Partition Coefficient of Metsulfuron Methyl. DuPont Agricultural Products. AMR 5003-98. GLP or GEP: yes Published: no	
All 2.9.2	McFetridge, Richard D., and Cadwgan, Gordon E.	1985	"Photodegradation of [Triazine-2- ¹⁴ C] Metsulfuron Methyl in Water." DuPont Report No. AMR 451-85. E. I. du Pont de Nemours and Company, Agricultural Products Department, Research Division, Wilmington, DE, U.S.A. GLP or GEP: no Published: no	FR : 11 June 1997
All 2.9.3	Massey, JH	1998	IN-T6376 and Quantum Efficiency. DuPont Agricultural Products. GLP or GEP: no (Position Paper) Published: no	
All 2.9.4	Duffy	1998	Compound Specific Determination of Acid Dissociation Constants from Water Solubility Data. DuPont Agricultural Products, GLP or GEP: no (Position Paper) Published: no	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 2.9.4	Huntley, K; Ambroz, J	1999	Determination of the Dissociation Constant of Metsulfuron Methyl. ABC Laboratories. DuPont-1790. GLP or GEP: yes Published: no	
All 2.10	Schmuckler, M	1998	Atmospheric Oxidation Rates of Metsulfuron Methyl (T6376). DuPont Agricultural Products. GLP or GEP: no (Position Paper) Published: no	
All 2.11-2.15	Gravell, R.L.	1995	DuPont Report No. AMR 3099-94, "Flammability, Explosive Properties - Oxidizing Properties of Metsulfuron Methyl". E. I. du Pont de Nemours and Company, DuPont Agricultural Products, Wilmington, Delaware 19880-0402, U.S.A GLP or GEP: yes Published: no	FR : 11 June 1997
All 2.14	Hammond, RW	1998	Surface Tension of Metsulfuron Methyl DuPont Agricultural Products AMR 5019-98. GLP or GEP: yes Published: no	

B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 4.1.1.	Neal, L. Warnell	1994	Analytical Method T6376.555 for the Determination of Metsulfuron Methyl in Ally [®] 20DF, Ally [®] 60DF and Metsulfuron Methyl Technical. AMR 2968-94. E. I. du Pont de Nemours and Company, DuPont Agricultural Products, Wilmington, Delaware, U.S.A. November 1994 GLP or GEP: yes Published: no	FR : 11 June 1997
All 4.2.1.	Bollin, Ernest Jr.; Stephen W. George.	1992	Analytical Method (Column-Switching/Eluent-Switching) for Metsulfuron Methyl (DPX-T6376) in Wheat and Barley, Forage, Grain, and Straw. DuPont Report No. AMR 2519-92. E. I. du Pont de Nemours and Company, DuPont Agricultural Products, Wilmington, Delaware, U.S.A. GLP or GEP: no Published: no	FR : 11 June 1997
All 4.2.2.	Amoo, Jennifer S.	1994	Analytical Method for the Quantitation of DPX-T6376 in Soil by Liquid Chromatography. DuPont Report No. AMR 2885-93. E. I. du Pont de Nemours and Company, DuPont Agricultural Products, Wilmington, Delaware, U.S.A. GLP or GEP: no Published: no	FR : 11 June 1997
All 4.2.3.	Wheeler, J. R., Shalaby, L.M., and Wadsley, M. P.	1988	Simultaneous Extraction and Analysis of Glean [®] and Ally [®] from Water Matrices Using HPLC with UV Detection and Thermospray LC/MS Confirmation. DuPont Report No. AMR 1274-88. E. I. du Pont de Nemours and Company, DuPont Agricultural Products, Wilmington, Delaware, U.S.A. GLP or GEP: no Published: no	
All 4.2.3	Powley, C., de Bernard, PA Mulcahey, LJ	1995	Analytical Method for the Determination of Thifensulfuron Methyl, Metsulfuron Methyl, Chlorsulfuron, Tribenuron Methyl and DPX-KE459 in Water. DuPont Report n° AMR2479-93 GLP or GEP: no Published: no	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 4.2.3	Duffy	1998	Levels of Metsulfuron Methyl Causing Phytotoxicity and Methods of Analysis in Soil to Detect these Levels GLP or GEP: no (Position Paper) Published: no	
All 4.2.4	Freeman, CJ	1995	Analytical Enforcement Method for the Determination of DPX-T6376 in Air. DuPont Report n° AMR 3687-95 GLP or GEP: no Published: no	

