

# Berichte

aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft

## Reports

from the Federal Biological Research Centre for Agriculture and Forestry

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Heft 100

2002

**EU-Beurteilungsbericht Flupyrsulfuron-methyl  
Rechtliche Regelungen der Europäischen Union  
zu Pflanzenschutzmitteln und deren Wirkstoffen  
Band D 29**

Review Report Flupyrsulfuron-methyl  
Legal Regulations of the European Union  
for Plant Protection Products and their Active Substances  
Volume D 29

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Herausgeber

Biologische Bundesanstalt für Land- und Forstwirtschaft  
Braunschweig, Deutschland

**Verlag**

Eigenverlag

**Vertrieb**

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**ISSN 0947-8809**

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## Vorwort

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

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

Die Biologische Bundesanstalt stellt die Beurteilungsberichte als Berichte aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft als Band D in der Reihe "Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen" über den Saphir Verlag gegen Erstattung der Unkosten zur Verfügung. Das vorliegende 29. Heft dieser Reihe (Band D 29) 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 Flupyrsulfuron-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) <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 29<sup>th</sup> report belonging to this series (Volume D 29) 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 flupyrsulfuron-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 <sup>rd</sup> Edition, date: 1 November 1997) <i>in progress</i>
68/2000	Volume B: Regulations and Protocols regarding the Evaluation of Active Substances (4 <sup>th</sup> Edition, date: 1 July 2000) <i>in progress</i>
	Volume C: <i>in progress</i>

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.

#### Artikel 3

Hinsichtlich der Beurteilung der vorläufigen Zulassungen aufgrund des Beurteilungsberichts und für die Anwendung der einheitlichen Grundsätze von Anhang VI der Richtlinie 91/414/EWG werden die vorläufigen Zulassungen jedoch widerrufen und gegebenenfalls bis zum 30. November 2002 durch eine vollwertige Zulassung ersetzt. Bei Pflanzenschutzmitteln, die DPX KE 459 (Flupyrsulfuron-Methyl) zusammen mit einem anderen, noch nicht in Anhang I aufgeführten Wirkstoff enthalten, wird der vorgenannte Zeitraum allerdings insoweit verlängert, als die Vorschriften der Richtlinie über die Änderung des Anhangs I der Richtlinie 91/414/EWG eine längere Umsetzungsfrist vorsehen, um den Wirkstoff in den Anhang aufzunehmen.

#### Artikel 4

Die Mitgliedstaaten stellen den Beurteilungsbericht für DPX KE 459 (Flupyrsulfuron-Methyl) (mit Ausnahme von vertraulichen Informationen im Sinne des Artikels 14 der Richtlinie) allen Betroffenen zur Einsicht zur Verfügung oder machen ihn gegebenenfalls auf besonderen Antrag zugänglich.

#### Artikel 5

Diese Richtlinie tritt am 1. Juli 2001 in Kraft.

#### Artikel 6

Diese Richtlinie ist an alle Mitgliedstaaten gerichtet.

Brüssel, den 28. Juni 2001

Für die Kommission

David BYRNE

Mitglied der Kommission



## RICHTLINIE 2001/49/EG DER KOMMISSION

vom 28. Juni 2001

### zur Änderung des Anhangs I der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln zur Aufnahme des Wirkstoffs DPX KE 459 (Flupyrsulfuron-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<sup>(1)</sup>, zuletzt geändert durch die Richtlinie 2001/36/EG der Kommission<sup>(2)</sup>, insbesondere auf Artikel 6 Absatz 1,

in Erwägung nachstehender Gründe:

- (1) Die Behörden Frankreichs haben am 26. Oktober 1995 gemäß Artikel 6 Absatz 2 der Richtlinie 91/414/EWG (im Folgenden die „Richtlinie genannt“) einen Antrag von Du Pont de Nemours S.A.S. („der Antragsteller“) auf Aufnahme des Wirkstoffs DPX KE 459 (Flupyrsulfuron-Methyl) in Anhang I der Richtlinie erhalten.
- (2) Gemäß Artikel 6 Absatz 3 der Richtlinie wurde in der Entscheidung 97/164/EG der Kommission<sup>(3)</sup> bestätigt, dass die für Flupyrsulfuron-Methyl eingereichten Unterlagen grundsätzlich die an die Daten und Informationen gestellten Anforderungen des Anhangs II bzw. für ein Pflanzenschutzmittel, das diesen Wirkstoff enthält, diejenigen des Anhangs III der Richtlinie erfüllen.
- (3) Die Auswirkungen von Flupyrsulfuron-Methyl auf die menschliche und tierische Gesundheit und auf die Umwelt wurden von Frankreich in seiner Funktion als Bericht erstattender Mitgliedstaat gemäß Artikel 6 Absätze 2 und 4 der Richtlinie für die von dem Antragsteller vorgeschlagenen Anwendungen geprüft. Frankreich hat der Kommission am 2. Dezember 1997 einen Entwurf des Bewertungsberichts über den Wirkstoff übermittelt.
- (4) Die Unterlagen und die aus der Prüfung von Flupyrsulfuron-Methyl hervorgegangenen Informationen wurden am 15. Juli 1999 auch dem Wissenschaftlichen Ausschuss „Pflanzen“ zur Stellungnahme vorgelegt. Dieser Ausschuss hat seine Stellungnahme am 20. November 2000<sup>(4)</sup> abgegeben.
- (5) Die Bewertungen haben ergeben, dass davon ausgegangen werden kann, dass den Wirkstoff Flupyrsulfuron-Methyl enthaltende Pflanzenschutzmittel im Allgemeinen die Anforderungen gemäß Artikel 5 Absätze 1 und 3 der Richtlinie erfüllen, insbesondere hinsichtlich der geprüften und in den Beurteilungsberichten der Kommission behandelten Anwendungen. Daher sollte der Wirkstoff in Anhang I der Richtlinie aufgenommen werden, damit Pflanzenschutzmittel mit diesem Wirk-

stoff in allen Mitgliedstaaten gemäß der Richtlinie zugelassen werden können.

- (6) Nach der Aufnahme ist den Mitgliedstaaten eine angemessene Frist einzuräumen, um die Bestimmungen dieser Richtlinie umzusetzen und insbesondere bereits bestehende vorläufige Zulassungen für Pflanzenschutzmittel, die Flupyrsulfuron-Methyl enthalten, zu überprüfen; diese Zulassungen sollten durch gemäß Artikel 4 der Richtlinie 91/414/EWG gewährte Zulassungen ersetzt werden. Für Pflanzenschutzmittel, die Flupyrsulfuron-Methyl und andere in Anhang I aufgeführte Wirkstoffe enthalten, kann auch eine längere Frist erforderlich sein.
- (7) Der Beurteilungsbericht ist erforderlich für die ordnungsgemäße Umsetzung bestimmter Teile der einheitlichen Grundsätze gemäß Anhang VI der Richtlinie durch die Mitgliedstaaten, soweit sich diese Grundsätze auf die Bewertung der Angaben beziehen, die zwecks Aufnahme des Wirkstoffs in Anhang I der Richtlinie vorgelegt wurden. Es ist vorzuschreiben, dass die Mitgliedstaaten den endgültigen Beurteilungsbericht (mit Ausnahme von vertraulichen Informationen im Sinne des Artikels 14 der Richtlinie) allen Betroffenen zur Einsicht zur Verfügung stellen oder zugänglich machen.
- (8) Wird dieser Beurteilungsbericht aktualisiert, um den technischen und wissenschaftlichen Entwicklungen Rechnung zu tragen, so müssen die Bedingungen für die Aufnahme von Flupyrsulfuron-Methyl in Anhang I der Richtlinie möglicherweise auch nach dem in der Richtlinie festgelegten Verfahren geändert werden.
- (9) Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz vom 27. April 2001 —

HAT FOLGENDE RICHTLINIE ERLASSEN:

#### Artikel 1

Die Tabelle in Anhang I der Richtlinie 91/414/EWG wird geändert, indem der Eintrag bezüglich DPX KE 459 (Flupyrsulfuron-Methyl) in den Anhang der vorliegenden Richtlinie aufgenommen wird.

#### Artikel 2

Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens 31. Dezember 2001 nachzukommen. Sie unterrichten die Kommission unverzüglich davon.

<sup>(1)</sup> ABl. L 230 vom 19.8.1991, S. 1.

