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EU-Beurteilungsbericht Fluroxypyr
Rechtliche Regelungen der Europäischen Union
zu Pflanzenschutzmitteln und deren Wirkstoffen
Band D 1

Review Report Fluroxypyr
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 1

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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 1. Heft dieser Reihe (Band D 1) 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 Fluroxypyr war Deutschland Berichtersteller.

In der Reihe "Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen" sind bisher erschienen:

Heft	Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen
35/97	Band A: Richtlinie 91/414/EWG und diesbezügliche Protokolle (3. Auflage, Stand: 01. November 1997)
36/97	Band B: Richtlinien, Verordnungen, Entscheidungen und Protokolle zur Wirkstoffprüfung (3. Auflage, Stand 01. November 1997)
	Band C: <i>Wird zur Zeit bearbeitet</i>

Preface

According to the Directives for the inclusion of active substances in Annex I with regard to new active substances, EU-Member States are obliged to keep available or make available on special request the review report which is prepared after completion of all evaluations including its appendices (excluding confidential information, in accordance with article 14 of Directive 91/414/EEC) to all interested parties. For existing active substance this obligation for Member States already arises from article 7 (6) subparagraph 2 of Regulation (EEC) No 3600/92.

Member States and the European Commission agreed that requests of review reports including their background documents which are partly very voluminous, shall preferably be addressed to the Rapporteur Member State.

The Federal Biological Research Centre makes available review reports as reports from the Federal Biological Research Centre for Agriculture and Forestry, Volume D of the series "Legal Regulations of the European Union for Plant Protection Products and their Active Substances" via Saphir Verlag against reimbursement of expenses. The present 1st report belonging to this series (Volume D 1) 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 fluroxypyr Germany acted as Rapporteur Member State.

In the series Legal Regulations of the European Union for Plant Protection Products and their Active Substances the following Reports have been published:

Report	Legal Regulations of the European Union for Plant Protection Products and their Active Substances
35/97	Volume A: Directive 91/414/EEC and respective Protocols (3 rd Edition, date: 1 November 1997)
36/97	Volume B: Directives, Regulations, Decisions and Protocols regarding the Evaluation of Active Substances (3 rd Edition, date: 1 November 1997)
	Volume C: <i>In Progress</i>

RICHTLINIE 2000/10/EG DER KOMMISSION

vom 1. März 2000

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

(Text von Bedeutung für den EWR)

DIE KOMMISSION DER EUROPÄISCHEN GEMEINSCHAFTEN —

gestützt auf den Vertrag zur Gründung der Europäischen Gemeinschaft,

gestützt auf die Richtlinie 91/414/EWG des Rates vom 15. Juli 1991 über das Inverkehrbringen von Pflanzenschutzmitteln ⁽¹⁾, zuletzt geändert durch die Richtlinie 1999/80/EG der Kommission ⁽²⁾, insbesondere auf Artikel 6 Absatz 1 und Artikel 8 Absatz 2 Unterabsatz 4,

in Erwägung nachstehender Gründe:

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

tender Mitgliedstaat im Rahmen der Verordnung (EG) Nr. 933/94 hat Deutschland der Kommission am 27. September 1996 den betreffenden Bewertungsbericht übermittelt.

- (6) Der vorgelegte Bewertungsbericht wurde von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses für Pflanzenschutz geprüft. Diese Prüfung wurde am 30. November 1999 in Form des Prüfungsberichts der Kommission für Fluroxypyr abgeschlossen. Der Bericht muß möglicherweise unter Berücksichtigung technischer und wissenschaftlicher Entwicklungen aktualisiert werden. Gegebenenfalls sind gemäß deren Artikel 6 Absatz 1 auch die Bedingungen für die Aufnahme von Fluroxypyr in Anhang I der Richtlinie 91/414/EWG zu ändern. Die Unterlagen und die aus der Prüfung hervorgegangenen Informationen wurden dem Wissenschaftlichen Pflanzenausschuß ebenfalls zur Stellungnahme vorgelegt.
- (7) Aufgrund der Bewertungen kann davon ausgegangen werden, daß den betreffenden Wirkstoff enthaltende Pflanzenschutzmittel im allgemeinen die Anforderungen gemäß Artikel 5 Absatz 1 Buchstaben a) und b) der Richtlinie, insbesondere hinsichtlich der geprüften Anwendungen, erfüllen. Der betreffende Wirkstoff ist in Anhang I aufzunehmen, damit in allen Mitgliedstaaten die etwaige Erteilung, Änderung bzw. Rücknahme der Zulassung von Fluroxypyr enthaltenden Pflanzenschutzmitteln gemäß der Richtlinie organisiert werden kann und weitere Verzögerungen vermieden werden.
- (8) Der Wissenschaftliche Pflanzenausschuß hat in seiner Stellungnahme darauf hingewiesen, daß die Umweltsicherheit bestimmter Abbauprodukte von Fluroxypyr in Boden und Wasser durch zusätzliche Daten bestätigt werden sollte.
- (9) Gemäß Artikel 5 Absatz 5 der Richtlinie 91/414/EWG kann die Aufnahme eines Wirkstoffes in Anhang I jederzeit überprüft werden, wenn etwas darauf hindeutet, daß die Kriterien für die Aufnahme nicht mehr erfüllt sind. Die Kommission wird die Aufnahme in Anhang I daher erneut prüfen, wenn die geforderten zusätzlichen Versuche gemäß Nummer 7 des Prüfungsberichts auf mögliche gefährliche Wirkungen hindeuten oder die geforderten zusätzlichen Daten und Angaben nicht übermittelt werden.
- (10) Vor der Aufnahme ist eine angemessene Frist vorzusehen, um es den Mitgliedstaaten zu ermöglichen, sich auf die sich daraus ergebenden neuen Anforderungen vorzubereiten. Nach der Aufnahme ist den Mitgliedstaaten eine angemessene Frist einzuräumen, in der sie die Richtlinie umsetzen, insbesondere bereits bestehende

⁽¹⁾ ABl. L 230 vom 19.8.1991, S. 1.

⁽²⁾ ABl. L 210 vom 10.8.1999, S. 13.

⁽³⁾ ABl. L 366 vom 15.12.1992, S. 10.

⁽⁴⁾ ABl. L 244 vom 16.9.1999, S. 41.

⁽⁵⁾ ABl. L 107 vom 28.4.1994, S. 8.

⁽⁶⁾ ABl. L 225 vom 22.9.1995, S. 1.

Zulassungen überprüfen oder zurückziehen bzw. neue Zulassungen gemäß den Bestimmungen der Richtlinie 91/414/EWG erteilen. Für die Einreichung und Bewertung der gemäß Anhang III für jedes Pflanzenschutzmittel vollständigen Unterlagen nach Maßgabe der einheitlichen Grundsätze von Anhang VI der Richtlinie ist ein längerer Zeitraum vorzusehen. Pflanzenschutzmittel, die mehrere Wirkstoffe enthalten, können jedoch auf der Grundlage der einheitlichen Grundsätze erst bewertet werden, wenn alle Wirkstoffe in Anhang I der Richtlinie aufgenommen sind.