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 5.2.1.	Ohta,	1991	Metsulfuron Methyl: Acute Oral Toxicity Study in Mice, Kodaira Laboratories, The Institute of Environmental Toxicology, Japan. IET 91-0094 GLP or GEP: yes Published: no	FR : 11 June 1997
All 5.2.5.	Brock	1992	Primary Eye Irritation Study with IN T6376-41. HLR 630-87 supp1, 1987; November 9, 1992 GLP or GEP: yes Published: no	FR : 11 June 1997
All 5.2.5 AIII 7.1.5	O'Neal, FO	1998	Adequacy of Dosing for DuPont Eye Irritation Studies. DuPont Agricultural Products, GLP or GEP: no (Position Paper) Published: no	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 5.3.2.	Sarver,	1989	Repeated Dose Dermal Toxicity: 21-Day Study with INT-6376 in Rabbits. HLR 35-87 Revision 1, supp1 Revised March 10, 1987; Supplemental No. 1 September 15, 1989 GLP or GEP: yes Published: no	FR : 11 June 1997

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 6.1.	Anderson	1984	Metabolism of [¹⁴ C]Metsulfuron Methyl in Field-Grown Barley. AMR 211-84 GLP or GEP: no Published: no	FR : 11 June 1997 NL : 17 October 1991
All 6.3.	Cicotti,	1987	The Determination of DPX M6316 and Metsulfuron Methyl (DPX T6376) in Cereals (From Switzerland) by Liquid Chromatograph BAT 86 12. Battelle Geneva. GLP or GEP: yes Published: no	FR : 11 June 1997
All 6.3.	Klemens,	1993	Metsulfuron Methyl, Metabolite A and Metabolite A1 Freezer Storage Study on Wheat Grain, Green Forage and Straw. AMR 2714-93 GLP or GEP: yes Published: no	FR : 11 June 1997

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 7.1.1.1.1	Fader, T	1998	Significant Soil Metabolites of Aerobic Metsulfuron Methyl Degradation in Soil. DuPont Agricultural Products. GLP or GEP: no (Position Paper) Published: no	
All 7.1.1.1.1	Gorman, M; Haney PE	1998	Aerobic Soil Metabolism of ¹⁴ C-DPX-T6376. DuPont Agricultural Products. AMR 3768-96. GLP or GEP: yes Published: no	
All 7.1.2	Li, Y; McFetridge, RD	1996	Batch Equilibrium (Adsorption/Desorption) Study of a Metabolite, Triazine Amine (IN-A4098), of DPX-T6376 on Soil. DuPont Agricultural Products. AMR 3656-95. GLP or GEP: yes Published: no	
All 7.1.2.3.	Kraut,	1993	Batch Equilibrium (Adsorption/Desorption) Study of [Phenyl(U)- ¹⁴ C]Sulfometuron Methyl, IN-X993, IN-D5803, and Saccharin. AMR 2607-93. GLP or GEP: yes Published: no	FR : 11 June 1997
All 7.4.4.6	Esterly	1995	Predicted Environmental Concentrations of Metsulfuron Methyl in Groundwater Resulting from the Application to Cereals, AMR 3228-94. GLP or GEP: no Published: no	FR : 11 June 1997