<sup>(2)</sup> ABl. L 164 vom 20.6.2001, S. 1.

<sup>(3)</sup> ABl. L 64 vom 5.3.1997, S. 7.

<sup>(4)</sup> Stellungnahme des Wissenschaftlichen Ausschusses „Pflanzen“ zur Beurteilung von Flupyrsulfuron-Methyl im Rahmen der Richtlinie 91/414/EWG über das Inverkehrbringen von Pflanzenschutzmitteln. SCP/FLUPYR/002-final vom 11. Dezember 2000.

## IN DIE TABELLE IN ANHANG I DER RICHTLINIE 91/414/EWG AUFZUNEHMENDER EINTRAG

Nr.	Gewöhnliche Bezeichnung, Kennnummer	IUPAC-Bezeichnung	Reinheit (%)	Inkrafttreten	Aufnahme befristet bis	Besondere Bedingungen
	„DPX KE 459 (Flupyr-sulfuron-Methyl) CAS-Nr. 144740-54-5 CIPAC-Nr. 577	2-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-6-trifluoromethylnicotinat Mononatriumsalz	903 g/kg	1. Juli 2001	30. Juni 2011	Nur Verwendungen als Herbizid dürfen zugelassen werden.  Bei der Entscheidungsfindung gemäß den einheitlichen Grundsätzen müssen die Mitgliedstaaten dem Grundwasserschutz besondere Aufmerksamkeit widmen.  Der Beurteilungsbericht wurde vom Ständigen Ausschuss für Pflanzenschutz am 27. April 2001 abgeschlossen.

(\*) Weitere Einzelheiten hinsichtlich der Identität und Spezifikation des Wirkstoffs sind den Beurteilungsberichten für DPX KE 459 (Flupyr-sulfuron-Methyl) (Dok. 5050/V1/97) zu entnehmen.\*

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

#### Article 3

However, with regard to the review of provisional authorisations granted in the light of the review report and for the application of the Uniform Principles provided in Annex VI to Directive 91/414/EEC, the provisional authorisations shall be withdrawn and where appropriate, replaced by a full authorisation by 30 November 2002. However for plant protection products containing DPX KE 459 (flupyrsulfuron-methyl) together with another active substance not yet in Annex I, the period referred to above is extended to the extent that a longer implementation period is provided for by the provisions laid down in the Directive amending Annex I to Directive 91/414/EEC to include the other substance in the Annex.

#### Article 4

Member States shall keep available the review report for DPX KE 459 flupyrsulfuronmethyl (except for confidential information within the meaning of Article 14 of the Directive) for consultation by any interested parties or shall make it available to them on specific request.

#### Article 5

This Directive shall enter into force on 1 July 2001.

#### Article 6

This Directive is addressed to the Member States.

Done at Brussels, 28 June 2001.

For the Commission

David BYRNE

Member of the Commission

## COMMISSION DIRECTIVE 2001/49/EC

of 28 June 2001

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include DPX KE 459 (flupyrsulfuron-methyl) as an active substance

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 <sup>(1)</sup>, as last amended by Commission Directive 2001/236/EC <sup>(2)</sup>, and in particular Article 6(1) thereof,

Whereas:

- (1) In accordance with Article 6(2) of Directive 91/414/EEC (hereinafter referred to as 'the Directive') on 26 October 1995 France received an application from Du Pont de Nemours SAS, ('the applicant') for the inclusion of the active substance DPX KE 459 (flupyrsulfuron-methyl) in Annex I to the Directive.
- (2) In accordance with the provisions of Article 6(3) of the Directive Commission Decision 97/164/EC <sup>(3)</sup> concluded that the dossier submitted for flupyrsulfuron-methyl could be considered as satisfying, in principle, the data and information requirements of Annex II, and for a plant protection product containing this active substance, of Annex III to the Directive.
- (3) The effects of flupyrsulfuron-methyl on human and animal health and the environment have been assessed by France, acting as nominated rapporteur Member State, in accordance with the provisions of Article 6(2) and (4) of the Directive, for the uses proposed by the applicant France submitted its draft assessment report concerning the substance to the Commission on 2 December 1997.
- (4) The dossier and the information from the review of flupyrsulfuron-methyl were also submitted to the Scientific Committee on Plants for opinion on 15 July 1999. This Committee gave its opinion on 20 November 2000 <sup>(4)</sup>.
- (5) In the light of these examinations, it appears that plant protection products containing flupyrsulfuron-methyl may be expected to satisfy, in general, the requirements laid down in Article 5(1) and (3) of the Directive, in particular with regard to the uses which were examined and detailed in the Commission review reports. It is therefore appropriate to include it in Annex I to the Directive, in order to ensure that in all Member States

plant protection products containing it can be authorised in accordance with the Directive.

- (6) After inclusion, a reasonable period is necessary to permit Member States to implement the provisions of this Directive and in particular to review, provisional authorisations granted for plant protection products containing flupyrsulfuron-methyl, which should be replaced by authorisations granted under Article 4 of Directive 91/414/EEC. A longer period may also be required for plant protection products containing flupyrsulfuron-methyl and other active substances included in Annex I.
- (7) 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 which refer to the evaluation of the data which were submitted for the purpose of the inclusion of the active substance in Annex I to the Directive. 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 party.
- (8) Should this review report be updated to take account of technical and scientific developments, the conditions for the inclusion of flupyrsulfuron-methyl in Annex I to the Directive may also need to be amended in accordance with the procedure specified in the Directive.
- (9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health delivered on 27 April 2001,

HAS ADOPTED THIS DIRECTIVE:

## Article 1

The table in Annex I to Directive 91/414/EEC shall be amended to include the entry in respect of DPX KE 459 (flupyrsulfuron-methyl) set out in the Annex hereto.

## Article 2

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. They shall forthwith inform the Commission thereof.

<sup>(1)</sup> OJ L 236, 19.8.1991, p. 1.

<sup>(2)</sup> OJ L 164, 29.6.2001, p. 1.

<sup>(3)</sup> OJ L 64, 5.3.1997, p. 7.

<sup>(4)</sup> Opinion of the Scientific Committee on Plants regarding the evaluation of flupyrsulfuron-methyl in the context of Directive 91/414/EEC concerning the placing of plant protection products on the market. SCP/FLUPYR/002, final dated 11 December 2000.

## ANNEX

## ENTRY TO BE INSERTED IN THE TABLE IN ANNEX 1 TO DIRECTIVE 91/414/EEC

No	Common name, identification numbers	IUPAC name	Purity (%)	Entry into force	Expiration of inclusion	Specific provisions
	DPX KE 459 (flupyr-sulfuron-methyl) CAS No 144740-54-5 CIPAC No 577	2-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-6-trifluoromethylnicotinate monosodium salt	903 g/kg	1 July 2001	30 June 2011	Only uses as a herbicide may be authorised.  In decision-making according to the Uniform Principles Member States must pay particular attention to the protection of groundwater.  Date of Standing Committee on Plant Health at which the review report was finalised: 27 April 2001.

(\*) Further details on identity and specification of active substances are provided in the review report for DPX KE 459 (flupyr-sulfuron-methyl) (5050/VI/97).

procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 97/164/EC<sup>1</sup> of 17 February 1997 that these requirements were satisfied.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that France would, as Rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to the Commission as soon as possible and at the latest within a period of one year.

France submitted to the Commission on 2 December 1997 the report of its detailed scientific examination, hereafter referred to as the draft report, including, as required, a recommendation concerning the possible inclusion of Flupyrulfuron-methyl in Annex I to the Directive.

On receipt of the draft report, the Commission forwarded it for consultation to all the Member States on 9 December 1997 as well as to Du Pont de Nemours (France) SA being the sole applicant on 18 December 1997.

The Commission organised further an intensive consultation of specialised scientific experts from a representative number of Member States, to review the draft 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 March 1998 to July 1998.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 23 September 1998.

The dossier, draft report and the peer review report (i.e. full report) including in particular an outline resumé of the remaining technical questions, were referred to the Standing Committee on Plant Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from December 1998 to April 2001, and was finalised in the meeting of the Standing Committee on 27 April 2001.

The present review report contains the conclusions of this final examination; given the importance of the draft report, the peer review report (i.e. full report) and the comments and

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<sup>1</sup> DPX KE 459 (flupyrulfuron-methyl) OJ No L 64, 05.03.1997, p.17.