- (11) Die für die Umsetzung dieser Richtlinie festgelegten Fristen gelten unbeschadet der Fristen, die für die Aufnahme anderer Wirkstoffe in Anhang I der Richtlinie festgelegt werden.
- (12) Der Prüfungsbericht ist erforderlich für die ordnungsgemäße Umsetzung bestimmter Teile der einheitlichen Grundsätze gemäß Anhang VI durch die Mitgliedstaaten, soweit sich diese Grundsätze auf die Bewertung der Angaben nach Anhang II beziehen, die zwecks Aufnahme des Wirkstoffs in Anhang I der Richtlinie vorgelegt wurden.
- (13) Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz —

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

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

Artikel 2

(1) Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens 1. Juni 2001 nachzukommen. Gemäß den Bestimmungen der Richtlinie 91/414/EWG ändern oder widerrufen sie innerhalb dieses Zeitraums erforderlichenfalls insbesondere beste-

hende Zulassungen für Pflanzenschutzmittel, die Fluroxypyr als Wirkstoff enthalten.

(2) Hinsichtlich der Bewertung und Zulassung gemäß den einheitlichen Grundsätzen von Anhang VI der Richtlinie 91/414/EWG wird der in Absatz 1 festgesetzte Zeitraum auf der Grundlage von Unterlagen, die die Anforderungen von Anhang III derselben Richtlinie erfüllen,

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

verlängert.

(3) Wenn die Mitgliedstaaten die Vorschriften gemäß Absatz 1 erlassen, nehmen sie in den Vorschriften selbst oder durch einen Hinweis bei der amtlichen Veröffentlichung auf diese Richtlinie Bezug. Die Mitgliedstaaten regeln die Einzelheiten dieser Bezugnahme.

Artikel 3

Die Mitgliedstaaten informieren die Kommission, wenn die geforderten zusätzlichen Versuche und Angaben gemäß Nummer 7 des Prüfungsberichts bis zum 1. Dezember 2000 noch nicht vorliegen.

Artikel 4

Diese Richtlinie tritt am 1. Dezember 2000 in Kraft.

Artikel 5

Diese Richtlinie ist an alle Mitgliedstaaten gerichtet.

Brüssel, den 1. März 2000

Für die Kommission

David BYRNE

Mitglied der Kommission

ANHANG

FLUROXYPYR

1. Identität:

Gebräuchliche Bezeichnung: Fluroxypyr

IUPAC Bezeichnung: 4-Amino-3,5-dichloro-6-fluoro-2-pyridloxy-Essigsäure

2. Zu erfüllende Bedingungen:

2.1. Der hergestellte Wirkstoff muß eine Reinheit von mindestens 950 g/kg aufweisen.

2.2. Nur Verwendungen als Herbizid dürfen zugelassen werden.

2.3. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlußfolgerungen des vom Ständigen Ausschuß für Pflanzenschutz am 30. November 1999 abgeschlossenen Prüfungsberichts über Fluroxypyr und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten:

- die unter Nummer 7 des Prüfungsberichts angeforderten zusätzlichen Angaben berücksichtigen;
- dem Grundwasserschutz besondere Aufmerksamkeit widmen;
- insbesondere die Auswirkungen auf Wasserorganismen berücksichtigen und sicherstellen, daß die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikobegrenzung enthalten.

3. Aufnahme befristet bis: 30. November 2010.

COMMISSION DIRECTIVE 2000/10/EC

of 1 March 2000

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, as last amended by Commission Directive 1999/80/EC ⁽²⁾, and in particular Article 6(1) and the fourth subparagraph of Article 8(2) thereof,

Whereas:

- (1) Commission Regulation (EEC) No 3600/92 ⁽³⁾, as last amended by Regulation (EC) No 1972/1999 ⁽⁴⁾, has laid down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC (hereinafter referred to as 'the Directive'). Pursuant to that Regulation, Commission Regulation (EC) No 933/94 ⁽⁵⁾, as last amended by Regulation (EC) No 2230/95 ⁽⁶⁾, 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) Those active substances should be included in that Annex when it may be expected that there will not be any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment.
- (3) Such inclusion should be made for a period not exceeding 10 years.
- (4) The Directive, at Article 8(2), provides that after inclusion of an active substance in Annex I to the Directive, Member States shall, within a prescribed period, grant, vary or withdraw, as appropriate, the authorisations of the plant protection products containing the active substance. In particular, Articles 4(1) and 13(1) of the Directive require that plant protection products are not authorised unless account is taken of the conditions associated with the inclusion of the active substance in Annex I and the uniform principles laid down in Annex VI on the basis of a dossier satisfying the data requirements laid down in Article 13.
- (5) For fluroxypyr the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a number of uses proposed by the notifiers. Germany, acting as designated rapporteur Member State

under Regulation (EC) No 933/94, submitted to the Commission on 27 September 1996 the relevant assessment report.

- (6) The submitted report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. This review was finalised on 30 November 1999 in the format of the Commission review report for fluroxypyr. It may be necessary to update this report to take account of technical and scientific developments. In such case the conditions for the inclusion of fluroxypyr in Annex I to Directive 91/414/EEC will also need to be amended pursuant to Article 6(1) of that Directive. The dossier and the information from the review have also been submitted to the Scientific Committee for Plants for consultation.
- (7) It has appeared from the assessments made that plant protection products containing the active substance concerned may be expected to satisfy in general the requirements laid down in Article 5(1)(a) and (b) of the Directive, in particular with regard to the uses which were examined. Therefore it is necessary to include the active substance concerned in Annex I, in order to ensure that, in all Member States, the granting, varying or withdrawing, as appropriate, of the authorisations of plant protection products containing fluroxypyr can be organised in accordance with the provisions of the Directive, and to ensure that this activity is not further delayed.
- (8) The Scientific Committee for Plants in its opinion identified the need to confirm by additional data the environmental safety of certain breakdown products of fluroxypyr occurring in soil and water.
- (9) Article 5(5) of Directive 91/414/EEC provides that the inclusion of an active substance in Annex I can be reviewed at any time if there are indications that the criteria for inclusion are no longer satisfied. Therefore, the Commission will reconsider the inclusion in Annex I if the results of the requested additional trials as outlined in point 7 of the review report were to indicate potential adverse effects, or if the requested additional data results and information were not submitted.
- (10) Before inclusion a reasonable deadline is necessary to permit Member States and the interested parties to prepare themselves for the new requirements which will result from the inclusion. Moreover after inclusion a reasonable period is necessary for the Member States to implement the Directive and in particular to vary or

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 210, 10.8.1999, p. 13.

⁽³⁾ OJ L 366, 15.12.1992, p. 10.

⁽⁴⁾ OJ L 244, 16.9.1999, p. 41.

⁽⁵⁾ OJ L 107, 28.4.1994, p. 8.

⁽⁶⁾ OJ L 225, 22.9.1995, p. 1.

withdraw, as appropriate, existing authorisations or grant new authorisations in accordance with the provisions of Directive 91/414/EEC. A longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product in accordance with the uniform principles laid down in Annex VI to the Directive. However, for plant protection products containing several active substances, the complete evaluation on the basis of the uniform principles can only be carried out when all the active substances concerned have been included in Annex I to the Directive.

- (11) The periods laid down for implementation of this Directive do not prejudice the periods which will be established for the inclusion of other active substances in Annex I of the Directive.
- (12) The review report is required for the proper implementation by the Member States, of several sections of the uniform principles laid down in Annex VI to the Directive, where these principles refer to the evaluation of the Annex II data which were submitted for the purpose of the inclusion of the active substance in Annex I to the Directive.
- (13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive, at the latest by 1 June 2001. In particular they shall, in accordance with the provisions of Directive 91/414/EEC,

where necessary, amend or withdraw existing authorisations for plant protection products containing fluroxypyr as an active substance within such period.

2. However, with regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto, the period laid down in the first paragraph is extended:

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

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

Article 3

Member States shall inform the Commission if the requested additional trials and information as outlined in point 7 of the review report are not submitted by 1 December 2000.

