

Berichte

aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft

Reports

from the Federal Biological Research Centre for Agriculture and Forestry

Heft 99

2002

**EU-Beurteilungsbericht Thifensulfuron-methyl
Rechtliche Regelungen der Europäischen Union
zu Pflanzenschutzmitteln und deren Wirkstoffen
Band D 28**

Review Report Thifensulfuron-methyl
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 28

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Herausgeber

Biologische Bundesanstalt für Land- und Forstwirtschaft
Braunschweig, Deutschland

Verlag

Eigenverlag

Vertrieb

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ISSN 0947-8809

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92/2001	D26: Glyphosat	Deutschland Germany
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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 28. Heft dieser Reihe (Band D 28) 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 Thifensulfuron-methyl war Griechenland 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) <i>wird zur Zeit bearbeitet</i>
68/2000	Band B: Verordnungen und Protokolle zur Wirkstoffprüfung (4. Auflage, Stand 01. Juli 2000) <i>wird zur Zeit bearbeitet</i>
	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 28th report belonging to this series (Volume D 28) 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 thifensulfuron-methyl Greece 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) <i>in progress</i>
68/2000	Volume B: Regulations and Protocols regarding the Evaluation of Active Substances (4 th Edition, date: 1 July 2000) <i>in progress</i>
	Volume C: <i>in progress</i>



RICHTLINIE 2001/99/EG DER KOMMISSION

vom 20. November 2001

zur Änderung von Anhang I der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln zur Aufnahme der Wirkstoffe Glyphosat und Thifensulfuron-methyl

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 2001/87/EG der Kommission⁽²⁾, insbesondere auf Artikel 6 Absatz 1,

in Erwägung nachstehender Gründe:

- (1) Mit der Verordnung (EWG) Nr. 3600/92 der Kommission vom 11. Dezember 1992 mit Durchführungsbestimmungen für die erste Stufe des Arbeitsprogramms gemäß Artikel 8 Absatz 2 der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln⁽³⁾, zuletzt geändert durch die Verordnung (EG) Nr. 2266/2000⁽⁴⁾, wurden die Durchführungsbestimmungen für die erste Stufe des Arbeitsprogramms gemäß Artikel 8 Absatz 2 der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln (im Folgenden „die Richtlinie“ genannt) erlassen. Gemäß der Verordnung (EWG) Nr. 3600/92 wurde mit der Verordnung (EG) Nr. 933/94 der Kommission vom 27. April 1994 über die Festsetzung der Wirkstoffe von Pflanzenschutzmitteln und die Bestimmung der Bericht erstattenden Mitgliedstaaten zur Durchführung der Verordnung (EWG) Nr. 3600/92⁽⁵⁾, zuletzt geändert durch die Verordnung (EG) Nr. 2230/95⁽⁶⁾, die Liste der Wirkstoffe in Pflanzenschutzmitteln festgelegt, die im Hinblick auf ihre mögliche Aufnahme in Anhang I der Richtlinie zu bewerten sind.
- (2) Die Auswirkungen von Glyphosat und Thifensulfuron-methyl auf die menschliche Gesundheit und auf die Umwelt wurden gemäß den Bestimmungen der Verordnung (EWG) Nr. 3600/92 für eine Reihe von durch den Antragsteller vorgeschlagenen Anwendungen geprüft. Gemäß der Verordnung (EG) Nr. 933/94 wurden Deutschland und Frankreich zu Bericht erstattenden Mitgliedstaaten für Glyphosat bzw. Thifensulfuron-methyl benannt. Die Bericht erstattenden Mitgliedstaaten haben der Kommission ihre Bewertungsberichte und Empfehlungen am 1. Februar 1999 (Glyphosat) und am 30. April 1996 (Thifensulfuron-methyl) gemäß Artikel 7 Absatz 1 Buchstabe c) der Verordnung (EWG) Nr. 3600/92 übermittelt.
- (3) Diese Bewertungsberichte wurden von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses für Pflanzenschutz geprüft. Die Prüfung

wurde am 29. Juni 2001 in Form der Beurteilungsberichte der Kommission für Glyphosat und Thifensulfuron-methyl abgeschlossen.

- (4) Die Unterlagen und die aus den Prüfungen von Glyphosat und Thifensulfuron-methyl hervorgegangenen Informationen wurden auch dem Wissenschaftlichen Ausschuss für Pflanzen übermittelt. An den Ausschuss wurden keine besonderen Fragen gerichtet. Der Ausschuss stellte fest, dass er keine Fragen hinsichtlich der möglichen Aufnahme der Wirkstoffe in Anhang I der Richtlinie aufzuwerfen wünsche⁽⁷⁾. Der Ausschuss merkte an, dass die Nichtabgabe von Kommentaren nur bedeute, dass es keine offensichtlichen Gründe für einen Kommentar gebe.
- (5) Die Bewertungen haben ergeben, dass davon ausgegangen werden kann, dass die betreffenden Wirkstoffe enthaltende Pflanzenschutzmittel im Allgemeinen die Anforderungen gemäß Artikel 5 Absatz 1 Buchstaben a) und b) der Richtlinie erfüllen, insbesondere hinsichtlich der geprüften und in dem Beurteilungsbericht der Kommission behandelten Anwendungen. Daher sollten die betreffenden Wirkstoffe in Anhang I aufgenommen werden, damit die Zulassung von Pflanzenschutzmitteln mit den betreffenden Wirkstoffen in allen Mitgliedstaaten gemäß den Bestimmungen der genannten Richtlinie gewährt werden kann.
- (6) Gemäß der Richtlinie stellen die Mitgliedstaaten nach Aufnahme eines Wirkstoffs in Anhang I sicher, dass die Zulassungen von Pflanzenschutzmitteln, die diesen Wirkstoff enthalten, innerhalb eines vorgeschriebenen Zeitraums erteilt, geändert bzw. widerrufen werden. Pflanzenschutzmittel dürfen nur zugelassen werden, wenn die Bedingungen in Zusammenhang mit der Aufnahme des betreffenden Wirkstoffs in Anhang I sowie die einheitlichen Grundsätze gemäß der Richtlinie auf der Grundlage von Unterlagen, die den Datenanforderungen entsprechen, erfüllt sind.
- (7) Vor der Aufnahme eines Wirkstoffs in Anhang I ist eine angemessene Frist vorzusehen, um es den Mitgliedstaaten und Interessierten zu ermöglichen, sich auf die sich daraus ergebenden neuen Anforderungen vorzubereiten. Nach der Aufnahme ist den Mitgliedstaaten außerdem eine angemessene Frist einzuräumen, um die Bestimmungen der Richtlinie über Pflanzenschutzmittel, die Glyphosat oder Thifensulfuron-methyl enthalten, umsetzen zu können. Die Mitgliedstaaten müssen innerhalb dieser Frist gemäß den Bestimmungen der Richtlinie

⁽¹⁾ ABl. L 230 vom 19.8.1991, S. 1.

⁽²⁾ ABl. L 276 vom 19.10.2001, S. 17.

⁽³⁾ ABl. L 366 vom 15.12.1992, S. 10.

⁽⁴⁾ ABl. L 259 vom 13.10.2000, S. 27.

⁽⁵⁾ ABl. L 107 vom 28.4.1994, S. 8.