<sup>2</sup> Opinion of the scientific Committee on Plants regarding the inclusion of DPX KE 459 (flupyrulfuron-methyl) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

flupyrsulfuron-methyl

5050/VI/97-final

7 November 2001

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

**FINAL**

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

Finalised in the Standing Committee on Plant Health at its meeting on **27 April 2001** in view of the inclusion of flupyrsulfuron-methyl in Annex I of Directive 91/414/EEC.

**1. Procedure followed for the evaluation process**

This review report has been established as a result of the evaluation of the new active substance DPX KE 459 (flupyrsulfuron-methyl), made in the context of the work provided for in Articles 5 and 6 of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the French authorities received on 26 October 1995 an application from DU PONT DE NEMOURS (France) SA, hereafter referred to as the applicant, for the inclusion of the active substance Flupyrsulfuron-methyl in Annex I to the Directive. The French authorities indicated to the Commission on 22 July 1996 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on Flupyrsulfuron-methyl was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on Plant Health in the meeting of the working group 'legislation' thereof on 16 August 1996, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the

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 on 15 July 1999. The report of this Committee was formally adopted on 30 November 2000<sup>3</sup>.

## **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 2001/49/EC concerning the inclusion of flupyrsulfuron-methyl methyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing flupyrsulfuron-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 parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to the applicant.

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

## **3. Overall conclusion in the context of Directive 91/414/EEC**

The overall conclusion from the evaluation is that it may be expected that plant protection products containing Flupyrsulfuron-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(I) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each Flupyrsulfuron-methyl containing plant protection product for which Member States will grant or review the authorisation.

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<sup>3</sup> Opinion of the scientific Committee on Plants regarding the inclusion of DPX KE 459 (flupyrsulfuron-methyl) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market



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

- Herbicide for use in cereals

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

#### **4. Specific conclusions highlighted in this evaluation**

##### **4.1 Residues of DPX KE 459 (flupyr sulfuron-methyl)**

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) for a 60 kg adult is < 0.5 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This low intake value reflects the current limited use pattern for this active substance.

For infants, toddler and child this figure was respectively 1.30%, 1.23% and 0.82% of the of the Acceptable Daily Intake (ADI)

##### **4.2 Exposure of operators, workers and bystanders**

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

##### **4.3 Environment**

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

#### **5. Identity and Physical/chemical properties**

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

The active substance shall have a minimum purity of 903 g/kg technical product.

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

## **6. Endpoints and related information**

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

## **7. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing Flupyr-sulfuron-methy**

On the basis of the proposed and supported uses, the following particular issues have been identified which require particular and short term (within 12 months at the latest) attention from the Member States, in the framework of authorisations to be granted, varied or withdrawn, as 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 extreme climatic conditions.

## **8. List of studies to be generated**

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

## **9. Information on studies with claimed data protection**

For information of any interested parties, Appendix III gives information about the studies for which the applicant has claimed data protection and which are not present in the original dossier neither mentioned in the monograph. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the time this review report was prepared; but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

## **10. Updating of this review report**

The technical information in this report may require periodic updating to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on Plant Health, in connection with any amendment of the inclusion conditions for flupyr-sulfuron methyl in Annex I of the Directive.

## APPENDIX I

## Identity, physical and chemical properties

## FLUPYRSULFURON-METHYL

<b>Common name (ISO)</b>	Flupyrsulfuron-methyl
<b>Chemical name (IUPAC)</b>	2-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-6-trifluoromethylnicotinate monosodium salt
<b>Chemical name (CA)</b>	Methyl 2-[[[(4,6-dimethoxy-2-pirimidinyl)amino]carbonyl]-amino]sulfonyl]-6-(trifluoromethyl)-3-pyridinecarboxylate sodium salt
<b>CIPAC No</b>	577
<b>CAS No</b>	144740-54-5
<b>EEC No</b>	Not available
<b>FAO SPECIFICATION</b>	Not available
<b>Minimum purity</b>	903 g/kg
<b>Molecular formula</b>	C <sub>15</sub> H <sub>13</sub> F <sub>3</sub> N <sub>5</sub> O <sub>7</sub> Na
<b>Molecular mass</b>	487.4
<b>Structural formula</b>	<p>The structural formula shows a central sodium ion (Na<sup>+</sup>) coordinated to the nitrogen of a pyridine ring. The pyridine ring has a trifluoromethyl group (F<sub>3</sub>C) at the 6-position and a methyl ester group (CO<sub>2</sub>CH<sub>3</sub>) at the 3-position. The pyridine ring is connected at the 2-position to a carbonyl group (C=O), which is further connected to an amino group (NH). This amino group is connected to another carbonyl group (C=O), which is connected to a 4,6-dimethoxy-2-pyrimidinyl group. The pyrimidine ring has methoxy groups (OCH<sub>3</sub>) at the 4 and 6 positions.</p>

<b>Melting point</b>	Not determined because of decomposition of the active substance (decomposition at 165-170°C)
<b>Boiling point</b>	Not required
<b>Appearance</b>	white solid with chalk-like odour (93.4 %)
<b>Relative density</b>	1.55 (95 %)
<b>Vapour pressure</b>	$< 1 \times 10^{-9}$ Pa at 20°C
<b>Henry's law constant</b>	$< 10^{-8}$ Pa m <sup>3</sup> mol <sup>-1</sup> at pH 5 $< 10^{-9}$ Pa m <sup>3</sup> mol <sup>-1</sup> at pH 6
<b>Solubility in water</b>	pH5 : 0.06 g/l at 20°C (93.4 %) pH6 : 0.61 g/l at 20°C pH7 : instability of the solution
<b>Solubility in organic solvents</b> (g/l at 20 °C)	Acetone : 3.1 (93.4 %) Acetonitrile : 4.3 Benzene : 0.028 Dichloromethane : 0.60 Ethyl acetate : 0.49 Hexane : <0.001 Methanol : 5.0 n-octanol : 0.19
<b>Partition co-efficient (log P<sub>ow</sub>)</b>	pH5 : 9.17 (P <sub>ow</sub> = 0.96) (93.4 %) pH6 : 1.16 (P <sub>ow</sub> = 0.06)
<b>Hydrolytic stability (DT<sub>50</sub>)</b>	pH5 : DT <sub>50</sub> = 44 days pH7 : DT <sub>50</sub> = 12 days pH9 : DT <sub>50</sub> = 0.42 days
<b>Dissociation constant</b>	pK <sub>a</sub> = 4.94 (93.4 %)
<b>Quantum yield of direct photo-transformation in water at <math>\lambda &gt; 290</math> nm</b>	$1.59 \cdot 10^{-3}$ mol x einstein <sup>-1</sup> at pH7
<b>Flammability</b>	not flammable
<b>Explosive properties</b>	not explosive
<b>UV/VIS absorption (max.)</b>	$\epsilon = 1.92 \cdot 10^4$ l mol <sup>-1</sup> cm <sup>-1</sup> (95 %) No absorption >290 nm
<b>Photostability in water (DT<sub>50</sub>)</b>	DT50 (days) DPX JE138 Sunlight      Photodegradation pH5 :      40                      470 pH7 :      8.7                      33 pH9 :      0.39                      5.4

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## 5. REFERENCES

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1. Opinion of the Scientific Committee on Plants regarding the draft guidance document on relevant metabolites (Document SANCO/221/2000-rev2) adopted on 30 November 2000  
[http://europa.eu.int/comm/food/fs/sc/scp/outcome\\_ppp\\_en.html](http://europa.eu.int/comm/food/fs/sc/scp/outcome_ppp_en.html)