Article 4

This Directive shall enter into force on 1 December 2000.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 1 March 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX

FLUROXYPYR

1. Identity:

Common name: fluroxypyr

IUPAC name: 4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid

2. Particular conditions to be fulfilled:

2.1. Purity of the active substance as manufactured shall have a minimum purity of 950 g/kg.

2.2. Only uses as herbicide may be authorised.

2.3. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fluroxypyr, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 30 November 1999 shall be taken into account. In this overall assessment, Member States:

- shall take into account the additional information requested in point 7 of the review report,
- must pay particular attention to the protection of groundwater,
- must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.

3. Expiry date of the inclusion: 30 November 2010.

European Commission
Directorate-General Health & Consumer Protection
Unit E.1: Legislation relating to crop products and animal nutrition

Fluroxypyr
6848/VI/98-rev.13
15 December 1999

Review report for the active substance **fluroxypyr**

Finalised in the Standing Committee on Plant Health at its meeting on 30 November 1999 in view of the inclusion of fluroxypyr 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 fluroxypyr, 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 1199/97⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Fluroxypyr 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, Dow Elanco Europe on 9 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance fluroxypyr 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 2230/95⁽⁴⁾, designated Germany as rapporteur Member State to carry out the assessment of fluroxypyr 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

¹ OJ No L 366, 15.12.1992, p.10

² OJ No L 170, 28.6.1997, p.19

³ 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. OJ No L 107, 28.4.1994, p.8.

⁴ OJ No L 225, 22.9.1995, p.1

other parties with regard to further technical and scientific information; for fluroxypyr this deadline was 30 April 1995.

Dow Elanco Europe submitted to the rapporteur Member State a dossier which did not contain substantial data gaps, taking into account the supported uses. Information has furthermore been submitted by third parties, including the European Federation of Agricultural Workers, the Pesticide Action Network, the European Environmental Bureau and the Comité Regional Phyto (Université Catholique de Louvain, Belgium).

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Germany submitted on 27 September 1996 to the Commission the report of its examination, hereafter referred to as the monograph, including, as required, a recommendation concerning the possible inclusion of fluroxypyr 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 fluroxypyr from Dow Elanco Europe, on 6 January 1997.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the monograph to all the Member States on 25 October 1996 as well as to Dow Elanco Europe being the main data submitter, on 4 November 1996.

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

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

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, 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 10 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 monograph, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on Plant Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from February to May 1998, and was finalised in the meeting of the Standing Committee on 30 November 1999.

These documents were also submitted to the Scientific Committee for Plants for a separate independent consultation.

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

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 91/414/EEC concerning the inclusion of fluroxypyr in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing fluroxypyr they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

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

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

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

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

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

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

- **herbicide against broad leaved weeds in cereals, maize, apple trees, olive trees and sorghum.**

Extension of the use pattern beyond those described 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 0.22 % 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.

Given the results of the evaluation of the information submitted on fate and behaviour and ecotoxicology, particular conditions have been provided for as explained in section 6 of this report, which need short term attention from the Member States when granting new authorisations or varying existing authorisations. These conclusions were reached, in particular, for the methylheptylester of fluroxypyr, for which detailed information was submitted. Further studies, in particular bridging studies, may be necessary in relation to the acceptance of esters and salts of fluroxypyr other than the methylheptylester evaluated.

4. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of fluroxypyr are given in Appendix I. The active substance shall comply with the specification mentioned in the inclusion Directive and there seem not to be reasons for deviating from that specification.

The review has established that for the active substance notified by the data submitter DowElanco Europe, 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 are listed in Appendix II. For esters and salts of fluroxypyr other than the methylheptylester evaluated, it may be necessary to use other endpoints than those listed in Appendix II.

6. Particular conditions to be taken into account on short term basis

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

- on the basis of current information only a maximum application rate of 400 g a.s. (as acid)/ha, to be applied in the growing seasons, is acceptable. For higher application rates or for use in autumn further data will be required, in particular in the fields of ecochemistry and ecotoxicity,
- to support use on non-crop land, potential for ground water contamination as well as effects on biological sewage treatment would have to be investigated,
- to support uses on pasture and amenity, potential for ground water contamination would have to be investigated,
- intended uses in bulb vegetables (onions, garlic etc.) have to be supported by a plant metabolism study,
- suitable risk management to protect aquatic life has to be taken into account,
- uses in nordic countries may have to be supported by soil degradation data at low temperatures.

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 fluroxypyr in Annex I under the current inclusion conditions. However, the Scientific Committee on Plants, in its opinion provided on June 4, 1999 identified the need to confirm by additional data the environmental safety of certain breakdown products of fluroxypyr occurring in soil and water. This confirmatory data has to be provided to the Member States as outlined in Article 3 and the Annex of the inclusion Directive.

In addition, some endpoints may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under specific, local conditions. Additional studies, in particular bridging studies, may also be necessary in relation to the acceptance of esters and salts of fluroxypyr other than the methylheptylester evaluated.

Use rates higher than 400 g a.s. (as acid)/ha. and/or applications outside the growing season have to be supported by additional information in the fields of ecochemistry and ecotoxicity.

8. Information on studies with claimed data protection

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

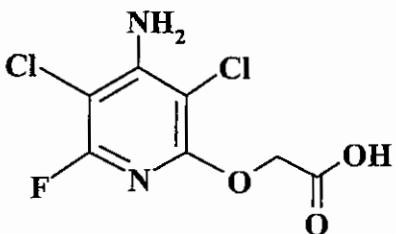
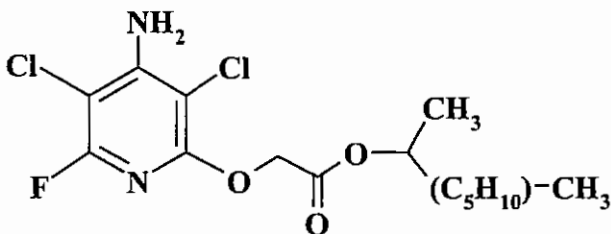
9. Updating of this review report

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

APPENDIX I

Identity, physical and chemical properties

FLUROXYPYR

Common name (ISO)	Fluroxypyr	Fluroxypyr-meptyl
Chemical name (IUPAC)	4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid	1-methylheptyl (4-amino-3,5-dichloro-6-fluoro-2-pyridyloxy)acetate
Chemical name (CA)	[(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetic acid	[(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetic acid, 1-methylheptyl ester
CIPAC No	431	431.214
CAS No	69377-81-7	81406-37-3
EEC No	---	279-752-9
FAO SPECIFICATION	---	---
Minimum purity of the active substance as manufactured (g/kg)	950	950
Notable impurities (g/kg)	---	---
Molecular formula	C ₇ H ₅ Cl ₂ FN ₂ O ₃	C ₁₅ H ₂₁ Cl ₂ FN ₂ O ₃
Molecular mass	255	367.3
Structural formula		