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 8.1.3	Beavers, JB; Foster, JW; Mitchell, LR; Jaber, M	1996	DPX-T6376-141 (Metsulfuron Methyl): A Reproduction Study with the Northern Bobwhite (<i>Colinus virginianus</i>). Wildlife International. AMR 3412-95 GLP or GEP: yes Published: no	
All 8.1.3	Beavers, JB; Foster, JW; Mitchell, LR; Jaber, M	1996	DPX-T6376-141 (Metsulfuron Methyl): A Reproduction Study with the Mallard (<i>Anas platyrhynchos</i>). Wildlife international. AMR 3413-95 GLP or GEP: yes Published: no	
All 8.2.1	Palmer, SJ; Krueger, HO	1999	IN-JX909: A 96-Hour Static Acute Toxicity Test with the Rainbow Trout (<i>Oncorhynchus mykiss</i>). Wildlife International. DuPont-1273 GLP or GEP: yes Published: no	
All 8.2.4	Palmer, SJ; Krueger, HO	1999	IN-JX909: A 48-Hour Static Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>). Wildlife International. DuPont-1274 GLP or GEP: yes Published: no	
All 8.2.6	Hicks, SL	1997	DPX-T6376: Influence on Growth and Reproduction of <i>Anabaena flos-aquae</i> . ABC Laboratories. AMR 3838-96, GLP or GEP: yes Published: no	
All 8.2.6	Hicks, SL	1997	DPX-T6376: Influence on Growth and Reproduction of <i>Skeletonema costatum</i> . ABC Laboratories. AMR 3840-96 GLP or GEP: yes Published: no	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 8.2.6	Palmer, SJ; Krueger, HO	1999	IN-JX909: Influence on Growth and Reproduction of the Green Algae <i>Selenastrum capricornutum</i> . Wildlife International. DuPont-1271 GLP or GEP: yes Published: no	
All 8.2.8	Sloman, TL; Leva, S	1998	IN-A4098: Influence on Growth and Reproduction of <i>Lemna gibba</i> G3. DuPont Agricultural Products. DuPont-1223 GLP or GEP: yes Published: no	
All 8.2.8	Palmer, SJ; Krueger, HO	1999	IN-JX909: Influence on Growth and Reproduction of <i>Lemna gibba</i> G3. Wildlife International. DuPont-1272 GLP or GEP: yes Published: no	
All 8.3.1.1	Nengel, S	1998	Metsulfuron Methyl Technical (DPX-T6376): Acute Oral and Contact Toxicity to the Honey Bee, <i>Apis mellifera</i> L.. GAB Biotechnologie GmbH. AMR 5182-98 GLP or GEP: yes Published: no	
All 8.3.2	Austin, H	1998	Metsulfuron Methyl (DPX-T6376) 20WG: A Laboratory Study to Evaluate the Effects on the Greenlacewing, <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae). Ecotox Ltd. UK. DuPont-1081 GLP or GEP: yes Published: no	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 8.3.2	Austin, H	1999	Metsulfuron Methyl (DPX-T6376) 20WG: A Laboratory Study to Evaluate the Effects on the Parasitic Wasp, <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae). Ecotox Ltd. UK. DuPont-1082 GLP or GEP: yes Published: no	
All 8.3.2	Tessier, C	1999	Metsulfuron Methyl (DPX-T6376) 20WG: A Laboratory Study to Evaluate the Effects on the Predatory Mite, <i>Typhlodromus pyri</i> (Acari: Phytoseiidae). Ecotox Ltd. UK. DuPont-1083 GLP or GEP: yes Published: no	
All 8.3.2	Sankanu, A	1999	Metsulfuron Methyl (DPX-T6376) 20WG: A Laboratory Study to Evaluate the Effects on the Ground Beetle, <i>Poecilus cupreus</i> L. (Coleoptera: Carabidae). Ecotox Ltd. UK. DuPont-1084 GLP or GEP: yes Published: no	
All 8.4.1	Gossmann, A	1998	IN-A4089 a Degradate of Metsulfuron Methyl: Acute Toxicity to the Earthworm, <i>Eisenia fetida</i> (Savigny) in Artificial Soil. IBACON GmbH. AMR 5167-98 GLP or GEP: yes Published: no	
All 8.4.1	Gossmann, A	1999	IN-00581: Acute Toxicity to the Earthworm <i>Eisenia fetida</i> (Savigny) in Artificial Soil. IBACON GmbH. DuPont-2004 GLP or GEP: yes Published: no	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
All 8.4.1	Gossman, A	1999	IN-NC148: Acute Toxicity to the Earthworm <i>Eisenia fetida</i> (Savigny) in Artificial Soil. IBACON GmbH. DuPont-2005 GLP or GEP: yes Published: no	
All 8.4.1	Gossman, A	1999	IN-B5067: Acute Toxicity to the Earthworm <i>Eisenia fetida</i> (Savigny) in Artificial Soil. IBACON GmbH. DuPont-2007 GLP or GEP: yes Published: no	
1.8., 1.9. <i>Doc J</i>	<i>Davis</i>	1995	<i>Metsulfuron Methyl Product Description and Composition. AMR 3118-94</i> GLP or GEP: yes Published: no	
1.11. <i>Doc J</i>	<i>Brennan</i>	1995	<i>Technical Grade Metsulfuron Methyl: Analysis and Certification of Product Ingredients, AMR 2732-93</i> GLP or GEP: no Published: no	
<i>Doc J</i>	<i>Brennan, DE</i>	1998	<i>The Presence of Nitrosamines in Metsulfuron Methyl. DuPont Agricultural Product</i> GLP or GEP: no (Position Paper) Published: no	
<i>Doc J</i>	<i>Parsells, AJ</i>	1998	<i>Metsulfuron Methyl - Active Substance, Composition Statement. DuPont Agricultural Products</i> GLP or GEP: no Published: no	
<i>Doc J</i>	<i>Frost, NM; Brennan, DE</i>	1998	<i>Impurity Profile of Metsulfuron Methyl Technical. DuPont Agricultural Products</i> GLP or GEP: no (Position Paper) Published: no	