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## 6. DOCUMENTATION MADE AVAILABLE TO THE COMMITTEE

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1. Terms of reference: Evaluation of flupyrsulfuron-methyl in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Doc. SCP/FLUPYR/001-Rev.1) – submitted 3 August 1999.
2. “Model assessment of the potential groundwater concentrations of flupyrsulfuron-methyl (DPX-KE459) and its major degradates for 32 years of continuous use” – D. Esterly, E.I du Pont de Nemours and Company, 29 April 1999 (Doc. SCP/FLUPYR/003) - submitted 20 December 1999.
3. Questions from the SCP to the Notifier (Doc. SCP/FLUPYR/004) – submitted 31 January 2000.
4. Response from the Notifier to clarification sought by the SCP relating to the evaluation of flupyrsulfuron-methyl (Doc. SCP/FLUPYR/006) – submitted 8 February 2000.
5. “Position paper for flupyrsulfuron-methyl: calculation of half-lives of IN-JV460, the major soil degradate of flupyrsulfuron-methyl, under field conditions”, S. Koch Singles, E.I. du Pont de Nemours and Company, 2 February 2000 (doc. SCP/FLUPYR/007) – submitted 8 February 2000.
6. Flupyrsulfuron-methyl: Draft review report 5050/VI/97-rev.2, 5 September 1999 (Doc. SCP/FLUPYR/008) – submitted 31 May 2000.
7. Evaluation of flupyrsulfuron-methyl in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market: appendices, 4 June 1999 (Doc. SCP/FLUPYR/009) – submitted 4 June 2000.
8. Evaluation of flupyrsulfuron-methyl in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market: Evaluation table, 5051/VI/98-rev.7, 2 June 1999 (Doc. SCP/FLUPYR/010) – submitted 19 June 2000.
9. “IN-JV460 (Metabolite of flupyrsulfuron-methyl): effects on reproduction and growth of earthworm, *Eisenia fetida* (Savigny, 1826), in artificial soil” Final report - U. Lührs, Institut für Biologische Analytik und Consulting IBACON GmbH, 19 July 2000 [Submitted by du Pont de Nemours] (Doc. SCP/FLUPYR/011) – submitted 11 August 2000.
10. Flupyrsulfuron-methyl and its two metabolites: steady state concentration, submitted by Dr. Boesten. (Doc. SCP/FLUPYR/012) – 5 October 2000.

**Long term toxicity and carcinogenicity**

Target / critical effect:

Indications of liver toxicity

Lowest relevant NOAEL:

18-month oral mouse : 25 ppm ( 3.51 mg/kg bw/day)

Carcinogenicity:

(Liver tumours in mice)

**Reproductive toxicity**

Target/critical effect - Reproduction:

Decrease pup weight at parental toxicity dose level

Lowest relevant reproductive NOAEL/NOEL:

1 500 ppm (84 mg/kg bw/day) , two generations rat study

Target/critical effect - Developmental toxicity

Reduced foetal weight, retarded ossification

Lowest relevant developmental NOEL:

20 mg/kg bw/day (rat)

**Delayed neurotoxicity**

No evidence of neurotoxicity in standard toxicity tests and functional observation battery test.

**Other toxicological studies**

No other studies submitted (not necessary).

**Medical data**

No case of intoxication reported (New substance).

**Summary**

ADI

Value	Study	Safety factor
0.035 mg/kg	18 month mouse	100
0.08 mg/kg	1 year dog	100, corrected by 60 % oral absorption
AOEL inhalation		
Not allocated (not necessary)		
AOEL dermal		
Not allocated (not necessary)		
ARfD (Acute Reference Dose)		
Not allocated (not necessary)		

AOEL systemic :

AOEL inhalation

AOEL dermal

ARfD (Acute Reference Dose)

**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:

relevant metabolites above 10 % of applied active  
substance: name and/or code

% of applied (range and maximum)

< 2 % (both labels)
29 % (pyridine label, 90 days) - 41 % (1 year)
39 % (pyrimidine label, 90 days) - 34 % (1 year)
IN-JV460 max. 24 %
IN-KY374 max. 32 %

#### Supplemental studies

##### Anaerobic:

IN-JV460 max. 42.1 %
IN-KV996 max. 11.8 %
Bound residue max. 30 %

##### Soil photolysis:

IN-JE127 max. 13.1 %
No significant effect of light

##### Remarks:

None
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#### Rate of degradation

##### Laboratory studies:

Lab. : first order ( $R^2$ not reported)
Field : non linear regression ( $R^2 = 0.74 - 0.90$ )

DT<sub>50</sub>lab (20 °C, aerobic):

soil	sa. l. (UK)	l. (G)	sa. l. (F)	si. l. (F)	cl. l. (UK)
OM %	2.6	2.2	1.2	2.2	3.3
pH	6.5	6.1	7.6	6.4	7.1
DT50	26/24	16/16	8/8	16/18	10/9
(days at 50/70 % MWHC)					
Metabolites - first approach					
IN-JV460 : 373 days (UK sandy loam soil)					
IN-KC576 : 248 days (UK sandy loam soil)					
Metabolites - modelling					
IN-JV460 : 120 days (UK sandy loam soil)					
IN-KC576 : 30 days (UK sandy loam soil)					

DT<sub>90lab</sub> (20 °C, aerobic):

soil	sa. l. (UK)	l. (G)	sa. l. (F)	si. l. (F)	cl. l. (UK)
	85/80	53/53	27/27	52/60	32/30
(days at 50/70 % MWHC)					

DT<sub>50lab</sub> (10°C, aerobic):

58 days (UK sandy loam soil, 50 % MWHC)

DT<sub>50lab</sub> (20°C, anaerobic):

31 days (UK sandy loam soil)

**Field studies (country or region):**

DT<sub>50f</sub> from soil dissipation studies:

DT<sub>50f</sub>:  
 10 d UK site (cl. l. soil, 1.9% OC, pH 7.3), Dec. appl.  
 11 d UK site, April appl.  
 6 d F site (sa. si. l. soil, 1.1% OC, pH 7.6), Dec. appl.  
 6 d US Delaware site (si. l. soil, 2.1% OC, pH 5.8),  
 May appl.

Metabolites

IN-JV460 : 49 / 231 d (UK site, Dec. / April appl.),  
 128 d (F site), 180 d (US site).  
 max. amounts 13-27 %

IN-KC576 : 150 d  
 only significant at the US site, max. 58 %

No other significant metabolites

DT<sub>90f</sub> from soil dissipation studies:

DT<sub>90f</sub>:  
 104 - 70 - 35 - 123 d (same conditions as above)

Soil accumulation studies:

- DT<sub>50lab</sub> for IN-JV460 estimated to be 120 d in the UK sandy loam by modelling (instead of 373 d, first approach). Max. concentration 4 µg/kg after 65 d (modelling PRZM3, 10 g as/ha). For yearly application, estimated accumulation would be < 1 µg/kg (lower plateau level).

- DT<sub>50lab</sub> for IN-KC576 estimated to be 30 d in the UK sandy loam by modelling (instead of 248 d, first approach). DT<sub>50f</sub> not reliable (R<sup>2</sup> 0.37). Accumulation not relevant.

Soil residue studies:

See above

**Remarks:**

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

None



**Adsorption/desorption**

$K_f / K_{oc}$ :

$K_d$

K <sub>oc</sub> derived from K <sub>f</sub> (or from K <sub>d</sub> )						
Soil	OC %	pH	a.s.	KC576	JV460	KY374
sa. l. (UK)	1.5	7.4	15	19	196	(39)
sa. l. (F)	0.7	8.8	19	26	148	(12)
si. l. (F)	1.3	7.4	22	-	-	-
cl. l. (UK)	1.9	8.1	23	(48)	(106)	(4)
Speyer 2.2	2.3	5.8	22	(22)	(79)	(17)
l. (G)	1.3	6.6	(55)	21	202	(3)
si. l. (G)	0.9	8.0	(34)	-	-	-
sa. l. (F)	2.1	7.9	(30)	-	-	-
si. l. (US)	1.8	5.7	-	(40)	(65)	(24)

**Mobility**

**Laboratory studies:**

- Column leaching:

No data required		
UK sandy loam, 17 d incubation		
leachates	IN-JV460	32 %
	a.s.	5.7 %
	others	< 5 % each

- Aged residue leaching:

**Field studies:**

Lysimeter/Field leaching studies:

Field dissipation studies	
<u>F site (Nambenheim) and UK site (Alconbury)</u>	
15 - 30 cm	< 13.5 % AR (a.s. < 2 %)
30 - 60 cm	max. 5.7 - 9.8 % AR (20 % one sample)
60 - 90 cm	2 samples with 2.4 and 15.2 % AR
<u>USA site (Newark, Delaware)</u>	
0 - 5 % AR in 15 - 30 cm, 30 - 60 cm and 60 - 90 cm	

**Remarks:**

None
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## 2.2 Fate and behaviour in water