Melting point	232 - 233 °C	58.2 - 60 °C
Boiling point	No boiling point observed up to 360 °C	No boiling point observed up to 360 °C
Appearance	White crystalline solid	White crystalline solid
Relative density	1.09	1.322
Vapour pressure	$3.78 \cdot 10^{-9}$ Pa at 20 °C	$1.3 \cdot 10^{-6}$ Pa at 20 °C
Henry's law constant	$1.06 \cdot 10^{-8}$ Pa·m ³ ·mol ⁻¹	$5.5 \cdot 10^{-3}$ Pa·m ³ ·mol ⁻¹
Solubility in water	pH 5: 5.7 g/l pH 7: - pH 9: 7.3 g/l	0.0813 mg/l 0.109 mg/l hydrolysis
Solubility in organic solvents	At 25 °C: - hexane: 0.002 g/l - methanol: 35 g/l - 2-propanol: 9 g/l - dichloromethane: 0.15 g/l - ethylacetate: 11 g/l - toluene: 0.77 g/l - xylene: 0.3 g/l acetone: 9.2 g/l	At 25 °C: - hexane: 45 g/l - methanol: 469 g/l - 2-propanol: 288 g/l; - xylene, toluene, dichloromethane, acetone, ethylacetate: >500 g/l
Partition co-efficient (log P_{ow})	2.0	4.5
Hydrolytic stability (DT₅₀)	pH 5: stable pH 7: stable pH 9: stable	pH 5: 9.8 d pH 7: 17.5 d pH 9: 10.2 d
Dissociation constant	pKa (25 °C) = 2.94	no dissociation in water
UV/VIS absorption (max.)	Absorption in the range of 210 to 218 nm, only	No maximum between 290 and 900 nm
Photostability (DT₅₀)	---	63 d in water
Flammability	Not available	Non-flammable Not-autoflammable
Explosive Properties	Not available	non-explosive

APPENDIX II

END POINTS AND RELATED INFORMATION

FLUROXYPYR

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	~100 %; < 0.5 d; oral [acid, MHE]
Distribution:	Highest residues: Gastro-intestinal-tract and kidneys [acid, MHE]
Potential for accumulation:	No indication of accumulation after repeated administration [MHE]
Rate and extent of excretion:	Efficiently eliminated within 2 days: urine (91 - 94 %); faeces (4 - 6 %) [acid, MHE]
Toxicologically significant compounds:	MHE; rapidly and completely hydrolysed to fluroxypyr; sodium salt; unchanged excreted

Acute toxicity

Rat LD ₅₀ oral:	> 2000 mg/kg bw [MHE]
Rat LD ₅₀ dermal:	> 2000 mg/kg bw [MHE]
Rat LC ₅₀ inhalation:	>1.0 mg/l (highest attainable concentration) [MHE]
Skin irritation:	Not irritating [MHE]
Eye irritation:	Not irritating [MHE]
Sensitization:	Not sensitising [MHE]

Short term toxicity

Target / critical effect:	Kidney [acid, MHE]
Lowest relevant NOAEL:	80 mg/kg bw/d; 13 weeks; oral; mouse and rat [acid] NOEL 300 mg/kg bw/d; dermal [MHE]

Genotoxicity

No evidence of genotoxicity [acid]

Long term toxicity and carcinogenicity

Target / critical effect:

Kidney [acid]

Lowest relevant NOAEL:

80 mg/kg bw/d; 2 y; oral; rat (Wistar) [acid]

Carcinogenicity:

No evidence of carcinogenicity [acid]

Reproductive toxicity

Reproduction:

No conclusive adverse effects [acid]
NOAEL 150 mg/kg bw/d for reproductive and maternal toxicity [acid]

Developmental toxicity:

No evidence of teratogenicity in rats or rabbits [acid]

Delayed neurotoxicity

Not a primary neurotoxin, delayed neurotoxicity studies are not required [acid, MHE]

Other toxicological studies

None of toxicological relevance

Medical data

No reports of adverse effects in humans [acid, MHE]

Summary

ADI:

0.8 mg/kg bw; SF=100; 2 y rat [acid]

AOEL:

0.8 mg/kg bw/d (oral); SF=100; 2 y rat [acid]

ARfD:

Not allocated – not necessary

Dermal absorption

Default value of 10% dermal absorption based on the physical chemical properties of this active ingredient [acid, MHE]

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

Up to 65 % at 20 °C

Non-extractable residues after 100 days:

Up to 29.7 % at 20 °C

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

4-Amino-3,5-dichloro-6-fluoro-2-pyridinol (metabolite II) up to 11.5 % after 7 d

% of applied rate (range and maximum)

4-Amino-3,5-dichloro-6-fluoro-methoxypyridine (metabolite III) up to 17.8 % after 28 d

Supplemental studies

Anaerobic:

Mineralization < 0.1%, non-extractables up to 33.5 % (after 56 d, 25 °C)

Relevant metabolites: metabolite III, up to 12 % after 112 d

Soil photolysis:

DT₅₀ = 153 d [MHE]

Rate of degradation

Laboratory studies

DT_{50lab} (20 °C, aerobic):

3 - 55 d at 20 - 22 °C [acid]⁵

DT_{90lab} (20 °C, aerobic):

15 - 40 d [acid]; 53 - 220 d [MHE plus acid]

DT_{50lab} (10 °C, aerobic):

No data available, if use required in Nordic region then data will be required.

DT_{50lab} (20 °C, anaerobic):

91 - 210 d at 25 °C [acid]

Field studies (country or region)

Canada, UK

⁵ Metabolite II, DT₅₀ = 21 - 53 d
Metabolite III, DT₃₀ = 20 - 429 d

Under worst case conditions, metabolite III exceeds the DT₅₀ trigger value.

DT_{50f} from soil dissipation studies:

< 3 d [MHE]
 34 - 68 d [acid]
 11 - 38 d [acid, MHE]

DT_{90f} from soil dissipation studies:

Metabolite II: 3 - 16 %, but not detectable after 16 months
 Metabolite III: 9 - 43 % after 16 months

Soil accumulation studies:

No data available

Soil residue studies:

UK, Italy, Germany: [MHE plus acid]
 - spring wheat: 0.12 mg/kg (74 d)
 - winter wheat, bean, turnip: 0.025 mg/kg (404 d)
 - soft wheat, winter barley, durum wheat each:
 < 0.01 mg/kg (88, 72, 101 d)
 - summer wheat 0.018 mg/kg (95 d)
 - winter rye, winter barley each: < 0.01 mg/kg (92, 75 d)/0-5, 10, 20 cm

Remarks

e.g. effect of soil pH on degradation rate

In general, as soil pH decreases then DT₅₀ increases

Adsorption/desorptionK_{oc} / K_{om}:

K_{oc} of adsorption: MHE: 6200 - 43000
 acid: 51 - 81

Soil type, pH, OC/OM content:

Silt loam (pH 5.9, OC 2.2 %)
 Sandy loam (pH 7.5, OC 0.2 %)
 Loam (pH 6.8, OC 3.1 %)
 Clay (pH 7.0, OC 1.3 %)

Mobility**Laboratory studies:**

Column leaching:

MHE: < 2 % in leachate
 Acid: 18 - 74 % (as equivalents) in leachate

Aged residue leaching:

60 d ageing (approximately equivalent to the worst case DT₅₀) at 22 °C:
 Acid: 10% in leachate
 Metabolite II: not detected at 5 µg/l
 Metabolite III : not looked for

Field studies:

Lysimeter/Field leaching studies:

Lysimeter studies:
Single spring application (200 and 400 g (as acid)/ha):
MHE: not detected
Acid: 0.008 and 0.0034 µg/l (2 y averages),
0.034 and 0.008 µg/l (maximum).
Metabolite II: 0.0009 and < 0.0001 µg/l
(2 y averages)
0.0038 and 0.001 µg/l (maximum)
Metabolite III: 0.0003 and 0.0002 µg/l
(2 y averages)
0.0009 and 0.0006 µg/l (maximum)

Remarks:

Lysimeter studies would be more useful if results were presented separately for each year rather than as 2 year averages.