**SUMMARY REPORT
OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH
HELD ON 16 JUNE 2000 IN LISBON**

It is the first time that the Standing Committee for Plant Health met outside of Brussels.

President : G. Del Bino

All Member States were present.

Extract

2 Examination and possible opinion on a Draft Commission Directive concerning the inclusion of metsulfuron-methyl in Annex I to Council Directive 91/414/EEC (SANCO/987/2000 rev 4).

The Commission presented the Review Report on Metsulfuron-methyl in document 7593/VI/97-rev. 6. The Committee took note of the Review Report.

The following declarations were made:

Denmark: The Danish delegation notes that the degradation rate for the breakdown product triazine amine given in the end point list of metsulfuron-methyl exceeds 6 months, which indicates that this metabolite is highly persistent. However, the notifier has submitted some of the new studies mentioned in the review report to Denmark, and on the background of these it is concluded that triazine amine is not persistent (DT50 < 3 months).

Sweden supports the declaration of Denmark.

The Netherlands: The Dutch delegation is of the opinion that the dermal AOEL provided in the list of endpoints seems not in accordance with the systemic AOEL, given the properties of metsulfuron-methyl. The delegation concludes that the dermal AOEL in the list of endpoints may not be appropriate for all decisions for authorisation of plant protection products containing metsulfuron-methyl and that the systemic AOEL should be used. The delegation requests the Commission to speed up the adoption of the Guidance document on AOEL setting, which is under development.

Denmark supports the declaration of The Netherlands.

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

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

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

The Commission subsequently presented the draft Commission Directive concerning the inclusion of Metsulfuron-methyl in Annex I to Council Directive 91/414/EEC.

Vote : unanimous favourable opinion.

The substance is an existing active substance used as herbicide in cereals and linseed.

A CHECCHI LANG
Director



EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH & CONSUMER PROTECTION

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

SCIENTIFIC COMMITTEE ON PLANTS

SCP/METSU/002-Final
5 April 2000

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

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

1. TITLE

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

2. TERMS OF REFERENCE

The Scientific Committee on Plants (SCP) is requested to respond to the following questions in the context of the Commission's work on the implementation of Directive 91/414/EEC¹ concerning the placing of plant protection products on the market.

- (1) Can it be confirmed that use scenarios exist which pose no unacceptable risk to groundwater?
- (2) Can it be confirmed that the uses reviewed are acceptable for the aquatic environment?

3. BACKGROUND

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

The Committee had been supplied with documentation comprising a dossier provided by du Pont de Nemours and Company, a monograph prepared by the French Authorities acting as Rapporteur Member State (RMS) and the recommendations of the ECCO² Peer Review Programme which involved contributions from experts of several Member States.

Metsulfuron methyl belongs to the sulfonylurea group of herbicides. It acts on sensitive plants by inhibition of the enzyme acetolactate synthase involved in the synthesis of branched-chain amino acids. It is currently authorised in certain Member States for use as a plant protection product on small grain cereal crops, rice, permanent meadows and linseed. It is effective in controlling a wide spectrum of broad-leaved weed species at rates of application between 4 to 8 g a.s./ ha.

¹ OJ L 230, 19. 08.1991, p.1

² European Community Co-ordination

4. OPINION

4.1 Question 1

Can it be confirmed that use scenarios exist which pose no unacceptable risk to groundwater?

Opinion

Use scenarios exist which pose no unacceptable risk to groundwater.