### Abiotic degradation

Hydrolytic degradation :

pH = 5 (20° C) DT50 = 44 d  
 metabolites: IN-KT982 (15.1 %),  
 IN-JV460 (30.7 %),  
 IN-JE127 (12.5 %),  
 IN-J290 (11.4 %)

pH = 7 (20° C) DT50 = 12 d  
 metabolites : IN-JV460 (78 %), stable

pH = 9 (20° C) DT50 = 0.4 d  
 metabolite : IN-JV460 (96.7 %),  
 stable (DT50 = 320 d)

Relevant metabolites:

IN-JV460 (hydrolysis)

Photolytic degradation:

pH = 5 (20° C) DT50 = 40 d  
 metabolites : IN-KT982 (< 10 %),  
 IN-JV460 (< 10 %)

pH = 7 (20° C) DT50 = 8.7 d  
 metabolites : IN-KV994 (10.3 %),  
 IN-KF526 (21 %)

pH = 9 (20° C) DT50 = 0.39 d  
 metabolites : IN-JV460 (DT50 = 4.5 d)

Relevant metabolites

IN-KF526 and IN-KV994 (photolysis)

### Biological degradation

Readily biodegradable:

No

- Degradation in - DT<sub>50</sub> water
- water/sediment - DT<sub>90</sub> water
- DT<sub>50</sub> whole system
- DT<sub>90</sub> whole system

3-6 d  
 20-36 d  
 3-6 d  
 25-46 d

Distribution in water / sediment systems  
 (active substance)

mainly in water, < 9.1 % in sediment

Distribution in water / sediment systems  
 (metabolites)

IN-JV460 max. 69 % (after 30 d) in water, 24 %  
 (after 100 d) in sediment

Accumulation in water and/or sediment:

IN-JV460 < 0.005 µg/l in water and < 0.0003 µg/kg  
 in sediment (EXAMS II, 10 g as/ha, spray drift 0.6 %  
 at 5 m). Simple calculation based on data from water-  
 sediment studies would give < 0.014 µg/l (69 %) and

< 0.019 µg/kg (24 %)
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**Degradation in the saturated zone**

no data available, not required
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Remarks:

no particular remarks
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**2.3 Fate and behaviour in air****Volatility**

Vapour pressure:

< 10 <sup>-9</sup> Pa (20° C)
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Henry's law constant:

< 10 <sup>-8</sup> Pa m <sup>3</sup> mol <sup>-1</sup> at pH 5
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< 10 <sup>-9</sup> Pa m <sup>3</sup> mol <sup>-1</sup> at pH 6
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**Photolytic degradation**

Direct photolysis in air:

No data required
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Photochemical oxidative degradation in air (DT<sub>50</sub>):

0.053 d
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Volatilisation:

from plant surfaces : 0.1%
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from soil : 2.8%
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Remarks:

None
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### 3 Ecotoxicology

#### Terrestrial Vertebrates

Acute toxicity to mammals  
Acute toxicity to birds:  
Dietary toxicity to birds:  
Reproductive toxicity to birds:  
Long term oral toxicity to mammals.

LD50 > 5 000 mg/kg
LD50 (quail/mallard duck) > 2 250 mg/kg bw
LC50 (quail/mallard duck) > 5 620 mg/kg bw
NOEC (mallard duck) = 200 ppm
NOAEL (90 d, rat) = 2 000 ppm

#### Aquatic Organisms

##### Active substance:

Acute toxicity fish:  
Chronic toxicity fish  
  
Bioaccumulation fish:  
Acute toxicity invertebrate:  
Chronic toxicity invertebrate:  
Acute toxicity algae:  
  
Aquatic plants:  
Chronic toxicity sediment dwelling organism:

LC50 (trout): 470 mg/l
NOEC (trout, 28 d): 130 mg/l
NOEC (trout, 90 d): 9.2 mg/l
Not required
EC50 (daphnids): 721 mg/l
NOEC (daphnids, 21 d): 16 mg/l
EC50 ( <i>S. capricornutum</i> ): 0.0037 mg/l
EC50 ( <i>A. flos-aquae</i> ): 0.099 mg/l
EC50 ( <i>L. gibba</i> ): 0.0025 mg/l
not required

##### Preparation (WG 50%):

Acute toxicity algae:

EC50 ( <i>S. capricornutum</i> ): 0.0091 mg preparation/l
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##### Metabolites:

Acute toxicity fish:  
  
Acute toxicity invertebrate:  
  
Acute toxicity algae:

LC50 (trout, IN-KF526): > 10 mg/l
LC50 (trout, IN-KV994): > 0.001 mg/l
EC50 (daphnids, IN-KF526): > 0.5 mg/l
EC50 (daphnids, IN-KV994): > 0.001 mg/l
EC50 ( <i>S. capricornutum</i> , IN-JV460): > 0.0101 mg/l

**Honeybees**

Acute oral toxicity:

LD50 &gt; 30 µg a.s./bee

Acute contact toxicity:

LD50 &gt; 25 µg a.s./bee

**Other arthropod species***T. pyri*beneficial capacity: 7.1 % effect  
(0.016 kg a.s./ha DPX-KV953 <sup>1</sup>)*A. rhopalosiphi*beneficial capacity: 41.1 % effect  
(0.016 kg a.s./ha DPX-KV953 <sup>1</sup>)*A. rhopalosiphi*beneficial capacity: -6 % effect  
(0.016 kg a.s./ha DPX-KS999 <sup>2</sup>)*C. carnea*beneficial capacity: -56 % effect  
(0.016 kg a.s./ha DPX-KV953 <sup>1</sup>)*P. cupreus*beneficial capacity: -9.9 % effect  
(0.016 kg a.s./ha DPX-KV953 <sup>1</sup>)<sup>1</sup> DPX-KV953 50DF : 33.3% flupyr-sulfuron-methyl + 16.7% metsulfuron-methyl<sup>2</sup> DPX-KS999 50DF : 16.7% flupyr-sulfuron-methyl + 33.3% carfentrazone-ethyl**Earthworms**Active substance:

Acute toxicity:

LC50 &gt; 1000 mg/kg

Reproductive toxicity:

not required

Metabolite:

Reproductive toxicity IN-JV460:

NOEC = 0.065 mg/kg soil

**Soil micro-organisms**

Nitrogen mineralization:

20 g a.s./ha: no effect

Carbon mineralization:

20 g a.s./ha: no effect

## APPENDIX III

## FLUPYRSULFURON-METHYL

List of studies which were submitted during the evaluation process and were not cited in the draft assessment report:

**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 <sup>2</sup> on previous use in granting national authorizations
AII 2.2	Huntley, K; Edgar, L	1999	Determination of the Density of Flupyr sulfuron Methyl ABC Laboratories DuPont-1472 GLP/unpublished	
AII 2.5.1	Huntley, K; Ambroz, J	1999	Determination of the Ultraviolet-Visible Absorption of Flupyr sulfuron Methyl ABC Laboratories DuPont-1473 GLP/unpublished	
AII 2.10	Barefoot, AC; Schmuckler, ME	1996	Calculation of the Second-Order Rate Constant and Associated Half-Life T(1/2)E for the Reaction of DPX-KE459 in the Gas Phase in the Troposphere Using the Method of Atkinson DuPont Agricultural Products NA*/unpublished	
AII 2.11	Schmuckler, ME; LeSieur, LB	1994	Thermal Stability of DPX-KE459 DuPont Agricultural Products AMR 2727-93 GLP/unpublished	
AII 2.14	Huntley, K; Edgar, L	1999	Surface Tension Determination of Flupyr sulfuron Methyl ABC Laboratories DuPont-1471 GLP/unpublished	
AIII 2.7.1	Dejean, P	1998	Shelf Life Aging of 2 Years (DPX-KE459) DuPont Agricultural Products AMR 3503-95 GLP/unpublished	

<sup>2</sup> 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 <sup>2</sup> on previous use in granting national authorizations
AII 4.2.1	Dubey, L	1995	Method Validation for the Determination of Residues of DPX-KE459 in Wheat Grain, Forage and Straw by HPLC-UV/CS Battelle Geneva A-11-94-04 GLP/unpublished	
AII 4.2.2	Goodenowe, DB; Orescan, DB; Babicki, WA	1999	Multianalyte Method for the Simultaneous Quantitation and Confirmation of 21 Sulfonylurea Herbicides in Soil Using Electrospray LC-Triple-Stage Quadrupole Mass Spectrometry DuPont Agricultural Products and Covance, UK AMR 4808-97 GLP/unpublished	
AII 4.2.4	Freeman, CJ	1995	Analytical Enforcement Method for the Determination of DPX-KE459 in Air DuPont Agricultural Products AMR 3657-95 GLP/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
No studies submitted.				