Field leaching data submitted was not acceptable as the limit of detection was too high.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

	MHE:	acid:
DT ₅₀ at pH 4/5:	stable*	stable*
7:	stable*	stable*
9:	3.2 d	stable*
*no significant degradation during study period of 30 d		
None		
Molar absorption coefficient < 10 l·mol ⁻¹ ·cm ⁻¹ f wavelengths ≥ 290 nm [MHE]		

Relevant metabolites:

Photolytic degradation:

Biological degradation

Ready biological degradability:

Water/sediment study:

No		
DT ₅₀ (water): immediately release the sediment.	The MHE was found after application in the Hydrolysis occurred to more soluble acid in the water.	
DT ₅₀ (whole system): MHE: 2 d, acid: 24 d		
<u>Metabolite II</u>	<u>IV⁶</u>	(25 °C, aerobic, dark)
44	17.9	
14	28	
13.2	6.5	
7	28	

Relevant metabolites

- residues in the water phase (% of applied)

maximum at day

at the end of the study at day....

- residues in the sediment (% of applied)

maximum at day....

at the end of the study at day....

Accumulation in water and/or sediment:

Degradation in the saturated zone

No data available

Remarks:

⁶ 4-Amino-3-chloro-6-fluoro-2-pyridinol
20 °C: 4-Amino-3,5-dichloro-6-fluoro-2-pyridone
(tentatively identified), maximum 13 % (4 - 13 weeks) and 45 % (8 weeks)(whole systems),
DT₅₀: 28 and 34 d (whole systems)

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

MHE: $1.3 \cdot 10^{-6}$ Pa at 20 °C

Acid: $3.8 \cdot 10^{-9}$ Pa at 20 °C

Henry's law constant:

MHE: $5.5 \cdot 10^{-3}$ Pa·m³·mol⁻¹

Acid: $1.06 \cdot 10^{-8}$ Pa·m³·mol⁻¹

Photolytic degradation

Direct photolysis in air:

Molar absorption coefficient $< 10 \text{ l}\cdot\text{mol}^{-1}\cdot\text{cm}^{-1}$
for wavelengths $\geq 290 \text{ nm}$ [MHE]

Photochemical oxidative degradation in
air DT₅₀:

MHE: 3.3 - 9.8 h

Acid: 4.5 - 13.4 h

Remarks:

3 Ecotoxicology

Effects on terrestrial vertebrates

(Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

	Endpoint	Acid	MHE
Acute toxicity to mammals	LD ₅₀	---	> 2000 mg/kg bw
Acute toxicity to birds	LD ₅₀	> 2000 mg/kg bw	> 2000 mg/kg bw
Dietary toxicity to birds	LC ₅₀	> 5000 ppm	> 5000 ppm
Reproductive toxicity to birds	NOEL	---	500 ppm
Short term oral toxicity to mammals	NOEL	---	200 mg/kg bw/d

Effects on aquatic organisms

(Annex IIA, point 8.2, Annex IIA, point 10.2)

Group	Duration	Endpoint	Acid	MHE	Metabolit II Fluroxypyr Pyridinol	formulated product Starane 180
			Toxicity (mg/l)			
Acute Toxicity						
<i>L. macrochirus</i>	96 h	LC ₅₀	14.3			
<i>O. mykiss</i>	96 h	LC ₅₀		> 0.2	39	3.5
<i>D. magna</i>	48 h	EC ₅₀	> 100	> 0.2	> 49	0.8
<i>S. capricornutum</i>	120 h	LC ₅₀	49.8		> 45	
<i>S. subspicatus</i>	72 h	LC ₅₀		> 0.5		1.8
<i>L. gibba</i>	14 d	LC ₅₀	12.3			
Chronic Toxicity						
<i>O. mykiss</i>	21 d	NOEC	100	0.2	---	0.25
<i>D. magna</i>	21 d	NOEC	56	0.1	---	0.007

Chronic Toxicity sediment dwelling organisms:

Not relevant

Bioconcentration:

Bioconcentration factor (BCF)

Not relevant

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity
Acute contact toxicity

MHE	
LD ₅₀	Hazard Quotient
> 100 µg/bee	< 3.6
> 100 µg/bee	< 3.6

Effects on other arthropod species

(Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Stage	Test Substance (Starane 180)	Effect lethal/sublethal %
Laboratory test			
Aphidius rhopalosiphi	adult	578 g as/ha*	100
Typhlodromus pyri	adult	578 g as/ha*	33.3
Aleochara bilineata	adult	360 g as/ha**	7
Paradosa spp.	adult	360 g as/ha**	0
Poecilus cupreus	adult	360 g as/ha*	9.1
Extended laboratory test			
Aphidius rhopalosiphi	adult	439 g as/ha*	0

* MHE

** acid

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity
Reproductive toxicity

Acid	MHE	Metabolit III*	formulated product (Starane 180)
LC ₅₀ mg as/kg			
---	> 1000	313	49.7
---	---	---	---

Effects on soil micro-organisms

(Annex IIA, point 8.5, Annex IIIA, point 10.7)

	<i>Testing was carried out using a herbicide containing fluroxypyr and another active substance</i>	Metabolite III (Fluroxypyr Methoxy pyridin)
Nitrogen mineralization	No negative effects up to 2 kg as/ha	---
Carbon mineralization	No negative effects up to 2 kg as/ha	---
Soil respiration	---	No negative effects up to 495g as/ha
Nitrogen mineralisation	---	No negative effects up to 495g as/ha

Appendix III

FLUROXYPYR

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 inclusion⁷.

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 ⁸ on previous use in granting national authorisations
IIA, 1.9	Hummel, R. A.	1988	Assay of fluroxypyr 1-methylheptyl ester, AGR 248743, (A55) owner: DowElanco ML-AL 88-030273	
IIA, 1.10	Cowlyn, T. C.	1994	STARANE F: Determination of unknown impurities (A56) owner: DowElanco GHE-P-3949	
IIA, 1.10	Moreland, J.	1995	Confirmation of identity and quantitation of an unknown impurity in STARANE F Herbicide Ex-Drusenheim (A58) owner: DowElanco GHE-P-4147	
IIA, 1.10 IIA, 2.4	Moreland, J., Ghosh, D. and Peacock, J.	1993	Characterisation of STARANE F Herbicide (Batch 42 Ex-Drusenheim) (A35) owner: DowElanco GHE-P-3210	
IIA, 1.11 IIA, 4.1.1 IIA, 4.1.2	Comb, A. L.	1994	STARANE F: Five-batch Characterisation of Starane F herbicides (A53) owner: DowElanco GHE-P-3948	

⁷ List based on a detailed analysis from Germany in its submission of XX/XX/XX (background document C).