⁽⁶⁾ ABl. L 225 vom 22.9.1995, S. 1.

⁽⁷⁾ Protokoll über die Plenarsitzung des Wissenschaftlichen Ausschusses für Pflanzen vom 7. März 2001 (Glyphosat)/Protokoll über die Plenarsitzung des Wissenschaftlichen Ausschusses für Pflanzen vom 7. Juni 2001 (Thifensulfuron-methyl).

insbesondere bestehende Zulassungen überprüfen und gegebenenfalls neue Zulassungen erteilen. Für die Einreichung und Bewertung der für jedes Pflanzenschutzmittel vollständigen Unterlagen gemäß den in der Richtlinie festgelegten einheitlichen Grundsätzen ist ein längerer Zeitraum vorzusehen. Pflanzenschutzmittel, die mehrere Wirkstoffe enthalten, können jedoch auf der Grundlage der einheitlichen Grundsätze erst vollständig bewertet werden, wenn alle betroffenen Wirkstoffe in Anhang I der Richtlinie aufgenommen sind.

- (8) Der Beurteilungsbericht ist für die ordnungsgemäße Umsetzung bestimmter Abschnitte der in der Richtlinie festgelegten einheitlichen Grundsätze durch die Mitgliedstaaten erforderlich. Es ist daher vorzuschreiben, dass die Mitgliedstaaten die endgültigen Beurteilungsberichte (mit Ausnahme von vertraulichen Informationen) allen Interessierten zur Einsicht zur Verfügung stellen oder zugänglich machen. Falls ein Beurteilungsbericht unter Berücksichtigung technischer und wissenschaftlicher Entwicklungen aktualisiert werden muss, sind auch die Bedingungen für die Aufnahme des betreffenden Wirkstoffs in Anhang I der Richtlinie gemäß der Richtlinie zu ändern.
- (9) Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz —

hende Zulassungen für Pflanzenschutzmittel, die Glyphosat oder Thifensulfuron-methyl als Wirkstoff enthalten.

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

(2) Hinsichtlich der Bewertung und Entscheidungsfindung gemäß den einheitlichen Grundsätzen von Anhang VI der Richtlinie 91/414/EWG auf der Grundlage von Unterlagen, die die Anforderungen von Anhang III der genannten Richtlinie erfüllen, läuft die Frist für die Änderung oder den Widerruf von Zulassungen von Pflanzenschutzmitteln, die Glyphosat oder Thifensulfuron-methyl als einzigen Wirkstoff enthalten, bis zum 1. Juli 2006.

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

(4) Die Mitgliedstaaten stellen die Beurteilungsberichte für Glyphosat und Thifensulfuron-methyl (mit Ausnahme von vertraulichen Informationen im Sinne des Artikels 14 der Richtlinie 91/414/EWG) allen Interessierten zur Einsicht zur Verfügung oder machen ihn gegebenenfalls auf besonderen Antrag zugänglich.

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

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

Artikel 2

(1) Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens 1. Januar 2003 nachzukommen. Sie unterrichten die Kommission unverzüglich davon.

Gemäß der Richtlinie 91/414/EWG ändern oder widerrufen sie bis zu diesem Termin erforderlichenfalls insbesondere beste-

Artikel 3

Diese Richtlinie tritt am 1. Juli 2002 in Kraft.

Artikel 4

Diese Richtlinie ist an alle Mitgliedstaaten gerichtet.

Brüssel, den 20. November 2001

Für die Kommission

David BYRNE

Mitglied der Kommission

An das Ende der Tabelle in Anhang I der Richtlinie 91/414/EWG aufzunehmende Einträge:

Nr.	Gebräuchliche Bezeichnung, Kennnummern	IUPAC-Bezeichnung	Reinheit (%)	Inkrafttreten	Aufnahme befristet bis	Besondere Bedingungen
25	Glyphosat CAS-Nr. 1071-83-6 CIPAC-Nr. 284	N-(phosphonomethyl)-glycin	950 g/kg	1. Juli 2002	30. Juni 2012	<p>Nur Verwendungen als Herbizid dürfen zugelassen werden.</p> <p>Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 29. Juni 2001 abgeschlossenen Beurteilungsberichts über Glyphosat und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser übergreifenden Bewertung sollen die Mitgliedstaaten</p> <p>— dem Grundwasserschutz in gefährdeten Gebieten, insbesondere im Hinblick auf Anwendungen auf Nicht-Kulturland, besondere Aufmerksamkeit widmen.</p>
26	Thifensulfuronmethyl CAS-Nr. 79277-27-3 CIPAC-Nr. 452	Methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbonyl-sulfamoyl)thiophen-2-carboxylat	960 g/kg	1. Juli 2002	30. Juni 2012	<p>Nur Verwendungen als Herbizid dürfen zugelassen werden.</p> <p>Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 29. Juni 2001 abgeschlossenen Beurteilungsberichts über Thifensulfuron-methyl und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollen die Mitgliedstaaten</p> <p>— dem Grundwasserschutz besondere Aufmerksamkeit widmen;</p> <p>— den Auswirkungen auf Wasserpflanzen besondere Aufmerksamkeit widmen und sicherstellen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikobegrenzung umfassen.</p>

(¹) Weitere Einzelheiten hinsichtlich der Identität und Spezifikation des Wirkstoffs sind den Beurteilungsberichten zu entnehmen.



COMMISSION DIRECTIVE 2001/99/EC

of 20 November 2001

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include glyphosate and thifensulfuron-methyl as active substances

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, as last amended by Commission Directive 2001/87/EC ⁽²⁾, and in particular Article 6(1) thereof,

Whereas:

- (1) Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market ⁽³⁾, as last amended by Regulation (EC) No 2266/2000 ⁽⁴⁾, laid down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC (hereinafter referred to as 'the Directive'). Pursuant to Regulation (EEC) No 3600/92, Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member States for the implementation of Commission Regulation (EEC) No 3600/92 ⁽⁵⁾, as last amended by Regulation (EC) No 2230/95 ⁽⁶⁾, laid down the list of active substances of plant protection products to be assessed, with a view to their possible inclusion in Annex I to the Directive.
- (2) For glyphosate and thifensulfuron-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 range of uses proposed by the notifiers. Under Regulation (EC) No 933/94, Germany and France were designated as rapporteur Member States for glyphosate and thifensulfuron-methyl, respectively. The rapporteur Member States submitted the relevant assessment reports and recommendations to the Commission on 1 February 1999 (glyphosate) and on 30 April 1996 (thifensulfuron-methyl) in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.
- (3) These assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. The reviews were finalised

on 29 June 2001 in the format of the Commission review reports for glyphosate and thifensulfuron-methyl.