**B.7 Residue data**

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AII 6.1	Barefoot, AC; Christensen, O	1998	Metabolism of DPX-JE138 in Wheat DuPont Agricultural Products AMR 2391-92 Revision No. 1 GLP/unpublished	
AII 6.3	de Bernard, PA	1996	Freezer Storage Stability of Flupyrsulfuron Methyl in Wheat (Grain and Straw) DuPont Agricultural Products AMR 2887-93 GLP/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
AIII 9.1.3	Esterly, DM	1996	PRZM2 Assessment of the Potential Groundwater Concentrations of Flupyr sulfuron Methyl (DPX-KE459) and its Major Soil Degradates under European Agricultural Practices DuPont Agricultural Products AMR 4204-96 NA*/unpublished	
AIII 9.1.3	Esterly, DM	1998	Model Assessment of the Potential Groundwater Surface Water and Pond Sediment Concentrations of Flupyr sulfuron Methyl (DPX-KE459) and its Major Degradates under European Agricultural Practices DuPont Agricultural Products DuPont-1590 NA*/unpublished	
AIII 9.1.3	Esterly, DM	1999	Model Assessment of the Potential Groundwater Concentrations of Flupyr sulfuron Methyl (DPX-KE459) and its Major Degradates for 32 Years of Continuous Use DuPont Agricultural Products DuPont-2741 NA*/unpublished	
AIII 9.1.3	Koch Singles, S	2000	Position paper for flupyr sulfuron methyl : calculation of half-lives of IN-JV 460, the major soil degradate of flupyr sulfuron methyl, under field conditions DuPont-3801 revision 1 NA*/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
AII 8.2.6	Hughes, JS; Williams, TL	1998	IN-JV460 (Metabolite of Flupyr sulfuron Methyl): Influence on Growth and Reproduction of <i>Selenastrum capricornutum</i> DuPont Agricultural Products AMR 4823-97 GLP/unpublished	
AII 8.2.6	Thompson, SG	1996	DPX-KE459 Technical: Influence on Growth and Reproduction of <i>Anabaena flos aquae</i> Wildlife International AMR 4206-96 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 8.4.2	Lührs, U	2000	IN-JV460 (metabolite of flupyrsulfuron methyl) : Effects on Reproduction and Growth of the Earthworm, Eisenia fetida (Savigny 1826), in artificial soil. DuPont-3718 GLP/Not published	

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France

NA' GLP not applicable to position papers and modelling reports. The basic information used for these papers and reports are GLP compliant.

**SUMMARY REPORT  
OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH  
HELD ON 27 April 2001 IN BRUSSELS**

President : L. Smeets

*All Member States were present.*

**1 Examination and possible vote on a Draft Commission Directive concerning the inclusion of flupyrsulfuron methyl in Annex I to Council Directive 91/414/EEC (Sanco/4146/2000 rev 3; review report 5050/VI/97 rev 7).**

The Commission presented the Review Report on flupyrsulfuron methyl in document 5050/VI/97 rev7). The Committee took note of the Review Report.

The following declaration was made:

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 flupyrsulfuron methyl in Annex I to Council Directive 91/414/EEC.

*Vote : favourable opinion by unanimity.*

The substance is a new active substance to be used as herbicide.

A CHECCHI LANG  
Director

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## 1. TITLE

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### OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE EVALUATION OF FLUPYRSULFURON-METHYL IN THE CONTEXT 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 30 November 2000)

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## 2. TERMS OF REFERENCE

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

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

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## 3. BACKGROUND

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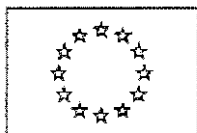
The draft Commission Directive for inclusion of flupyrsulfuron-methyl (DPX-KE459) in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market was submitted to the Committee for opinion.

In order to prepare the opinion the Committee had access to documentation consisting of a Monograph prepared by France as Rapporteur Member State based on a dossier submitted by the notifier (Dupont de Nemours), and a review report prepared by the Commission and the recommendation of the ECCO<sup>1</sup> Peer Review program.

Flupyrsulfuron-methyl is a post emergence selective herbicide belonging to the sulfonylurea class. It is for use in agricultural field situations only acting primarily through foliar uptake with little or no soil activity. Flupyrsulfuron-methyl affects sensitive weeds through inhibition of the enzyme acetolactate synthetase, which leads to the cessation of cell division and subsequent growth processes in plants. Flupyrsulfuron-methyl is used to control annual grass and broad-leaved weeds in winter and spring cereals and can be applied once per crop and season at a maximum rate of 12g a.s./ha.

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<sup>1</sup> European Community Co-ordination.



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions  
C3 - Management of scientific committees II; scientific co-operation and networks

**SCIENTIFIC COMMITTEE ON PLANTS**

**SCP/FLUPYR/002-Final  
11 December 2000**

**OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS  
REGARDING THE EVALUATION OF FLUPYRSULFURON-  
METHYL IN THE CONTEXT 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 30 November 2000)

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 on 15 July 1999. The report of this Committee was formally adopted on 30 November 2000<sup>3</sup>.

## **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 2001/49/EC concerning the inclusion of flupyrsulfuron-methyl methyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing flupyrsulfuron-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 parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to the applicant.

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

## **3. Overall conclusion in the context of Directive 91/414/EEC**

The overall conclusion from the evaluation is that it may be expected that plant protection products containing Flupyrsulfuron-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 Flupyrsulfuron-methyl containing plant protection product for which Member States will grant or review the authorisation.

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<sup>3</sup> Opinion of the scientific Committee on Plants regarding the inclusion of DPX KE 459 (flupyrsulfuron-methyl) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market

In the European field dissipation studies IN-JV460 was the major soil metabolite (maximum of 27% AR, average of both radio labels). In the US field study significant amounts of both IN-JV460 (maximum 23%, AR, average of both radio labels) and IN-KC576 (maximum of 58%, AR, average of both radio labels) were formed.

#### 4.1.2 Aquatic environment

Flupyr-sulfuron-methyl is toxic to fish and *Daphnia* at concentrations in the mg/l range and is therefore not likely to pose an unacceptable risk to these groups under the reviewed uses. As with other sulfonylurea herbicides, algae and aquatic plants (i.e., *Lemna gibba*) were the most sensitive of the aquatic species tested. Values for the acute EC<sub>50</sub><sup>4</sup> and NOEC<sup>5</sup> of flupyr-sulfuron-methyl to *Selenastrum capricornutum* were 3.7 and 0.51 microgram/l, respectively, for the technical active substance (or 9.1 and 1.61 microgram/l for the 50% WG formulation). The 14 day EC<sub>50</sub> and NOEC for *Lemna gibba* were 2.5 microgram/l and 0.49 microgram/l, respectively (technical active substance). Despite the high sensitivity of *Selenastrum capricornutum* and *Lemna gibba* to flupyr-sulfuron-methyl, reasonable worst case PEC<sub>sw</sub><sup>6</sup> estimates (i.e., 0.03 microgram/l) indicated that risks to algae and aquatic plants would not be unacceptable (i.e., TER > 10) given the proposed usage pattern of one application per growing season.

The three most important metabolites formed in water/sediment studies or in an aqueous photolysis experiment (at pH 7) were IN-JV460, IN-KF526 and IN-KV994. The metabolites IN-JV460 and IN-KC576 were the most important metabolites formed in laboratory and field soil studies. It is the SCP's opinion that all of these metabolites need to be evaluated with respect to aquatic organisms as they may either be formed in (IN-JV460, IN-KF526, IN-KV994) or transported to (IN-JV460 and IN-KC576) the aquatic compartment<sup>7</sup>.