⁸ 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 ⁸ on previous use in granting national authorisations
IIA, 2.1 IIA, 2.2 IIA, 2.6 IIA, 2.8 IIA, 2.11 IIA, 2.13 IIA, 2.15	O'Connor, J.	1991	Fluroxypyr 1-methylheptyl ester: Determination of Physico-Chemical Properties (A11) owner: DowElanco Report No. GHE-P-2473	FR: The study has been used for authorisation January 1996 (09.01.96) SE: The study has been used for authorisation in December 1991
IIA, 2.3	Schuurman, I. P.	1989	Determination of the autoflammability of STARANE 180 formulation (EF 1018) (Q6) owner: DowElanco report No. GHE-P-2029	FI: The study has been used for authorisation in April 1992 (22.4.1992) NL: Date of national decision: 01.04.1994
IIA, 2.3	Watson, P. A.	1994	Fluroxypyr 1-methylheptyl ester: Calculation of Henry's Law Constant (A39) owner: DowElanco HLC/2-4/94	
IIA, 2.4	Sydney, P.	1994	STARANE F; Determination of physico-chemical properties (A45) owner: DowElanco Report No. GHE-P-3735	
IIA, 2.5	Knowles, S.	1995	Generation of Spectral Data (UV-VIS) for fluroxypyr MH Ester pure, AGR 228289 (A57) owner: DowElanco Report No. GEHE-P-4231	
IIA, 2.5	Knowles, S. J., Peacock, G. and Portwood, D.	1991	Determination of Spectral Data for Starane F, Fluroxypyr 1-Methylheptyl Ester (Technical), VE 270 BX680 (A21) owner: DowElanco Report No. GHE-P-2457	
IIA, 2.5	Knowles, S. J., Peacock, G. and Portwood, D.	1991	Determination of Spectral Data of Fluroxypyr acid (Analytical), AGR 218256 (A24) owner: DowElanco Report No. GHE-P-2474	
IIA, 2.5 IIA, 2.9	Knowles, S. J., Peacock, G. and Portwood, D.	1991	Determination of Spectral Data for Fluroxypyr 1-Methylheptyl Ester (Analytical), AGR 228289 (A22) owner: DowElanco Report No. GHE-P-2458	SE: The study has been used for authorisation in December 1991
IIA, 2.7	Oliver, P. and Hamilton, A.	1992	STARANE 180 Herbicide: EC 1018 Packaging Stability data (Q8) owner: DowElanco Report No. GHE-P-2029	

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IIA, 2.8	O'Connor, J.	1991	Fluroxypyr: Determination of Partition Coefficient (A23) owner: DowElanco GHE-P-2475	
IIA, 2.9 IIA, 7.3.1.3.2	Lehmann, R. G.	1988	Formation of fluroxypyr from fluroxypyr-MHE by soil catalysis. (K34) Dow Chemical Company GH-C 2068	FI: The study has been used for authorisation in April 1992 (22.4.1992) SE: The study has been used for authorisation in December 1991 IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991
IIA, 2.9 IIA, 7.2.1.2	Cleveland, C. B. and Holbrook, D. L.	1992	Aqueous photolysis of fluroxypyr methylheptyl ester and fluroxypyr (acid) in natural sunlight. (K51) owner: DowElanco GH-C 2758	
IIA, 2.10	Müller, M.	1995	Estimation of the atmospheric half-life of Fluroxypyr (A59) owner: DowElanco Report No. GHE-P-4738	
IIA, 2.10	Müller, M.	1995	Estimation of the atmospheric half-life of Fluroxypyr-1-methylheptyl ester owner: DowElanco (A60) Report No. GHE-P-4736	
IIA, 3.5	Puvanesarajah, V. and Steward, C.	1991	Metabolism of ¹⁴ C-fluroxypyr MHE in wheat. (L2) owner: DowElanco REPORT #38701	SE: The study has been used for authorisation in December 1991
IIA, 4.1 IIA, 5.1	Anonymous	1991	Analytical method: STARANE EC Multimethod (O85) owner: DowElanco Report No: EU-AM-90-38 (DOWM 10098 8-DE 91A)	
IIA, 4.2.1	Anonymous	1990	Determination of fluroxypyr residues in grass and hay, ERC 86.1 (O30) owner: DowElanco	DE: The study has been submitted in 1987 in a national authorisation IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991

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IIA, 4.2.1	Butcher, S. M.	1994	Determination of fluroxypyr residues in olives, ERC 94.9 (O40) owner: DowElanco	
IIA, 4.2.1	Butcher, S. and Hastings, M.	1992	Determination of fluroxypyr residues in wheat and barley grain and straw, ERC 92.1 (O31) owner: DowElanco	DE: The study has been submitted in 1994 in a national authorisation
IIA, 4.2.1	Dawson, J.	1990	Determination of fluroxypyr residues in grapes, ERC 86.4 (O36) owner: DowElanco	SE: The study has been used for authorisation in December 1991
IIA, 4.2.1	Dawson, J.	1990	Determination of fluroxypyr residues in maize fractions, ERC 86.3 (O35) owner: DowElanco	BE: Date of national decision: 05.03.1992
IIA, 4.2.1	Maycock, R. C.	1991	Determination of fluroxypyr residues in apples and onions, ERC 89.2 (O37) owner: DowElanco	FR: The study has been used for authorisation March 1994 (17.03.94) SE: The study has been used for authorisation in December 1991
IIA, 4.2.1	Maycock, R. C. and Teasdale, R.	1990	Determination of fluroxypyr residues in maize plant and kernels, ERC 89.5 (O38) owner: DowElanco	BE: Date of national decision: 05.03.1992 DE: The study has been submitted in 1990 in a national authorisation
IIA, 4.2.1	Teasdale, R. J.	1994	Independent method validation of DowElanco Analytical Method ERC 92.1: Determination of Fluroxypyr residues in wheat and barley grain and straw (O32) owner: DowElanco GHE-P-3392	
IIA, 4.2.1	Teasdale, R. J.	1995	Independent method validation of DowElanco Analytical Method ERC 92.1 for the Determination of Fluroxypyr residues in wheat and barley immature plant (O32A) owner: DowElanco GHE-P-4190	
IIA, 4.2.1	Teasdale, R. J.	1995	Independent method validation of DowElanco Analytical Method ERC 90.3 for the Determination of Fluroxypyr residues in pasture (O33B) owner: DowElanco GHE-P-4648	

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IIA, 4.2.1	Teasdale, R. J.	1995	Independent validation of DowElanco Analytical Method ERC 89.5 for the Determination of Fluroxypyr residues in maize plant and cob (O38A) owner: DowElanco GHE-P-4647	
IIA, 4.2.2	Gill, J. P.	1995	Determination of residues of fluroxypyr, the 3,5-Dichloropyri- dinol and 2-methoxypyridine in soil, ERC 94.31 (O20D) owner: DowElanco	
IIA, 4.2.2	Van Dyke, M. E.	1991	Determination of residues of fluroxypyr methylheptyl-ester in soil by gas chromatography/mass spectrum (O20A) owner: DowElanco	
IIA, 4.2.3	Butcher, S. M.	1992	Determination of residues of the methoxy- pyridine and pyridinol metabolites of fluroxypyr in Drinking Water, ERC 92.17 (O16A) owner: DowElanco	DE: The study has been submitted in 1992 in a national authorisation
IIA, 4.2.4	Long, T. and Balluff, M.	1994	Development and validation of a low level air monitoring method for fluroxypyr 1-MHE (O45A) owner: DowElanco GHE-P-4045	
IIA, 4.2.4	Long, T. and Balluff, M.	1994	Development and validation of a low level air monitoring method for fluroxypyr (O46A) owner: DowElanco GHE-P-4046	
IIA, 4.2.4	Long, T. and Balluff, M.	1995	Monitoring low levels of fluroxypyr 1-MHE in air, ERC 94.24 (O45) owner: DowElanco	
IIA, 4.2.4	Long, T. and Balluff, M.	1995	Monitoring low levels of fluroxypyr in air, ERC 95.17 (O46) owner: DowElanco	
IIA, 4.2.5	Anonymous	1990	Determination of fluroxypyr residues in milk, ERC 87.11 include. Addendum (O25) owner: DowElanco	DE: The study has been submitted in 1989 in a national authorisation
IIA, 4.2.5	Anonymous	1991	Determination of fluroxypyr residues in urine, ERC 87.14 (O22) owner: DowElanco	
IIA, 4.2.5	Anonymous	1991	Determination of fluroxypyr residues in kidney, liver and muscle, ERC 87.13 include. Addendum (O23) owner: DowElanco	DE: The study has been submitted in 1989 in a national authorisation