Based on available soil metabolism studies the Committee concludes that the risk to groundwater should include evaluation of the metabolites ester sulfonamide, saccharine, triazine amine, O-demethyl metsulfuron methyl and carbamoyl guanidine. The full results from laboratory studies are not currently available to characterise these metabolites. Therefore the SCP has made its own assessment of leaching potential and concludes that use scenarios exist which pose no unacceptable risk to groundwater. Subject to confirmation by the outstanding laboratory studies on the half-life and adsorption of the metabolites Member States should assess leaching potential in vulnerable locations (e.g. soils with high pH values) to determine whether the GAP³ can achieve the desired result.

4.1.2 Scientific and Technical Background on Which the Opinion is Based

The assessment of risk to groundwater was based on modelling because no adequate field or lysimeter experiments are available for the soil metabolites of metsulfuron-methyl. Modelling should be based on estimation of the half-life (DT_{50}^4) in topsoil at reference conditions of (20°C) and the extent of sorption (quantified as the distribution coefficient over organic-matter and water, K_{OM}^5) for the parent compound and for relevant metabolites. For the metabolites the percentage of molecules formed from the parent compound is also needed (this percentage is estimated from the maximum of the percentage from the soil metabolism studies) and also the ratio of the molar masses of parent and metabolite.

For the parent compound twelve sorption studies are available but five of the reported K_{OM} measurements are considered unreliable because the decrease in the concentration in the liquid phase during the adsorption study was too low to be measured accurately. The remaining seven studies results in a median K_{OM} values of about 15 L/kg. The pH of the soil is above 5 for all reliable sorption studies and the pK_a^6 is 3.8. This implies that the K_{OM} applies to the anionic form of metsulfuron-methyl (so the most mobile form). Nine laboratory studies on the transformation rate of metsulfuron-methyl are available. Taking the median DT_{50} and converting for 20°C gives a DT_{50} of about 40 d. This value is reasonably consistent with the available field persistence studies.

³ Good Agricultural Practice

⁴ Degradation time for first 50% of compound

⁵ Organic matter adsorption coefficient

⁶ Negative logarithm (to the base 10) of the dissociation constant

For the assessment of the formation of metabolites two types of studies are available: (i) old studies with applied amounts of metsulfuron-methyl of 0.1-4 mg/kg and with uncontrolled or unknown temperature, and (ii) one new study with an applied amount stated to correspond with a normal use rate at 20 °C. Table 1 gives the seven metabolites which were formed in amounts of substance exceeding 10% in one of these soil metabolism studies. Ester sulfonamide, acid sulfonamide and phenyl urea are all transformed into saccharin. Carbamoyl guanidine is formed out of O-demethyl metsulfuron methyl. Given the results in Table 1 the Committee concludes that assessment of leaching of the following metabolites is needed: ester sulfonamide, saccharine, triazine amine, O-demethyl metsulfuron methyl and carbamoyl guanidine.

No sorption data are available for ester sulfonamide, accordingly its sorption was assumed to be zero. From the new laboratory study referred to in Table 1, a half-life of roughly 25 d at 20 °C was estimated. The percentage formed was assumed to be 11%.

The sorption of saccharine appeared too low to be measured so its sorption was assumed to be zero. The half-life at 20°C was estimated to be 156 d (conservative estimate based on field dissipation studies). The percentage formed was assumed to be 9%.

The K_{OC}^7 value of triazine amine was assumed to be 155 L/kg (average of studies with four soils). The half-life in soil at 20 °C was assumed to be 313 d (based on laboratory study giving 210 d at 25 °C). The percentage formed was assumed to be 33%.

In the absence of sorption data for O-demethyl metsulfuron methyl, its sorption was assumed to be zero. Its half-life in soil at 20 °C was tentatively estimated at 120 d (in the new metabolism study 11% was detected after 10 d and less than 2% after one year). The percentage formed was assumed to be 10%.

As no sorption data are available for carbamoyl guanidine its sorption was assumed to be zero. Its half-life in soil at 20 °C was tentatively estimated at 90 d (in the new metabolism study 16% was detected after 3 months and less than 3% after one year). The percentage formed was assumed to be 16%.

The Committee was informed that DuPont is currently conducting laboratory studies on the half-life and adsorption of saccharine, triazine amine, O-demethyl metsulfuron methyl and carbamoyl guanidine but the full results of these studies were not available at the time when preparing this opinion.