- (4) The dossiers and the information from the reviews of glyphosate and thifensulfuron-methyl were also submitted to the Scientific Committee for Plants. No specific questions were addressed to the Committee. The Committee considered that there were no issues that it wished to raise regarding the active substances in the context of a possible inclusion in Annex I to the Directive ⁽⁷⁾. The Committee noted that absence of comment should only be interpreted as an indication of no obvious reasons necessitating comment.
- (5) It has appeared from the various examinations made that plant protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of the Directive, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include the active substances concerned in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing the active substances concerned can be granted in accordance with the provisions of the said Directive.
- (6) The Directive provides that after inclusion of an active substance in Annex I, Member States must, within a prescribed period, grant, vary or withdraw, as appropriate, the authorisations of the plant protection products containing the active substance. In particular, plant protection products should not be authorised unless account is taken of the conditions associated with the inclusion of the active substance in Annex I and the uniform principles laid down in the Directive on the basis of a dossier satisfying the prescribed data requirements.
- (7) A reasonable period must be provided for before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion. Moreover, after inclusion, a reasonable period is necessary to permit Member States to implement the provisions of the Directive on plant protection products containing glyphosate or thifensulfuron-methyl. In particular, Member States

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 276, 19.10.2001, p. 17.

⁽³⁾ OJ L 366, 15.12.1992, p. 10.

⁽⁴⁾ OJ L 259, 13.10.2000, p. 27.

⁽⁵⁾ OJ L 107, 28.4.1994, p. 8.

⁽⁶⁾ OJ L 225, 22.9.1995, p. 1.

⁽⁷⁾ Minutes of the plenary of the Scientific Committee on Plants from March 7, 2001 (glyphosate).
Minutes of the plenary of the Scientific Committee on Plants from June 7, 2001 (thifensulfuron-methyl)

must, within that period, review existing authorisations and, where appropriate, grant new authorisations in accordance with the provisions of the Directive. A longer period should be provided for the submission and assessment of the complete dossier of each plant protection product in accordance with the uniform principles laid down in the Directive. For plant protection products containing several active substances, the complete evaluation on the basis of the uniform principles can only be carried out when all the active substances concerned have been included in Annex I to the Directive.

- (8) The review report is required for the proper implementation by the Member States, of several sections of the uniform principles laid down in the Directive. It is, therefore, appropriate to provide that the finalised review reports (except for confidential information) are kept available or made available by the Member States for consultation by any interested parties. If a review report has to be updated to take account of technical and scientific developments, the conditions for the inclusion of the substance concerned in Annex I to the Directive should also be amended in accordance with the Directive.
- (9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

In particular they shall, in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing glyphosate or thifensulfuron-methyl as active substance by that date.

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

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

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC shall be amended in accordance with the Annex hereto.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive, by 1 January 2003 at the latest. They shall forthwith inform the Commission thereof.

Article 3

This Directive shall enter into force on 1 July 2002.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 November 2001.

For the Commission

David BYRNE

Member of the Commission

ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common name, identification Nos	IUPAC name	Purity (%)	Entry into force	Expiration of inclusion	Specific provisions
25	Glyphosate CAS No 1071-83-6 CIPAC No 284	N-(phosphonomethyl)-glycin	950 g/kg	1 July 2002	30 June 2012	<p>Only uses as herbicide may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on glyphosate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 29 June 2001 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of the groundwater in vulnerable areas, in particular with respect to non-crops uses
26	Thifensulfuron-methyl CAS No 79277-27-3 CIPAC No 452	Methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoyl-sulfamoyl) thiophene-2-carboxylate	960 g/kg	1 July 2002	30 June 2012	<p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on thifensulfuron-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 29 June 2001 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of groundwater, — must pay particular attention to the impact on aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures

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





EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Food Safety: plant health, animal health and welfare, international questions
E1 - Plant health

Thifensulfuron-methyl
SANCO/7577/VI/97-final

12 December 2001

**COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT
THE VIEWS OF THE COMMISSION SERVICES**

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

Finalised in the Standing Committee on Plant Health at its meeting on 29 June 2001 in view of the inclusion of thifensulfuron-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 thifensulfuron-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 3600/92⁽¹⁾ laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1972/99⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Thifensulfuron-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 (France) S.A.S. on 23 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance thifensulfuron-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 933/94⁽³⁾, as last amended by Regulation (EC) No

¹ OJ No L 366, 15.12.1992, p.10

² OJ No L 244, 16.09.1999, p.41.

³ OJ No L 107, 28.4.1994, p.8.

2230/95⁴), designated France as rapporteur Member State to carry out the assessment of thifensulfuron-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 thifensulfuron-methyl this deadline was 30 April 1995.

Du Pont de Nemours (France) S.A.S. submitted a dossier to the rapporteur Member State which was considered as complete.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, France submitted on 30 April 1996 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of thifensulfuron-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 thifensulfuron-methyl from Du Pont de Nemours (France) S.A.S., on 9 December 1996.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 17 October 1996 as well as to Du Pont de Nemours (France) S.A.S. being the main data submitter, on 20 November 1996.

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

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

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from January to April 1997.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 14 April 1997 for comments and further clarification.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the

⁴ OJ No L 225, 22.9.1995, p.1

Standing Committee on Plant Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. December 1999 to June 2001, and was finalised in the meeting of the Standing Committee on 29 June 2001.

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. No specific questions were addressed to the Committee. Following an exchange of views the Committee noted that there were no issues that it wished to raise regarding the active substances in the context of a possible inclusion in Annex I to the Directive⁵. The Committee reiterated its earlier statements that absence of comment should only be interpreted as an indication of no obvious reasons necessitating comment.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive 2001/99/EC concerning the inclusion of thifensulfuron-methyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing thifensulfuron-methyl they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

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

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

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

⁵ Minutes of the plenary of the Scientific Committee on Plants from June 7, 2001

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 thifensulfuron-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 implementation of the provisions of Article 4 (1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each thifensulfuron-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 against Grass and/or broad leaved weeds in cereals and pasture.

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 3 % 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 thifensulfuron-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 (France) S.A.S., 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 thifensulfuron-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 if this active substance is applied adjacent to surface waters. The exposure input from drain flow with respect to local conditions should also be considered. Risk mitigation measures (e.g. buffer zones) should be applied where appropriate.
- 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 and/or 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 thifensulfuron-methyl in Annex I under the current inclusion conditions. Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions.

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 thifensulfuron-methyl in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

THIFENSULFURON-METHYL

Common name (ISO)	Thifensulfuron-methyl
Chemical name (IUPAC)	Methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)carbamoylsulfamoyl)thiophene-2-carboxylate
Chemical name (CA)	3-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)=amino]carbonyl]amino]sulfonyl]-2-thiophenecarboxylic acid (- methylester)
CIPAC No	452
CAS No	79277-27-3 Methylester
EEC No	-
FAO SPECIFICATION	-
Minimum purity	960 g/kg
Molecular formula	$C_{11}H_{11}N_5O_6S_2$ ($C_{12}H_{13}N_5O_6S_2$)
Molecular mass	387.4
Structural formula	