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IIA, 4.2.5	Anonymous	1991	Determination of fluroxypyr residues in peritoneal and subcutaneous fat, ERC 87.12 (O24) owner: DowElanco	DE: The study has been submitted in 1989 in a national authorisation
IIA, 4.2.5	Woods, J. S. and Yeakle	1990	Determination of fluroxypyr in eggs, chicken muscle, liver, and fat tissues by gas chromatography ACR 90.4 (O39) owner: DowElanco	F1: The study has been used for authorisation in April 1992 (22.4.1992) SE: The study has been used for authorisation in December 1991
IIA, 5.2.1	Jones, J. R.	1994	STARANE F: Acute oral toxicity (Limit test) in the Rat (B11) owner: DowElanco	
IIA, 5.2.2	Jones, J. R.	1994	STARANE F: Acute dermal toxicity (Limit test) in the Rat (B12) owner: DowElanco	
IIA, 5.2.5	Jones, J. R.	1994	STARANE F: Acute dermal eye irritation test in the rabbit (B13) owner: DowElanco	
IIA, 5.2.6	Jones, J. R.	1994	STARANE F: Magnusson and Kligman Maximisation study in the Guinea pig (B14) owner: DowElanco	
IIA, 5.3.2	Cosse, P. F., Vedula, U. and Crissman, J. W.	1991	Fluroxypyr methylheptyl ester: 13-week dietary toxicity study and 5-week Recovery study in Fischer 344 rats (D14) owner: DowElanco DECO-HET K-137992-004	
IIA, 5.3.3	Cosse, P. F., Crissman, J. W. and Vedula, U.	1991	Fluroxypyr Methylheptyl Ester: Dermal Probe Study and 21-Day Dermal Toxicity Study in New Zealand White Rabbits (D13) owner: DowElanco DECO-HET K-137992-003	SE: The study has been used for authorisation in December 1991
IIA, 5.5	Cosse, P. F., Crissman, J. W., Markham, D. A. and Corley, R. A.	1993	Fluroxypyr: 18-month dietary oncogenicity study in CD-1 Mice (I5) owner: DowElanco K-129976-004	
IIA, 5.6.1	Dreef-van der Meulen, H. C.	1991	Oral Multigeneration Reproduction study with Dowco 433 Acid in Rats; Additional Pathology (F5) owner: DowElanco	SE: The study has been used for authorisation in December 1991

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IIA, 5.9.1	Lines, S.	1995	Fluroxypyr 1-methylheptyl ester (STARANE F) :Employee Medical Record Evaluations (U1) owner: DowElanco	
IIA, 5.10	Thies, E. P.	1998	STARANE 180 and STARANE 200 Evaluation Table Point 4.1. Doc 6849/VI/97 (Operator Exposure 7.2.) (M1018) owner: DowElanco	
IIA, 6.1	Caley, C. Y., Hall, B. E.	1995	Comparative Metabolism of ¹⁴ C-fluroxypyr butoxypropyl ester and ¹⁴ C-fluroxypyr MHE in winter wheat – field study (L5) Source: Dow Elanco Report No.: 10592	DE: The study has been submitted in 1996 in a national authorisation
IIA, 6.1	Lickly, L. S. <i>et al</i>	1990	[¹⁴ C] Fluroxypyr-MHE: Confined accumulation study on rotational crops planted at 30, 120 and 366 days after soil treatment (N38) Source: Dow Elanco Report No.: GH-C-2401	
IIA, 6.1	Phillips, A. M.	1993	Determination of residues of fluroxypyr in wheat and barley receiving ground application of fluroxypyr methylheptyl ester (Canada) (N39) Source: Dow Elanco Report No.: GH-C-3168	
IIA, 6.1	Puvanesaraja, V., Steward, C.	1991	Metabolism of ¹⁴ C-fluroxypyr MHE in wheat (L2) Source: Dow Elanco Report No.: GH-C 2650	SE: The study has been used for authorisation in December 1991
IIA, 6.2	Yackovich, P. R., Lardie, T. S., Miller, J. H.	1989	Fate of ¹⁴ C labelled fluroxypyr fed to laying hens (N87) Source: Dow Elanco Report No.: GH-C-2148	
IIA, 6.2	Yackovich, P. R., Lardie, T. S., Miller, J. H.	1990	Fate of ¹⁴ C labelled fluroxypyr fed to lactating goats (H4) Source: Dow Elanco Report No.: GH-C 2297	UK: The study has been used in 06/1998 in a national authorisation
IIA, 6.3	Butcher, S. M., Teasdale, R.	1994	Residues of fluroxypyr in olives at harvest following basal application of STARANE 20 – Spain (N43A) Source: Dow Elanco Report No.: GHE-P-3750	ES: Date of national regulatory decision: February 1995
IIA, 6.3	Day, S. R., Flatt, S.	1988	Fluroxypyr residues in bulb onions following application of STARANE 2 – Holland (N65) Source: Dow Elanco Report No.: GHE-P-1838	

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IIA, 6.3	Maycock, R.	1989	Fluroxypyr residues in bulb onions following application of STARANE 2 – UK (N66) Source: Dow Elanco Report No.: GHE-P-1934	
IIA, 6.3	Maycock, R.	1993	Fluroxypyr residues in apples following application of STARANE 2 – UK (N40) Source: Dow Elanco Report No.: GHE-P-1922	ES: Date of national regulatory decision: April 1997 FR: The study has been used for authorisation March 1994 (17.03.94) UK: The study has been used in 04/91 for a national authorisation.
IIA, 6.3	Teasdale, R.	1994	Residues of fluroxypyr in durum wheat at harvest and residues of fluroxypyr 1-methylheptl ester (MHE), fluroxypyr and two metabolites in soil following a single post-emergence application of STARANE (EF 1018). Italy (N22) Source: Dow Elanco Report No.: GHE-P-3912	
IIA, 6.3	Teasdale, R.	1995	Residues of fluroxypyr in soft wheat at harvest and residues of fluroxypyr 1-methylheptl ester (MHE), fluroxypyr and two metabolites in soil following a single post-emergence application of STARANE (EF 1018). Italy (N20) Source: Dow Elanco Report No.: GHE-P-3913	
IIA, 6.3	Teasdale, R.	1995	Residues of fluroxypyr in winter barley at harvest and residues of fluroxypyr 1-methylheptl ester (MHE), fluroxypyr and two metabolites in soil following a single post-emergence application of STARANE (EF 1018). Italy (N21) Source: Dow Elanco Report No.: GHE-P-3914	
IIA, 6.3	Teasdale, R.	1995	Residues of fluroxypyr in winter soft wheat and durum wheat at harvest following application of STARANE 20 (EF-689). Spain (N23) Source: Dow Elanco Report No.: GHE-P-4091	