Currently no agreed scenarios for assessing pesticide leaching for EU registration are available. So assessment of pesticide leaching was based on a national scenario (i.e. the Dutch standard scenario, published in J. Environ. Qual. 20: 425-435). All

metabolites were treated as if they were parent compounds. The Dutch standard scenario is based on a dose of 1kg/ha. The assessment was based on a metsulfuron-methyl application of 4 g/ha in spring assuming a linear relationship between dose and leaching (a conservative approach). For metsulfuron-methyl an estimated groundwater concentration in the order of 0.01µg/L was found.

⁷ Organic carbon adsorption coefficient

This order of magnitude is consistent with measured leaching of metsulfuron-methyl in a Swedish lysimeter study. For the metabolites estimated groundwater concentrations ranged from 0.001 to 0.02 µg/L.

Table 1. Maximum percentages of amounts of substance formed for seven soil metabolites of metsulfuron-methyl. "Old studies" refers to incubations with soils treated with amounts of metsulfuron-methyl corresponding with doses of about 0.1-5 kg/ha, "New study" refers to an incubation with a soil treated at a normal use rate; "n.d." = not detected, "n.a." = not analysed.

Soil metabolite	Old studies	New study
ester sulfonamide	17	11
acid sulfonamide	16	n.d.
phenyl urea	17	3
saccharine	47	9
triazine amine	n.a.	33
O-demethyl metsulfuron methyl	n.a.	11
carbamoyl guanidine	n.a.	16

4.2. Question 2

Can it be confirmed that the uses reviewed are acceptable for the aquatic environment?

Opinion

It is the Committee's opinion that with the employment of appropriate risk mitigation measures e.g. buffer zones the proposed uses of metsulfuron methyl will not pose an unacceptable risk to aquatic algae and plants.

The Committee concludes that whereas metsulfuron methyl does not appear to pose an unacceptable risk to aquatic animals, there is cause for concern with respect to algae and aquatic plants. Toxicity varies widely among algal species, and the species used by the Notifier to estimate risk to algae (*Selenastrum capricornutum*) appears to be relatively insensitive compared to other tested species. Also, whether the TER⁸ values for *S. capricornutum* and *Lemna* can be considered acceptable is critically dependent on the assumptions used to estimate both effects and exposure. It is recognised that each of these is associated with a large degree of uncertainty. Exposure assessments which consider all potential routes of entry e.g. drain flow in addition to spray drift and run-off should be made. Metabolites of this pesticide do not appear to cause unacceptable risk to aquatic organisms.

⁸ toxicity exposure ration

4.2.1. Scientific Background on Which the Opinion is Based

A wide range of effect concentrations for algae and aquatic plants were provided by the Notifier as well as in an independent study by Blanck & Björnsäter (1988).

The monograph (Volume 1, p. 43) employed a 120h-EC₅₀⁹ of 3.5 mg/L and a 120h-NOEC¹⁰ of 10 µg/L for the alga, *Selenastrum capricornutum*, to estimate TER_{acute} and TER_{long term}, respectively. For *Lemna minor* effect concentrations of 0.36 µg/L (14d-EC₅₀) and 0.16 µg/L (14d-NOEC) were determined. However, in calculating the TER_{long term} for this species, rather than using the NOEC, an effect concentration of 0.32 µg/L was employed. This was the highest tested concentration at which the culture showed recovery (defined as an increase in frond number during a subsequent 7-day depuration period). It should be noted that actual concentrations of metsulfuron methyl in the test system were not verified, and the effect concentrations are therefore nominal values. The choice of effect endpoint is critical in this case since use of 0.32 gives a TER_{long term} of 13.3 (above the cut-off of 10), whereas use of the NOEC gives a TER_{long term} of 6.7 (below the cut-off of 10).