Melting point	171 °C
Boiling point	decomposes
Appearance	White crystalline solid
Relative density	1.49 g/ml
Vapour pressure	7.5 · 10 ⁻⁹ Pa at 20 °C 1.7 X 10 ⁻⁸ Pa at 25 °C
Henry's law constant	1.3 · 10 ⁻¹² Pa·m ³ ·mol ⁻¹
Solubility in water	At 25 °C: pH 5: 0.223 g/l pH 7: 2.24 g/l pH 9: 8.83 g/l
Solubility in organic solvents	At 25 °C: acetone: 1.9 g/l acetonitrile: 7.3 g/l dichloromethane: 27.5 g/l ethanol: 0.9 g/l ethyl acetate: 2.6 g/l hexane: < 0.1 g/l methanol: 2.6 g/l xylene: 0.2 g/l
Partition co-efficient (log P_{OW})	- 1.7 at pH 7 and 25 °C
Partition co-efficient (log P_{OW})	- 1.7 at pH 7 and 25 °C - 2.10 at pH 9 and 25 °C 1.06 at pH 5 and 25 °C
Hydrolytic stability (DT₅₀)	pH 5: 5.5 d pH 7: 190 d pH 9: 92 d
Dissociation constant	pK _a : 4.0
Quantum yield of direct photo-transformation in water at λ >290nm	Not determined as no absorption at λ > 300 nm
Flammability	Not flammable
Explosive properties	Not explosive
UV/VIS absorption (max.)	pH7 : λ _{max} = 233 nm ε=26100 l·xmol ⁻¹ ·xcm ⁻¹
	PH10 : λ _{max} = 234 nm ε=26500 l·xmol ⁻¹ ·xcm ⁻¹
	PH2 : λ _{max} = 224 nm ε=18300 l·xmol ⁻¹ ·xcm ⁻¹
	Absorption at 290 nm : ε=4440-6720 l·xmol ⁻¹ ·xcm ⁻¹ ; no absorption at λ> 300 nm
Photostability (DT₅₀)	pH 5: 98 h pH 7: 125 h pH 9: 97 h

APPENDIX II**END POINTS AND RELATED INFORMATION****THIFENSULFURON(-METHYL)****1 Toxicology and metabolism****Absorption, distribution, excretion and metabolism in mammals**

Rate and extent of absorption:	Rapid (70 - 80 %)
Distribution:	Widely
Potential for accumulation:	No accumulation
Rate and extent of excretion:	> 90 % in 96 h, urine
Toxicologically significant compounds:	Parent compound
Metabolism in animals:	Radioactivity mainly excreted as the parent compound in rat and goat

Acute toxicity

Rat LD ₅₀ oral:	LD ₅₀ > 5000 mg/kg bw
Rat LD ₅₀ dermal:	LD ₅₀ > 2000 mg/kg bw
Rat LC ₅₀ inhalation:	LC ₅₀ > 7.9 mg/l
Skin irritation:	Not irritating
Eye irritation:	Not irritating
Skin sensitization (test method used and result):	Not sensitising (Magnusson and Kligman test)

Short term toxicity

Target / critical effect:	No target identified / decreased body weight gain and food consumption
Lowest relevant oral NOAEL / NOEL:	7 mg/kg bw/d, 90 d oral rat The lowest NOEL was 1.3 mg/kg bw/d in the 1 y dog study but was not considered relevant for setting AOEL
Lowest relevant dermal NOAEL / NOEL:	No data, Not required

Lowest relevant inhalation NOAEL /
NOEL:

No data, Not required

Genotoxicity

Negative

Long term toxicity and carcinogenicity

Target / critical effect:

Not identified / decreased body weight gain

Lowest relevant NOAEL:

0.96 mg/kg bw/d, 2 y rat

Carcinogenicity:

Negative

Reproductive toxicity

Target / critical effect -
Reproduction:

Not identified / decreased body weight gain

Lowest relevant reproductive
NOAEL / NOEL:

43 mg/kg bw/d, maternal toxicity

175 mg/kg bw/d, reproductive toxicity

Target / critical effect -
Developmental toxicity:

Retarded ossification (rat)

Lowest relevant developmental
NOAEL / NOEL:

200 mg/kg bw/d, maternal and developmental
toxicity (rat)

Delayed neurotoxicity

No data, no concern from other studies

Other toxicological studies

No other studies submitted (not necessary)

Medical data

No occupational or accidental poisoning reported

Summary

	Value	Study	Safety factor
ADI:	0.01mg/kg bw/d	2 y rat	100
AOEL systemic:	0.07 mg/kg bw/d	90 d rat	100
AOEL inhalation:	Not allocated (not necessary)		
AOEL dermal:	Not allocated (not necessary)		
ARfD (acute reference dose):	Not allocated (not necessary)		

Dermal absorption

10% default value (no study required)
--

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

Non-extractable residues after 100 days:

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

¹⁴ C-thiophene thifensulfuron methyl, 2 soil types, 0.05 mg/kg, 25 °C
¹⁴ C-triazine amine, 1 soil type, 0.12 mg/kg, 25 °C
Thifensulfuron : 27 - 40 % (40 - 48 % at 52 weeks) Triazine amine : 10 % (38 % at 65 weeks)
Thifensulfuron : 30 - 37 % (19 - 34 % at 52 weeks) Triazine amine : 6 % (10 % at 65 weeks)
Lab. studies: (¹⁴ C-thiophene thifensulfuron) IN-L9225 thifensulfuron acid ⁶ 25 % IN-L9226 O-desmethyl thifen. methyl 15 % IN-W8268 thiophene sulfonimide 28 % (usually < 10 % after 52 weeks)
Field studies : (¹⁴ C-triazine or thiophene thifensulfuron methyl) IN-A4098 triazine amine 30 % IN-L9225 56 % IN-L9226 27 % IN-W8268 4 %

Supplemental studies

Anaerobic:

¹⁴ C-triazine thifensulfuron methyl, 1 soil type, 0.05 mg/kg, 25 °C
CO ₂ 1.2 %
Bound 9.5 %
Major metabolite: IN-L9225 (thifensulfuron acid)

⁶ Including 2-acid-3-sulfonamide (not relevant in field contrary to thifensulfuron acid)

Soil photolysis:

¹⁴C-thiophene or triazine thifensulfuron methyl, 1 soil type, 83 g as/ha, 25 °C
 CO₂ < 8 %, bound < 6 %
 2-ester-3-sulfonamide: 20 - 24 %
 IN-A4098 triazine amine: 19 - 32 %
 DT₅₀ (darkness): 21 - 26 d
 DT₅₀ (sunlight) : 14 - 18 d

Remarks:

No

Rate of degradation**Laboratory studies**DT₅₀lab (20 °C, aerobic):

	1st order	non linear
Thifensulfuron methyl	2-6 d	< 1-2.6 d
IN-L9225 thifen. acid ⁷		2.2- >365 d
IN-L9226 O-desmethyl	10.8-15.3 d	
IN-W8268 thiophen sulf.		9.6-96.6 d
IN-A4098 triazine amine	8 months	176 d
2-ester-3-sulfonamide		6-7 d
New studies (20° C)		
IN-A4098 (triazine amine)		
	DT ₅₀ 22 - 43 d, mean 31.6 d (3 soils pH 5.7-7.7)	
IN-L9225 (thifensulfuron acid)		
	DT ₅₀ 20 - 157 d, mean 74 d (3 soils pH 5.9-7.5)	
IN-L9226 (O-desmethyl thifensulfuron methyl)		
	DT ₅₀ < 2.9 d (same soils)	
IN-W8268 (thiophene sulfonimide)		
	DT ₅₀ 41 - 69 d, mean 56 d (3 soils pH 5.7-7.8)	

⁷ Including 2-acid-3-sulfonamide (not separated in laboratory studies only)