The acute toxicity of IN-JV460 to fish and *Daphnia* was considered to be adequately covered in tests with the parent compound. For the two remaining metabolites formed in water studies, no acute effects in fish or *Daphnia* were detected at the highest concentrations tested [i.e., these were: IN-KV994, 1 microgram/l for both fish and *Daphnia*; IN-KF526: 100 microgram/l (fish) and 500 microgram/l (*Daphnia*)]. The toxicity of IN-JV460 to *Selenastrum capricornutum* was reported to be less than for the parent compound (i.e., EC<sub>50</sub>=10.1 microgram/l). There were no toxicity data for algae or aquatic plants provided for IN-KF526 or IN-KV994. However, as neither of them retains an intact sulfonylurea bridge, they are not considered to be more toxic to these groups than the active substance. IN-KC576 was tested for insecticidal activity and evaluated for its effects on earthworms (see below), but it was not tested for toxicity to aquatic organisms. However, the SCP is of the opinion that this metabolite will not pose an unacceptable risk for aquatic organisms because 1) it lacks an intact sulfonylurea bridge and should therefore be less toxic to aquatic plants and algae than the parent compound, and 2) this metabolite showed low toxicity to non-target (terrestrial) invertebrates.

#### 4.1.3 Earthworms

The parent compound has a variety of metabolites in soil: IN-JV460 and its derivative IN-KC576 are the primary metabolites, although other metabolites IN-KV996, IN-KF311 and IN-KY374 have been detected in degradation studies.

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<sup>4</sup> Median effective concentration.

<sup>5</sup> No observed effect concentration.

<sup>6</sup> Predicted environmental concentration in surface water.

<sup>7</sup> See ref. 1 Opinion of the SCP on the draft guidance document on relevant metabolites.

### Ecotoxicity:

Earthworms (*Eisenia fetida andrei*) were exposed for 14 days to artificial soil treated with flupyrsulfuron-methyl at 1000 mg a.s./kg soil (14 replicates with 10 individuals, including 4 replicates as controls). There were no significant differences in mortality and weight change between treatments and controls and there were also no signs of abnormal behaviour. The test dose employed was unrealistically high compared to the maximum predicted environmental concentration of the parent in the soil (highest estimate of the maximum PEC<sub>soil</sub><sup>8</sup> 0.024 mg/kg soil).

### Basis for decision:

- i. Annex II criteria propose that a long-term sub-lethal test on the parent compound is not required if both the DT<sub>90</sub><sup>9</sup> (field) is less than 100 days and the number of applications is less than 3, and
- ii. metabolites which reach a concentration greater than a pragmatic 10% of the dose applied should also be tested for long-term sublethal effects, unless they are formed so rapidly that potential effects are covered by the available earthworm tests for the parent compound<sup>10</sup>.

Given that:

- i. flupyrsulfuron-methyl will be applied once per year,
- ii. the *mean* DT<sub>90</sub> (field) is less than 100 days, and that
- iii. no sublethal effects were observed when earthworms were exposed to unrealistically high concentrations,

***the SCP is of the opinion that no further evaluations of the sub-lethal effects of the parent compound on earthworms are needed.***

Of all the metabolites, IN-JV460 consistently reached a peak of > 10% in European and American field studies, typically after several weeks. Where it was observed, IN-KC576 similarly reached peak concentrations > 10%. In theory (and most likely in practice), the unrealistically high concentrations used in the original test meant that earthworms were exposed to much higher concentrations of metabolites for 2 weeks from day 0 than the maximum concentration they are likely to be exposed to under field conditions. However, the SCP also notes that:

- i. IN-KC576 is likely to be formed by the microbial degradation of IN-JV460. Given that artificial soils were used, we are uncertain whether IN-KC576 would indeed be capable of forming at realistic rates under the test condition, and that
- ii. in general, there is often somewhat slower degradation of plant protection products at high concentrations (for example, chlorothalonil degrades to a hydroxy metabolite, which can inhibit the degradation of the parent compound if the metabolite concentration is sufficiently high). Given that extremely high concentrations were used, it is possible that the rates of degradation differed significantly from field situations<sup>11</sup>.

Overall, since Annex II limits are exceeded and there is some question of the validity of the specific 14 day test for assessing long-term effects of metabolites, the SCP had provisionally

<sup>8</sup> Predicted environmental concentration in soil.

<sup>9</sup> Period required for 90% dissipation.

<sup>10</sup> See also the SCP opinion on guidance document for relevant metabolites.

<sup>11</sup> See SCP opinion on guidance document for relevant metabolites.

recommended that an appropriate long-term test be conducted to evaluate the sublethal effects of flupyr-sulfuron-methyl metabolites on earthworms.

In the recently submitted sub-lethal study, adult earthworms (*Eisenia fetida*) were exposed to two concentrations of the flupyr-sulfuron-methyl metabolite IN-JV460 in artificial soils at rates equivalent to 1x and 5x times a proposed maximum PEC for the metabolite of 10 g IN-JV460/ha, i.e. 0.013 and 0.065 mg IN-JV460/kg dry soil. After 28 days exposure the adult worms were counted and weighed and the soil replaced with fresh soil (untreated). After a further 28 days the soil was examined for juveniles. No mortality was observed in the study, and the body weights of earthworms did not differ significantly from the controls. Similarly, the number of juveniles produced by the end of the study did not differ significantly.

The rate at which IN-JV460 is likely to break down to IN-KC576 in the above laboratory test is not known, but given the data provided in the two separate studies, it is highly unlikely that a single use of flupyr-sulfuron-methyl at the recommended application rate will pose a significant risk to earthworms. The steady-state concentrations of flupyr-sulfuron-methyl and its two metabolites following repeated use can be estimated by incorporating degradation data into a simple first-order kinetic model (plough layer 25 cm and dry bulk density of 1.3 kg/l). This calculation results in estimates of 0.56 micrograms/kg soil for parent, 2.4 micrograms/kg for IN-JV460 and 1.6 micrograms/kg for IN-KC576. Thus, the parent degrades so quickly that only a negligible steady state concentration builds up. If we use the NOEC of > 0.065 mg JV460/kg soil for both main metabolites then the minimum long-term TER for the main metabolites is 27.083. Given that this estimated figure is well above the standard trigger value, the SCP is of the opinion that no significant long-term risks will arise from the use of flupyr-sulfuron-methyl at the recommended rate.

## 4.2 Question 2

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

### **Opinion of the Committee:**

**On the basis of field studies and the modelling data presented, neither flupyr-sulfuron-methyl nor its metabolite IN-JV460 are likely to contaminate groundwater in excess of 0.1 µg/l. Insufficient data are available to reliably state that the metabolite IN-KC576 will not leach to groundwater in concentrations in excess of 0.1 µg/l. Predictions using worst case input parameters and the Dutch standard modelling scenario, indicate that the concentration of the metabolite is unlikely to exceed 0.4 µg/l. The SCP toxicological assessment indicates that there will be no direct health risk from the expected level of this metabolite in groundwater. The SCP is therefore of the opinion that use scenarios exist, which pose no unacceptable risk from drinking water derived from groundwater.**



## Scientific background on which the opinion is based

### 4.2.1 Sorption and leaching:

Flupyr-sulfuron-methyl and its metabolites are weakly sorbed to soil and  $K_{oc}^{12}$  values for the active substance and the two metabolites are shown in Table 2.

**Table 2.  $K_{oc}$  values of Flupyr-sulfuron-methyl and two soil metabolites**

Analyte	$K_{oc}$
DPX-KE459	15-23
IN-JV460	148-202
IN-KC576	19-26

In an aged soil column leaching study DPX-JE138 constituted 2-6% and IN-JV460 16-32% of radioactivity in leachate with higher values relating to fast water fluxes ( $19.2 \text{ ml hr}^{-1}$ ). No lysimeter studies were carried out based on the rapid field degradation of flupyr-sulfuron-methyl (DT50 6-11 days) and there was no detection of any radioactivity below 60 cm in field soil dissipation studies.

### 4.2.2 Further assessment:

Sorption and field dissipation data indicated that the metabolites IN-JV460 and IN-KC576 can be produced in excess of 10% of the applied active substance and may have the potential to leach to groundwater. As a consequence of this assessment additional studies were requested by ECCO. The applicant submitted predictive modelling studies and subsequently responded to specific questions raised by the SCP concerning input parameters and scenario characterisation. Following continued uncertainty an assessment of the toxicity of the metabolite IN-KC576 was carried out by the SCP to determine its relevance with regard to groundwater contamination.