The exposure concentrations used to estimate the TER values in the monograph assumed spray drift from a distance of 5 m + runoff to a water body of 1 m depth (assuming a single application at 8 g a.s./ha). For drift alone from 1 m into a 30 cm deep water body (the standard scenario normally used) the initial PEC_{SW}¹¹ would be 0.107 µg/L. If this latter PEC_{SW} is used, the TER_{acute} values become: *S. capricornutum*=3500/0.107=3.3 x 10⁴; *Lemna minor*=0.36/0.107=3.4. Likewise, the TER_{long term} values for the standard scenario are: *S. capricornutum*=10/0.106=94; *Lemna minor*=0.16/0.103=1.6. Drift from a distance of 5 m alone (i.e., without runoff) would give the following: TER_{acute} *S. capricornutum*=3.5/0.016=219; TER_{long term} *S. capricornutum*=10/0.016=625; TER_{acute} *Lemna minor*=0.36/0.016=22.5; TER_{long term} *Lemna minor*=0.16/0.0151=10.7. Thus whether or not TER estimates indicate acceptable risk is critically dependent on the assumptions used to calculate exposure, as well as effects. The Committee notes that none of the exposure estimates provided in the monograph consider inputs from drain flow. In some situations input from drain flow could increase PEC_{SW}, and this additional source of input should be considered by Member States with respect to local conditions.

Additional tests with two other algal species gave 120h-EC_{50s} > 95.4 µg/L (*Anabaena flos-aquae*) and 93.6 µg/L (*Skeletonema costatum*), but it should be noted that these additional tests used only one exposure concentration. Using the latter two effect endpoints with an initial PEC_{SW} from spray drift of 0.107 g/L (at 1 m) resulted in TER values of >891 and >874.

Additional effects on microalgal species were provided in a study by Blanck & Björnsäter (1988) in which a total of 40 species were tested with the formulated product Ally (20% a.s.). The most sensitive of the 20 freshwater microalgae had an EC₅₀ (growth inhibition during 7d) of 0.006 M a.s. (=2.29 g a.s./L). This species was at least 2 orders of magnitude more sensitive than

⁹ Effective concentration 50%

⁸ No Observed Effect Concentration

¹¹ Predicted environmental concentration surface water

the other freshwater species tested. The most sensitive of the 20 marine species tested had an $EC_{50} < 0.0001$ M, (i.e., $< 0.04 \mu\text{g/L}$), but this species was also ≥ 2 orders of magnitude more sensitive than the other marine species tested..

Using the most sensitive freshwater alga from Blanck & Björnsäter (1988) gives a TER of $2.29/0.0248 = 92$ (or $2.29/0.107=21.4$ for the standard scenario); or if we use the EC_{50} for the most sensitive marine species we get $TER < 0.04/0.0248=1.6$ or $0.04/0.107=0.4$). In Blanck & Björnsäter's study, the EC_{50} for *S. capricornutum* was 13 M (=5 mg/L). Thus this species was four orders of magnitude less sensitive than the most sensitive freshwater alga and ranked 13th in sensitivity (from most to least sensitive) of the 20 freshwater species tested.

TER calculations for metsulfuron methyl with respect to aquatic algae and plants indicate that there may be unacceptable risks to these groups. Although there are uncertainties in both exposure and effects estimates, the calculations suggest that risk mitigation, in the form of buffer zones, could be employed to avoid unacceptable risks to the aquatic environment.