DT₉₀lab (20 °C, aerobic):

	non linear
Thifensulfuron methyl	3.1 - 29 d
IN-L9225 thifen. acid ²	> 365 d
IN-W8268 thiophen sulf.	324 - > 365 d
2-ester-3-sulfonamide	346 - > 365 d
New studies (20° C)	
IN-A4098 (triazine amine)	
DT ₉₀ 74 - 144 d, mean 105 d (soils as above)	
IN-L9225 (thifensulfuron acid)	
DT ₉₀ 68 - 522 d, mean 245 d (soils as above)	
IN-L9226 (O-desmethyl thifensulfuron methyl)	
DT ₉₀ < 9.6 d (soils as above)	
IN-W8268 (thiophene sulfonimide)	
DT ₉₀ 135 - 228 d, mean 185 d (soils as above)	
DT ₅₀ lab (10 °C, aerobic):	6.2 - 18.6 d (according to Arrhenius equation)
DT ₅₀ lab (20 °C, anaerobic):	5 d (25 °C)

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

¹⁴C-thiophene or triazine thifensulfuron methyl,
80 g as/ha, 9 US and Canada locations

Thifensulfuron methyl : 3 - 20 d, mean 10 d
IN-L9225 thifensulfuron acid : 8 - 49 d

DT_{90f} from soil dissipation studies:

	1st order	non linear
Thif. methyl	10 - 66 d	< 1 - 50 d
Metabolites	not calculated	

Soil accumulation studies:

No data, not required

Remarks

No

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

Soil type, pH, OC/OM content:

Soil type	pH	OC %	K _{OC}
Sandy loam	6.6	0.64	13
Sandy loam	6.5	1.22	16
Silt loam	5.4	2.5	55
Silt loam	5.2	4.4	29
mean			28
New studies			
IN-A4098 : Koc 46 - 226, mean 155 (4 soils OC 0.46 - 3.02 %, pH 5.3 - 6.3)			
IN-L9225 : Koc 6.9 - 13.5, mean 11.2 (3 soils OC 1.2 - 2.6 %, pH 5.7 - 7.7)			
IN-L9226 : Koc 34 - 199, mean 111 (same soils)			
IN-W8268 : Koc 2.6 - 4.3 (3 soils OC 1.2 - 2.6 %, pH 5.7 - 7.7)			

Mobility**Laboratory studies:**

Column leaching:

¹⁴C-thiophene (4 soils) and triazine (1 soil)
thifensulfuron methyl
(56 - 77 g as/ha), 500 mm water
Leachates: 67 - 98 %
Thifensulfuron methyl: 60 - 92 %
Thifensulfuron acid: 3 - 5 %

Aged residue leaching:

Silt loam soil, 56 - 77 g as/ha, aging period
6 d, 500 mm water
¹⁴C-thiophene: soil 23 % (bound), leachate
83 %, (thifensulfuron methyl 35 %,
thifensulfuron acid 29 %)
¹⁴C-triazine: soil 19 % (bound, triazine amine
4 %), leachate 60 % (thifensulfuron methyl
24 %, thifensulfuron acid 26 %)

Field studies:

Lysimeter/Field leaching studies:

¹⁴C-thiophene or triazine thifensulfuron methyl (36 g as/ha), 3 soil types (loamy sand),
pH 5.6 - 5.9, OM 1 - 1.8 %, outdoor, 1 year, 1288 mm water

soil : no radioactivity below 30 cm (bound, triazine amine, polar metabolites)

leachate : volume 9 - 37 %, concentrations not detected - 0.5 µg/l, average concentrations not detected - 0.07 µg/l, amounts not detected - 0.5 %

Remarks:

No

2.2 Fate and behaviour in water**Abiotic degradation**

Hydrolytic degradation:

¹⁴C-thiophene or triazine thifensulfuron methyl

DT ₅₀	pH 5	4 - 6 d
	pH 7	180 d
	pH 9	90 d (pH not stable)

Relevant metabolites:

2-ester-3-sulfonamide (up to 64 %)
Triazine amine
(2-ester-3-triuret 8 - 32 %)

Photolytic degradation:

¹⁴C-thiophene or triazine thifensulfuron methyl

DT ₅₀	pH 5	darkness	sunlight
		25 d	4.1 d
		183 d	5.2 d
	pH 9	16 d	4 d

Triazine amine: 14 %
Triazine urea: 11 %
Methyl-3-(4-methoxy-6-methyl-1,3,5-triazine-2-yl-amino)-2-thiophene carboxylate: < 10 %

Biological degradation

Ready biological degradability:

No

- IN-A4098 (triazine amine): 19 %, DT ₅₀ 49 - 71 d No major metabolite in sediment
Not expected

Accumulation in water and/or sediment

Degradation in the saturated zone

No data, not required

Remarks:

2.3 Fate and behaviour in air**Volatility**

Vapour pressure:

 $7.37 \cdot 10^{-9}$ Pa at 20 °C

Henry's law constant:

 $2.8 \cdot 10^{-8}$ Pa·m³·mol⁻¹ at pH 5 $9.6 \cdot 10^{-10}$ Pa·m³·mol⁻¹ at pH 7**Photolytic degradation**

Direct photolysis in air:

No data, not required

Photochemical oxidative degradation in air:

41.4 hours

DT₅₀:

Volatilisation:

Negligible

Remarks:

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:

Short term oral toxicity to mammals:

Long term oral toxicity to mammals:

Acute toxicity to birds:

Dietary toxicity to birds:

Reproductive toxicity to birds:

LD ₅₀ (rat) > 5000 mg/kg bw
LD ₅₀ (rabbit) > 2600 mg/kg bw
NOEL (10 doses oral, rat) = 2200 mg/kg bw
NOAEL (reproduction, rat) = 175 mg/kg bw
LD ₅₀ (mallard duck) > 2510 mg/kg bw
LC ₅₀ (bobwhite quail and mallard duck) > 5620 ppm
NOEC (bobwhite quail) = 250 ppm

Aquatic Organisms

Thifensulfuron(-methyl)

Acute toxicity fish:

Long term toxicity fish:

Bioaccumulation fish:

Acute toxicity invertebrate:

Chronic toxicity invertebrate:

Acute toxicity algae:

Chronic toxicity sediment dwelling organism:

Acute toxicity aquatic plants:

LC ₅₀ > 100 mg/l
NOEC = 250 mg/l
BCF < 0.8 (Annex VI trigger: 1000)
EC ₅₀ (<i>Daphnia</i>) = 470 mg/l
NOEC = 100 mg/l
EC ₅₀ (<i>S. capricornutum</i> - 72 h) = 0,0159 mg/l
not required
EC ₅₀ (<i>L. gibba</i>) = 0.0013 mg/l

Metabolite : IN-L9225 (thifen. Acid)

Acute toxicity fish:

Acute toxicity invertebrate:

Acute toxicity algae:

Acute toxicity aquatic plants:

LC ₅₀ (<i>O. mykiss</i>) > 1 mg/l
EC ₅₀ (<i>Daphnia</i>) > 0.8 mg/l
EC ₅₀ (<i>S. capricornutum</i>) > 1.02 mg/l
EC ₅₀ (<i>L. gibba</i>) > 1 mg/l

Metabolite : IN-L9223 (2-acid-3-sulfonamid)

Acute toxicity fish:

Acute toxicity invertebrate:

Acute toxicity algae:

Acute toxicity aquatic plants:

LC ₅₀ (<i>O. mykiss</i>) > 1.1 mg/l
EC ₅₀ (<i>Daphnia</i>) > 1.2 mg/l
EC ₅₀ (<i>S. capricornutum</i>) > 1.3 mg/l
EC ₅₀ (<i>L. gibba</i>) > 1 mg/l

Metabolite : IN-JZ789 (O. desmethyl thifen. acid)

Acute toxicity fish:

LC₅₀ (*O. mykiss*) > 0.94 mg/l

Acute toxicity invertebrate:

EC₅₀ (*Daphnia*) > 1.1 mg/l

Acute toxicity algae:

EC₅₀ (*S. capricornutum*) > 1.28 mg/l

Acute toxicity aquatic plants:

EC₅₀ (*L. gibba*) > 1 mg/l**Metabolite : IN-V7160 (triazine urea)**

Acute toxicity fish:

LC₅₀ (*O. mykiss*) > 1 mg/l

Acute toxicity invertebrate:

EC₅₀ (*Daphnia*) > 1.3 mg/l

Acute toxicity algae:

EC₅₀ (*S. capricornutum*) > 11 mg/l

Acute toxicity aquatic plants:

EC₅₀ (*L. gibba*) > 10 mg/l**Formulated product : HARMONY 75 WG**

Acute toxicity fish:

LC₅₀ (*O. mykiss*) = 410 (a.s. 300) mg/l

Long term toxicity fish:

NOEC(*O. mykiss*) = 200 (a.s. 156) mg/l

Acute toxicity invertebrate:

EC₅₀ (*Daphnia*) = 320 (a.s. 250) mg/l**Honeybees**

Acute oral toxicity:

LD₅₀ > 7.1 µg as/bee

Acute contact toxicity:

LD₅₀ > 100 µg as/bee

Other arthropod species

Test species

Aphidius rhopalosiphi
(adults; lab. test)

Typhlodromus pyri
(protonymphs; lab. test)

Poecilus cupreus
(adults; lab. test)

Poecilus cupreus
(adults; lab. test)

Chrysoperla carnea
(larvae; lab. test)

Aleochara bilineata
(adult; lab. Test)

% Effect
Effect(mortality)= - 11% Effect(fecundity) : R = 1.3 (82 g/ha; test substance: WG 75%)
Effect(mortality)= 4.6% Effect(fecundity) : R = 1.24 (82 g/ha; test substance: WG 75%)
Effect (mortality) = 0 % Effect (food consumption) = 26 % (10 g/ha; test substance: WG 75%)
Effect (mortality) = 3.3 % Effect (food consumption) : R = 0.69 (82 g/ha; test substance: WG 75%)
Effect (mortality) = 3.6% Effect (reproduction) : R = 1.2 (82 g/ha; test substance: WG 75%)
Effect (mortality) = 0 % Effect (food consumption) = 0 % Effect (ovoposition) = 35 % Effect (hatching rate) = 6 % (10 g/ha; test substance: WG 75%)

Earthworms

Acute toxicity:

LC₅₀ > 2000 mg as/kg soil

Reproductive toxicity:

not required

Soil micro-organisms

Nitrogen mineralization:

No effect up to 0.4 kg as/ha

Carbon mineralization:

No effect up to 0.4 kg as/ha

APPENDIX III**THIFENSULFURON (-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, 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 on previous use in granting national authorizations
All, 2.1.	Anom.	-	DPX M6316 and DuPont Harmony Herbicide Physical and Chemical Characteristics 6316/PC31 DuPont Agricultural Products No GLP Unpublished	
All, 2.1.1	Huntley, K. and L. Edgar	1999	Determination of the melting temperature of thifensulfuron methyl. DuPont-1500 ABC Laboratories, Columbia, Missouri, USA. GLP Unpublished	
All, 2.5.1	Huntley, K. and J. Ambroz	1999	Determination of the ultraviolet- visible absorption of thifensulfuron methyl. DuPont-1498 ABC Laboratories, Columbia, Missouri, USA. GLP Unpublished	

¹ List based on a detailed analysis from RMS.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
All, 2.6.	Barefoot, A.C. and L.A. Cooke	1990	Water Solubility of DPX-M6316 Using Continuous Sample Agitation AMR 1662-90 DuPont Agricultural Products GLP Unpublished	
All, 2.8	Huntley, K.	2000	Determination of octanol/water partition coefficient (Shake flask method of thifensulfuron methyl). DuPont-1502 ABC Laboratories, Columbia, Missouri, USA. GLP Unpublished	
All, 2.9.4	Huntley, K. and P. Sarff	1999	Determination of the dissociation constant of thifensulfuron methyl. DuPont-1501 ABC Laboratories, Columbia, Missouri, USA. GLP Unpublished	
All, 2.9.2	Schmuckler, M.E.	2000	Photochemical oxidative degradation of thifensulfuron methyl. DuPont-3459 DuPont Agricultural Products. GLP Unpublished	
All, 2.9.1, 2.9.3	Peter, J. and N.-M. Frost	2000	Hydrolysis and photolysis rate of thifensulfuron methyl - DuPont Agricultural Products. Not applicable Unpublished	
All, 2.11-2.15.	Gravell, R.L.	1995	Flammability-Explosive Properties-Oxidizing Properties of Thifensulfuron Methyl AMR 3100-94 DuPont Agricultural Products GLP Unpublished	

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 on previous use in granting national authorizations
All, 4.1.1.	Rodriguez, M.	1993	Validation of Analytical Method for the Determination of Thifensulfuron Methyl (M6316) in Harmony® Herbicide, Pinnacle® Herbicide and Technical Grade Thifensulfuron Methyl AMR 2937-94 DuPont Agricultural Products GLP Unpublished	
All, 4.1.1.	Styles, D.	1994	Validation of Analytical Method for the Determination of DPX-M6316 and DPX-T6376 in Harmony® M 75DF Herbicide AMR 2929-94 DuPont Agricultural Products GLP Unpublished	
All, 4.2.1	Powley, C.R. and N.L. Gagnon	2000	Analytical enforcement method for the determination of metsulfuron methyl and thifensulfuron methyl in cereal grain, straw, and forage and for the determination of thifensulfuron methyl in corn grain, forage and stover using liquid chromatography with ultraviolet detection DuPont-3715 DuPont Agricultural Products Not applicable Unpublished	
All, 4.2.1	Reichert, N.	2000	Independent Laboratory Validation of DuPont Method Report Number DuPont- 3715, "Analytical Enforcement Method For The Determination of Metsulfuron Methyl and Thifensulfuron Methyl in Cereal Grain, Straw, and Forage And for the Determination of Thifensulfuron Methyl in Corn Grain, Forage and Stover using Liquid Chromatography with Ultraviolet Detection DuPont-3716 + supplement 1 Institut Fresenius GLP Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
All, 4.2.1	Powley, C.R. et al	1995	Analytical method for the determination of thifensulfuron methyl, metsulfuron methyl, chlorsulfuron, tribenuron methyl and DPX-KE 459 in soil AMR 2480-92 DuPont Agricultural Products Yes Unpublished	
All, 4.2.3	Powley, C.R. et al	1995	Analytical method for the determination of thifensulfuron methyl, metsulfuron methyl, chlorsulfuron, tribenuron methyl and DPX-KE 459 in water AMR 2479-92 DuPont Agricultural Products Yes Unpublished	
All, 4.2.5	De Bernard, P.A. and C.R. Powley	1993	Enforcement method for the determination of thifensulfuron methyl, and chlorsulfuron in milk and animal tissues AMR 2715-93 DuPont Agricultural Products Not applicable Unpublished	