### 4.2.3 Predictive modelling

Extensive modelling data, not described in the monograph but submitted to ECCO, using PRZM-2, shows no potential for the active substance to contaminate groundwater above  $0.1 \mu\text{g/l}$ . Additional modelling studies have been carried out to determine whether the two metabolites have the potential to contaminate groundwater in excess of  $0.1 \mu\text{g/l}$ . Given that the modelling predictions were fundamental in determining whether the two soil metabolites pose an unacceptable risk to groundwater, the SCP was concerned that the choice of input parameters and scenarios for the modelling differed from the field study data presented, were not fully explained and therefore requested justification on a number of points. The applicant provided a comprehensive explanation and further study reports to support the basis for their choice of parameters. On the basis of these data the SCP was satisfied that the active substance and the metabolite IN-JV460 were unlikely to pose an unacceptable risk to groundwater.

The metabolite IN-KC576 appeared at a maximum concentration of 58% in the US study with a quoted half-life of 150 days. The predictive modelling study used a different half-life on the basis that the value derived in the field study was from a very poor fit due to highly variable experimental concentrations. In order to use any of the current predictive models the SCP acknowledges that it is necessary to use degradation data based on first-order kinetics and

<sup>12</sup> Organic carbon adsorption coefficient

therefore the applicant fitted a first-order analytical equation to the experimental data using conventional least-squares-fit criteria to derive the 30 day half life used in the prediction. The metabolite was not found to be significant under European field study conditions (maximum 6.6%) and no further assessments of half-life were made for these studies. The uncertainty in the variable generation of the metabolite and the possibility that the half life may be in excess of 30 days have led the SCP to the opinion that there is insufficient data to confirm that IN-KC576 will not exceed  $0.1 \mu\text{g l}^{-1}$  in groundwater. The SCP has therefore carried out a basic modelling using the Dutch standard scenario and worst case input parameters. The following assumptions have been made:

- the percentage of IN-KC576 formed was 58%;
- DT50 of 248 days (p. 131 of the Monograph);
- $K_{om}^{13}$  of 11 l/kg, based on Koc of 19 l/kg (lowest of the range);
- Application rate of 12 g a.s. ha<sup>-1</sup>;
- the calculation was made for 1 kg/ha giving 70.5  $\mu\text{g/l}$  in groundwater;
- the actual dose of 12 g/ha was multiplied with the percentage formed and with the ratio between the molar masses of metabolite divided by parent, ( $357.2/487.4 = 0.73$ ) which gives a "dose" for this metabolite of 5.1 g/ha;
- the estimated concentration in groundwater for the Dutch standard scenario is therefore  $70.5 * 0.0051 = 0.4 \mu\text{g/l}$ .

#### 4.2.4 Safety assessment of a metabolite IN-KC576 in groundwater.

The major biotransformation pathway for flupyr sulfuron-methyl forms IN-JV460 and the subsequent -desmethyl product, IN-KC576. For rat administered orally with flupyr sulfuron-methyl there are two urinary metabolites, the -desmethyl rearranged tricyclic component IN-KC576, and the pyridin mercapturic acid derivative IN-KW004. The IN-KC576 metabolite was present in higher proportions in females (8-14 %) than in males (5-9%) and, expressed as a percentage of the administered dose, was the metabolite with the largest presence. There are no toxicological data available on the metabolite IN-KC576 of flupyr sulfuron-methyl to enable a direct safety assessment of this metabolite.

However, IN-KC576 as the major metabolite of flupyr sulfuron-methyl is formed to roughly 10 % of the administered dose. Thus the metabolite can be considered to have been tested in the toxicity studies performed with the parent compound. If IN-KC576 was responsible for the toxic response seen with flupyr sulfuron-methyl then the NOAEL<sup>14</sup> used to derive the ADI<sup>15</sup> expressed as mg IN-KC576 would be  $3.5/10 = 0.35 \text{ mg kg bw}^{16}/\text{day}$ . The ADI would be 0.0035 mg/kg bw/day compared to the 0.035 mg/kg bw/day for flupyr sulfuron-methyl. In case IN-KC576 is not the only metabolite responsible for the toxicity, an ADI for the metabolite IN-KC576 would be expected to be higher. Therefore, with respect to the leaching of metabolites to groundwater which can be used to supply drinking water, it can be concluded that there is no direct health risk if the level reaching the groundwater is below 105  $\mu\text{g/l}$  water ( $0.0035 \text{ mg/kg} \times 1 \times 60 \text{ kg}/2 \text{ litres}$ ).

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<sup>13</sup> Organic matter adsorption coefficient.

<sup>14</sup> No observed adverse effect level.

<sup>15</sup> Acceptable daily intake.

<sup>16</sup> Body weight.

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## 5. REFERENCES

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1. Opinion of the Scientific Committee on Plants regarding the draft guidance document on relevant metabolites (Document SANCO/221/2000-rev2) adopted on 30 November 2000  
[http://europa.eu.int/comm/food/fs/sc/scp/outcome\\_ppp\\_en.html](http://europa.eu.int/comm/food/fs/sc/scp/outcome_ppp_en.html)

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## 6. DOCUMENTATION MADE AVAILABLE TO THE COMMITTEE

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1. Terms of reference: Evaluation of flupyrsulfuron-methyl in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Doc. SCP/FLUPYR/001-Rev.1) – submitted 3 August 1999.
2. “Model assessment of the potential groundwater concentrations of flupyrsulfuron-methyl (DPX-KE459) and its major degradates for 32 years of continuous use” – D. Esterly, E.I du Pont de Nemours and Company, 29 April 1999 (Doc. SCP/FLUPYR/003) - submitted 20 December 1999.
3. Questions from the SCP to the Notifier (Doc. SCP/FLUPYR/004) – submitted 31 January 2000.
4. Response from the Notifier to clarification sought by the SCP relating to the evaluation of flupyrsulfuron-methyl (Doc. SCP/FLUPYR/006) – submitted 8 February 2000.
5. “Position paper for flupyrsulfuron-methyl: calculation of half-lives of IN-JV460, the major soil degradate of flupyrsulfuron-methyl, under field conditions”, S. Koch Singles, E.I. du Pont de Nemours and Company, 2 February 2000 (doc. SCP/FLUPYR/007) – submitted 8 February 2000.
6. Flupyrsulfuron-methyl: Draft review report 5050/VI/97-rev.2, 5 September 1999 (Doc. SCP/FLUPYR/008) – submitted 31 May 2000.
7. Evaluation of flupyrsulfuron-methyl in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market: appendices, 4 June 1999 (Doc. SCP/FLUPYR/009) – submitted 4 June 2000.
8. Evaluation of flupyrsulfuron-methyl in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market: Evaluation table, 5051/VI/98-rev.7, 2 June 1999 (Doc. SCP/FLUPYR/010) – submitted 19 June 2000.
9. “IN-JV460 (Metabolite of flupyrsulfuron-methyl): effects on reproduction and growth of earthworm, *Eisenia fetida* (Savigny, 1826), in artificial soil” Final report - U. Lührs, Institut für Biologische Analytik und Consulting IBACON GmbH, 19 July 2000 [Submitted by du Pont de Nemours] (Doc. SCP/FLUPYR/011) – submitted 11 August 2000.
10. Flupyrsulfuron-methyl and its two metabolites: steady state concentration, submitted by Dr. Boesten. (Doc. SCP/FLUPYR/012) – 5 October 2000.

11. Flupyr sulfuron-methyl: Monograph prepared in the context of the inclusion of the Flupyr sulfuron-methyl in Annex I of Council Directive 91/414/EEC. Ministère de l'Agriculture, de la Pêche et de l'Alimentation, Direction générale de l'alimentation. France. October 1997. (Volumes 1, 2, 3 & 4).

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## **7. ACKNOWLEDGEMENTS**

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The Committee wishes to acknowledge the contributions of the working group that prepared the initial draft opinion:

Environmental assessment WG: Prof. Hardy (Chairman) and Committee experts: Mr. Koeppe, Dr. Nolting, Dr. Sherratt, Prof. Silva Fernandes, and invited experts: Dr. Boesten, Dr. Carter, Dr. Forbes and Dr. Luttik.

Toxicology: Prof. Maroni (Chairman) and Committee members: Dr. Delcour-Firquet, Dr. Meyer, Dr. Moretto, Prof. Savolainen, Prof. Silva Fernandes, Dr. Speijers, invited expert Dr. Fait.

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

- 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 Chlozofinat. 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 Spintzi, 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)
- Heft 99, 2002: EU-Beurteilungsbericht Thifensulfuron-methyl. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 28.  
Bearbeitet von Dr. Martina Erdtmann-Vourliotis und Susanne Schaper, getr. Zählung.