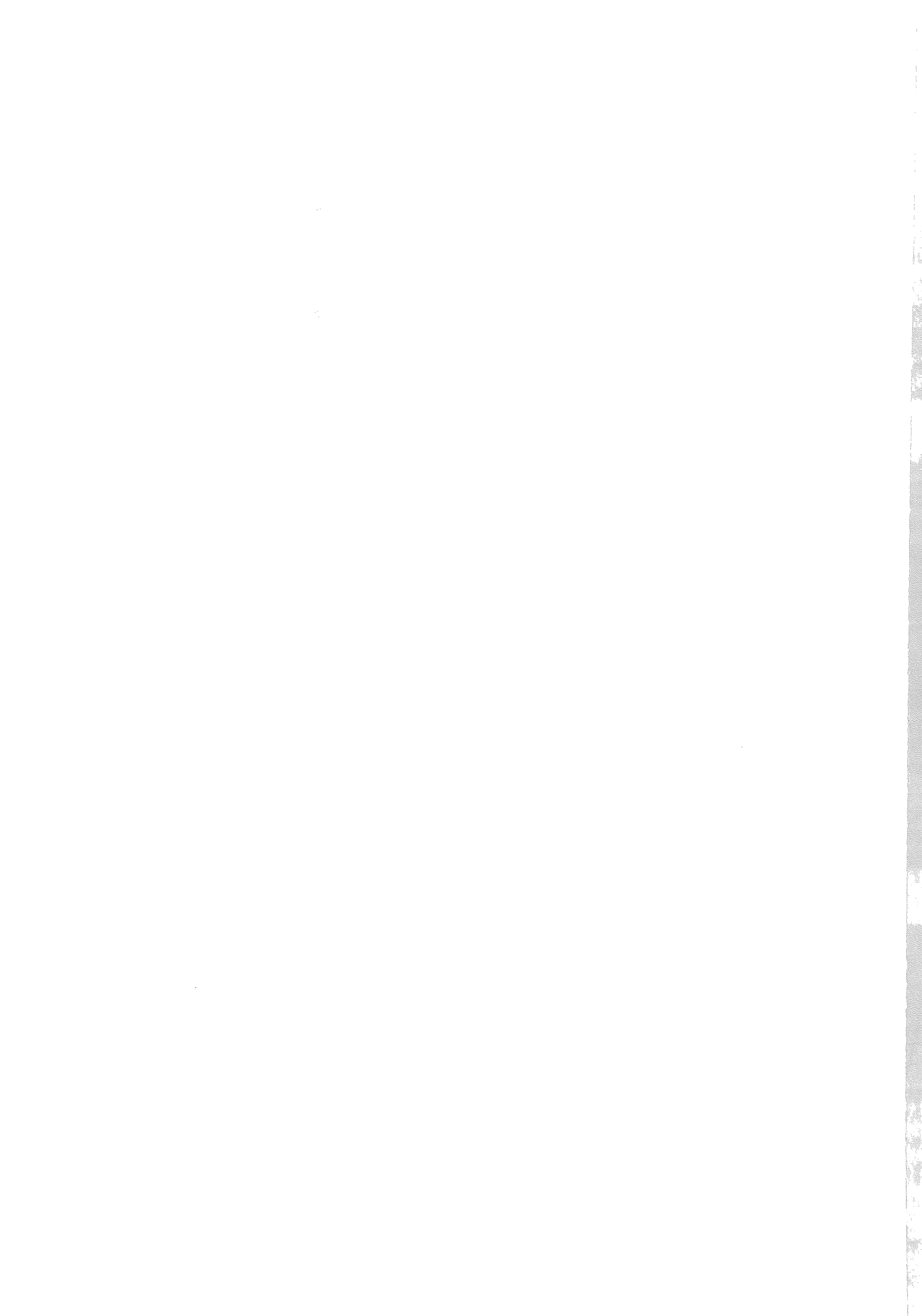
With regard to metabolite effects on aquatic organisms, the only metabolite occurring in water (bis-o-demethyl metsulfuron methyl, IN-JX909) showed low toxicity to *Lemna gibba* (14d- $EC_{50} = 30-47$ mg/L) and the freshwater alga, *Selenastrum capricornutum* (120h- $EC_{50} = 44-73$ mg/L). It also showed low toxicity to fish and *Daphnia*. This metabolite is therefore not expected to cause an unacceptable risk to aquatic organisms. Likewise, the toxicity of metabolite IN-A4098 (triazine amine) to *Lemna gibba* was low (14d- $EC_{50} > 10$ mg/L nominal concentration), and the TER is well above the cut-off value.

5. REFERENCES

Blanck H, Björnsäter B. 1988. Inhibition of growth of marine and freshwater microalgae by the sulfonylurea herbicides GLEAN and ALLY in the algal microtest battery. Final Report to Nordisk Alkali Biokemi A/S.

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

- 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.
- Heft 67, 2000: 100 ECCO-Peer Review Meetings Documentation. Compiled on the occasion of the 100. ECCO-Peer Review Meeting held at the BBA from 3 to 7 July 2000. Bearbeitet von Jürgen Sturma und Dr. Jan von Kietzell, 100 S.
- Heft 68, 2000: Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen . (Band B: , Verordnungen und Protokolle zur Wirkstoffprüfung) 4. Auflage, Stand: 01. Juli 2000. Bearbeitet von Dr. Jörg-Rainer Lundeohn, 176 S.
- Heft 69, 2000: EU-Beurteilungsbericht Imazalil. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 6. Bearbeitet von Edelgard Adam, Axel Wilkening und Jutta Plekat, getr. Zählung.
- Heft 70, 2000: EU-Beurteilungsbericht Prohexadion-calcium. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 7. Bearbeitet von Dr. Achim Holzmann, Dr. Henning Bruno und Jutta Plekat, getr. Zählung.