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
All, 5.2.6.	Romanelli, P.	1993	Delayed Contact Hypersensitivity Test (Maximization Method) with DPX-M6316-121 in Guinea Pigs HLO 370-93 Biosearch Inc. GLP Unpublished	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
All, 6.3.	Kennedy, S.M.	1987	Supplemental Data Concerning the Magnitude of the Residues on Grain and Straw from Wheat and Barley after Treatment with Harmony® Herbicide AMR 870-87 DuPont Agricultural Products GLP Unpublished	
All, 6.3..	Ciotti, M.	1998	The Determination of DPX-M6316 in Grass (From Switzerland) by Liquid Chromatography (Season 1987) BG-88-27 Battelle, Switzerland GLP DuPont Unpublished	

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
All, 7.1.1.2. 1	Scott, M.T.	2000	Rates of degradation of [¹⁴ C]IN-A4098, a metabolite of metsulfuron methyl, chlorsulfuron, and thifensulfuron methyl, in three aerobic soils. DuPont-1802 DuPont Agricultural Products. GLP Unpublished	
All, 7.1.1.2. 1	Manjunatha, S.	2000	Rates of degradation of IN-L9225 and IN-L9226 (metabolites of thifensulfuron methyl in three aerobic soils) DuPont-2326 Rallis Research Centre, Bangalore, India. GLP	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
			Unpublished	
All, 7.1.2.	Li, Y. and R.D McFetridge	1996	Adsorption of Triazine Amine on four soils AMR 3656-95 DuPont Agricultural Products GLP Unpublished	
All, 7.1.1.2. 1	Fang, C.	2000	Rates of degradation of IN-W8268, a metabolite of thifensulfuron methyl, in three aerobic soils. DuPont-3039 DuPont Agricultural Products. GLP Unpublished	
All, 7.1.2	Yeomans, P.	1999	[¹⁴ C]IN-A4098. Adsorption/desorption in soil. DuPont-1805 Covance Laboratories Europe, UK. GLP Unpublished	
All, 7.1.2	Yeomans, P.	1999	[¹⁴ C]IN-L9225. Adsorption/desorption in soil. DuPont-1812 Covance Laboratories Europe, UK. GLP Unpublished	
All, 7.1.2	Yeomans, P.	2000	[¹⁴ C]IN-L9226. Adsorption/desorption in soil. DuPont-1813 Covance Laboratories Europe, UK. GLP Unpublished	
All, 7.1.2	Yeomans, P.	2000	[¹⁴ C]IN-LW8268. Adsorption/desorption in soil. DuPont-3172 Covance Laboratories Europe, UK. GLP Unpublished	
All, 7.2.1.3. 2	Spare, W.C.	2000	Degradability and fate of thifensulfuron methyl in the aerobic aquatic environment (water/sediment system). Revision 1. DuPont-1206 RV1 Agriseach Inc., Maryland, USA. GLP	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
			Unpublished	
All, 7.2.1.3.2	Singles, S.K.	2000	Degradability and fate of thifensulfuron methyl in the aerobic aquatic environment (water/sediment system). DuPont-1206 RV1 SU1 DuPont Agricultural Products. GLP Unpublished	
All 9.2.1	Piyush, S.	2000	Model Assessment of the Potential Groundwater Concentrations of Thifensulfuron Methyl (DPX-M6316 75WG) and its Major Degradates for 20 Years of Continuous Use DuPont-4323 DuPont Agricultural Products GLP not applicable Unpublished	
All 9.2.3	Piyush, S. and M. Ball	2000	Predicted Environmental Concentrations of Thifensulfuron Methyl (DPX-M6316 75WG) and Metabolites in Animal Foods, Surface Water, Sediment, Soil and Air, Tier 1 Modelling for European Union DuPont-4319 DuPont Agricultural Products GLP not applicable Unpublished	

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
All, 8.1.3.1.	Beavers, J. et al.	1994	H-19,811 (M6316 [Thifensulfuron methyl]): A One-Generation Reproduction Study with the Northern Bobwhite (Colinus Virginianus) HLO 411-94 Wildlife International GLP Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
All, 8.1.3.2.	Beavers, J. et al.	1994	H-19,811 (M6316 [Thifensulfuron methyl]): A One-Generation Reproduction Study with the Mallard (<i>Anas platyrhynchos</i>) HLO 410-94 Wildlife International GLP Unpublished	
All, 8.2.1	Samel, A.	1999	IN-L9225. Static-Renewal, Acute, 96-Hour, Limit Test to Rainbow Trout, <i>Oncorhynchus mykiss</i> . DuPont-3219 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.1	Samel, .A.	1999	IN-L9223. Static-Renewal, Acute, 96-Hour, Limit Test to Rainbow Trout, <i>Oncorhynchus mykiss</i> DuPont-3217 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.1	Hoke, R.A.	1999	IN-JZ789. Static-Renewal, Acute, 96-Hour, Limit Test to Rainbow Trout, <i>Oncorhynchus mykiss</i> DuPont-1655 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.1	Samel, .A.	1999	IN-V7160. Static-Renewal, Acute, 96-Hour, Limit Test to Rainbow Trout, <i>Oncorhynchus mykiss</i> DuPont-3561 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.4.	Hutton, D.G.	1989	Static Acute 48-Hour EC50 of INN9134-1 to <i>Daphnia magna</i> HLR 137-89 DuPont Haskell Laboratory GLP Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
All, 8.2.4	Samel, A.	1999	IN-L9225. Static, Acute, 48-Hour Limit Test to <i>Daphnia magna</i> . DuPont-3218 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.4	Samel, .A.	1999	IN-L9223. Static, Acute, 48-Hour Limit Test to <i>Daphnia magna</i> . DuPont-3216 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.4	Hoke, R.A.	1999	IN-JZ789. Static, Acute, 48-Hour Limit Test to <i>Daphnia magna</i> . DuPont-1654 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.4	Samel, .A.	1999	IN-V7160. Static, Acute, 48-Hour Limit Test to <i>Daphnia magna</i> . DuPont-3560 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.6	Hicks, S.L.	1995	Thifensulfuron methyl (DPX-M6316): Influence on growth and reproduction of flour select algae species AMR 2890-93 ABC Laboratories Inc. GLP Unpublished	
All, 8.2.6	Boeri, R.L, J.P. Magazu and T.J. Ward	1999	Thifensulfuron methyl technical. Growth and reproduction test with the freshwater algae, <i>Anabaena flos- aquae</i> . DuPont-2378 T.R. Wilbury Laboratories, Massachusetts, GLP UnpublishedUSA	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
All, 8.2.6	Sloman, T.L.	1999	IN-V7160. Influence on Growth and Growth Rate of the Green Alga <i>Selenastrum capricornutum</i> . DuPont-3190 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.6	Sloman, T.L.	1999	IN-L9223. Influence on Growth and Growth Rate of the Green Alga <i>Selenastrum capricornutum</i> . DuPont-3012 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.6	Sloman, T.L.	1999	IN-JZ789. Influence on Growth and Growth Rate of the Green Alga <i>Selenastrum capricornutum</i> . DuPont-2850 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.6	Sloman, T.L.	1999	IN-L9225. Influence on Growth and Growth Rate of the Green Alga <i>Selenastrum capricornutum</i> . DuPont-2762 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.8	Sloman, T.L. and S.E. Leva	1997	IN-L9225. Influence on Growth and reproduction of <i>Lemna Gibba</i> G3. AMR 4302-97 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.8	Sloman, T.L.	1999	IN-JZ789. Influence on Growth and reproduction of <i>Lemna Gibba</i> G3. DuPont-2849 DuPont Haskell Laboratory GLP Unpublished	
All, 8.2.8	Sloman, T.L.	1999	IN-L9223. Influence on Growth and reproduction of <i>Lemna Gibba</i> G3. DuPont-3013 DuPont Haskell Laboratory GLP	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
			Unpublished	
All, 8.2.8	Sloman, T.L.	1999	IN-V7160. Influence on Growth and reproduction of <i>Lemna Gibba</i> G3. DuPont-3189 DuPont Haskell Laboratory GLP Unpublished	
All, 8.3.1.	Vinall, S.	1998	Thifensulfuron methyl technical. Acute oral and contact toxicity to the honeybee, <i>Apis mellifera</i> L. AMR 5091-98 University of Southampton, UK. GLP Unpublished	
All, 8.3.2	Austin, H.	1998	Thifensulfuron methyl 75WG (75DF). A laboratory study to evaluating the effects on the parasitic wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) AMR 5197-98 Ecotox Ltd., UK. GLP Unpublished	
All, 8.3.2	Tessier, C.	1999	Thifensulfuron methyl 75WG (75DF). A laboratory study to evaluating the effects on the predatory mite <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) AMR 5198-98 Ecotox Ltd., UK. GLP Unpublished	
All, 8.3.2	Austin, H.	1998	Thifensulfuron methyl 75WG (75DF). A laboratory study to evaluating the effects on the green lacewing <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae) AMR 5200-98 Ecotox Ltd., UK. GLP Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
All, 8.3.2	Sankanu, A.	1999	Thifensulfuron methyl 75WG (75DF). A laboratory study to evaluating the effects on the beetle <i>Poecilus cupreus</i> (Coleoptera, carabidae). AMR 5199-98 Ecotox Ltd., UK. GLP Unpublished	

B.10 Confidential information

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
<i>Doc.J, 1.8, 1.9</i>	<i>Davis, R.F.</i>	<i>1995</i>	<i>Thifensulfuron Methyl: Product Description and Composition AMR 3016-94 DuPont Agricultural Products GLP Unpublished</i>	
<i>Doc.J, 1.11</i>	<i>Waeghe, T.J.</i>	<i>1995</i>	<i>Technical Grade Thifensulfuron Methyl: Analysis and Certification of Product Ingredients AMR 2636-93 DuPont Agricultural Products GLP Unpublished</i>	



**SUMMARY REPORT
OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH
HELD ON 29 JUNE 2001 IN STOCKHOLM**

President : G. Del Bino

All Member States were present.

1 Examination and possible vote on a draft Commission Directive concerning the inclusion of Thifensulfuron-methyl in Annex 1 to Council Directive 91/414/EEC (Sanco/1787/2001 rev. 3; Review Report 7577/VI/97 rev. 5).

The Commission presented the Review Report in document 7577/VI/97 rev. 5. The Committee took note of the Review Report.

The following declaration was made:

Commission: Same declaration as for cyclanilide.

The Commission presented the draft Directive.

Vote : favourable opinion by unanimity.

The substance is an existing active substance used as herbicide.

A CHECCHI LANG
Director



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

- Heft 80, 2001: EU-Beurteilungsbericht Deiquat. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 14.
Bearbeitet von Dr. Jan von Kietzell und Elke Leske, getr. Zählung.
- Heft 81, 2001: EU-Beurteilungsbericht Pyridat. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 15.
Bearbeitet von Dr. Jan von Kietzell und Elke Leske, getr. Zählung.
- Heft 82, 2001: EU-Beurteilungsbericht Chlozolinat. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 16.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.
- Heft 83, 2001: EU-Beurteilungsbericht Lindan. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 17.
Bearbeitet von Edelgard Adam und Elke Leske, getr. Zählung.
- Heft 84, 2001: EU-Beurteilungsbericht Monolinuron. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 18.
Bearbeitet von Dr. Jan von Kietzell und Elke Leske, getr. Zählung.
- Heft 85, 2001: EU-Beurteilungsbericht Permethrin. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 19.
Bearbeitet von Edelgard Adam und Elke Leske, getr. Zählung.
- Heft 86, 2001: EU-Beurteilungsbericht Pyrazophos. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 20.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.
- Heft 87, 2001: EU-Beurteilungsbericht Quintozen. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 21.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.
- Heft 88, 2001: EU-Beurteilungsbericht Tecnazen. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 22.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.
- Heft 89, 2001: EU-Beurteilungsbericht Zineb. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 23.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.
- Heft 90, 2001: EU-Beurteilungsbericht Thiabendazol. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 24.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.
- Heft 91, 2001: EU-Beurteilungsbericht Fenhexamid. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 24.
Bearbeitet von Herbert Köpp und Elke Leske, getr. Zählung.
- Heft 92, 2001: Liste der zugelassenen Pflanzenschutzmittel (Stand: 1. Juli 2001).
Bearbeitet von Dr. Achim Holzmann, 88 S.
- Heft 93, 2001: Pflanzenschutz im ökologischen Landbau.
PD Dr. habil. Stefan Kühne, Dr. Marga Jahn, Dr. Mario Wick und Dr. Holger Beer, 52 S.
- Heft 94, 2002: EU-Beurteilungsbericht Glyphosat. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 26.
Bearbeitet von Dr. Henning Bruno und Susanne Schaper, getr. Zählung.
- Heft 95, 2002: Pflanzenschutz im ökologischen Landbau – Probleme und Lösungsansätze.
Fünftes Fachgespräch am 28. Juli 2001 in Kleinmachnow. Hinreichende Wirksamkeit von Pflanzenschutzmitteln im ökologischen Landbau. Saat- und Pflanzgut für den ökologischen Landbau.
Bearbeitet von PD Dr. habil. Stefan Kühne und Britta Friedrich, 177 S.
- Heft 96, 2002: Liste der zugelassenen Pflanzenschutzmittel (Stand: 1. Januar 2002).
Bearbeitet von Andreas Spinti, 74 S.
- Heft 97, 2002: EU-Beurteilungsbericht 2,4-D. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 27.
Bearbeitet von Dr. Martina Erdtmann-Vourliotis und Susanne Schaper, getr. Zählung.
- Heft 98, 2002: NEPTUN 2000 – Erhebung von Daten zum tatsächlichen Einsatz chemischer Pflanzenschutzmittel im Ackerbau Deutschlands. Dr. Dietmar Roßberg, Dr. Volkmar Gutsche, Dr. Siegfried Enzian und Dr. Mario Wick. (im Druck)