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IIA, 6.3	Teasdale, R.	1995	Residues of fluroxypyr in winter barley at harvest following application of STARANE 20 (EF-689). Spain (N24) Source: Dow Elanco Report No.: GHE-P-4092	
IIA, 6.3	Teasdale, R.	1995	Residues of fluroxypyr in winter wheat at intervals following application of STARANE 20 (EF-689). Spain (N25) Source: Dow Elanco Report No.: GHE-P-4093	
IIA, 6.3	Teasdale, R.	1995	Residues of fluroxypyr in winter barley at intervals following application of STARANE 20 (EF-689). Spain (N26) Source: Dow Elanco Report No.: GHE-P-4094	
IIA, 6.3	Teasdale, R.	1991	Fluroxypyr residues in apples following orchard floor application of STARANE 200 EC – France (N41) Source: Dow Elanco Report No.: GHE-P-2492	ES: Date of national regulatory decision: April 1997 FR: The study has been used for authorisation March 1994 (17.03.94)
IIA, 6.3	Teasdale, R., Maycock, R.	1990	Fluroxypyr residues in maize following application of STARANE 180 – Germany (N55) Source: Dow Elanco Report No.: GHE-P-2035	BE: Date of national decision: 05.03.1992 DE: The study has been submitted in 1990 in a national authorisation
IIA, 6.3	Teasdale, R., Maycock, R.	1990	Fluroxypyr residues in maize following application of STARANE 180 – Germany (N56) Source: Dow Elanco Report No.: GHE-P-1991	BE: Date of national decision: 05.03.1992 DE: The study has been submitted in 1990 in a national authorisation
IIA, 6.3	Teasdale, R.	1996	Frozen storage stability of fluroxypyr in wheat immature plant, grain and straw. (O32C) GHE-P-4830	

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IIA, 6.4	Woods, J. S.	1990	Determination of residues of fluroxypyr in eggs, muscle, liver and fat tissues from chickens administered fluroxypyr herbicide (N86) Source: Dow Elanco Report No.: GH-C 2327	FI: The study has been used for authorisation in April 1992 (22.4.1992) SE: The study has been used for authorisation in December 1991
IIA, 7.1.1.1.1	Grant, R. K.	1992	Degradation and metabolism of fluroxypyr 1-rnethylheptyl ester in soil under aerobic conditions. (K22) owner: DowElanco Dow Elanco id GHE-P-2754	
IIA, 7.1.1.1.1	Lehmann, R. G.	1988	Extraction of fluroxypyr and its metabolites from aged soil. (K2) Dow Chemical Company GH-C 2048	
IIA, 7.1.1.1.1	Lehmann, R. G. and Miller, J. R.	1989	Aerobic soil metabolism study of fluroxypyr-MHE. (K6) Dow Chemical Company GH-C 2149R	BE: Date of national decision: 05.03.1992 SE: The study has been used for authorisation in December 1991 IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991
IIA, 7.1.1.1.1	Lehmann, R. G. and Miller, J. R.	1989	Degradation of the methoxy pyridine metabolite of fluroxypyr in soils planted with grass. (K7) Dow Chemical Company GH-C 2256	BE: Date of national decision: 05.03.1992 SE: The study has been used for authorisation in December 1991
IIA, 7.1.1.1.1	Ballantine, L. G.	1993	Aerobic soil metabolism of ¹⁴ C-fluroxypyr – MHE. (K23) GH-C 3026	
IIA, 7.1.1.1.2	Batzer, F. R. and Lubinski, R. N.	1992	Soil photolysis of fluroxypyr 1-rnethylheptyl ester in natural sunlight (K50) owner: DowElanco Dow Elanco id GH-C 2717	
IIA, 7.1.1.2.2	Poletika, N. N., Roberts, D. W., Phillips, A. M. and Butter, I. W.	1994	Terrestrial field dissipation of fluroxypyr in Western Canada (K29) owner: DowElanco Dow Elanco id GH-C 3210	

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IIA, 7.1.2	Lehmann, R. G.	1988	Adsorption/desorption study of fluroxypyr Dow Chemical Company (K3) Dow Elanco id GH-C 2124	BE: Date of national decision: 05.03.1992 DE: The study has been submitted in 1989 in a national authorisation SE: The study has been used for authorisation in December 1991 IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991
IIA, 7.1.3.3	Brumhard, B., Fuhr, F. and Baloch, R.	1993	Behaviour of [2,6- ¹⁴ C] fluroxypyr 1- methylheptyl ester in sandy pseudogley- braunerde after post-emergence application to spring barley (K17B) Instit. Fur Radioagron. Forsch. Julich Dow Elanco id GHE-P 2803	DE: The study has been submitted in 1995 in a national authorisation
IIA, 7.1.3.3	McGibbon, A. S.	1990	Dissipation of fluroxypyr-methylheptyl ester in Swedish Soils. (K16) Dow Chemical Company GHE-P-1993	BE: Date of national decision: 05.03.1992 SE: The study has been used for authorisation in December 1991
IIA, 7.2.1.3.2	Yon, D. A. and Cresswell, D. G.	1988	Degradation of ¹⁴ C fluroxypyr 1-MHE in ditch waters and their associated sediments 1987 Hazleton Laboratories (K20) Dow Elanco id GHE-P-1785	BE: Date of national decision: 05.03.1992 DE: The study has been submitted in 1995 in a national authorisation FI: The study has been used for authorisation in April 1992 (22.4.1992) NL: Date of national decision: 01.04.1994 IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991

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IIA, 7.2.1.3.2	Cleveland, C. B. and Miller, J. R.	1993	Aerobic aquatic metabolism of fluroxypyr MHE. (K25) owner: DowElanco GH-C 3008	
IIA, 7.2.1.3.2	Cleveland, C. B. and Miller, J. R.	1993	Anaerobic aquatic metabolism of fluroxypyr methylheptyl ester. (K26) owner: DowElanco GH-C 3033	
IIA, 8.1.2	Grimes, J. and Jaber, M.	1988	Fluroxypyr, 1-methylheptyl Ester: A dietary LC50 study with the mallard (J58)	SE: The study has been used for authorisation in December 1991
IIA, 8.1.2	Grimes, J., Lynn, S. P. and Smith, G.J.	1991	Fluroxypyr: A dietary LC50 study with the mallard (J66)	SE: The study has been used for authorisation in December 1991
IIA, 8.1.3	Beavers, J., Lloyd, D. and Jaber, M.	1988	Fluroxypyr 1-methylheptyl ester: ((4-amino-3,5-dichloro -6-fluoro-2-pyridinyl)oxy)acetic acid, 1-methylheptyl ester: A pilot reproduction study with the mallard (<i>Anas platyrhynchos</i>) (J61)	SE: The study has been used for authorisation in December 1991
IIA, 8.1.3	Beavers, J., Lloyd, D. and Jaber, M.	1988	Fluroxypyr, 1-methylheptyl ester: ((4-amino-3,5-dichloro -6-fluoro-2-pyridinyl)oxy)acetic acid, 1-methylheptyl ester: A pilot reproduction study with the bobwhite (<i>Colinus virginianus</i>) (J63)	SE: The study has been used for authorisation in December 1991
IIA, 8.1.3	Beavers, J. B., Hoxter, K. A., Nichols, L., Hawrot, R. and Jaber, M. J.	1989	Fluroxypyr 1-methylheptyl ester herbicide, ((4-amino-3,5-dichloro -6-fluoro-2-pyridinyl)oxy)acetic acid, 1-methylheptyl ester: A one-generation reproduction study with the mallard (<i>Anas platyrhynchos</i>) (J62)	SE: The study has been used for authorisation in December 1991 IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991
IIA, 8.1.3	Beavers, J. B., Hawrot, R. and Jaber, M. J.	1989	Fluroxypyr 1-Methylheptyl ester herbicide, ((4-amino-3,5-dichloro -6-fluoro-2-pyridinyl)oxy)acetic acid, 1-methylheptyl ester: A one-generation reproduction study with the bobwhite (<i>Colinus virginianus</i>) (J64)	SE: The study has been used for authorisation in December 1991
IIA, 8.2.1	Douglas, M. T., Stonehever, R. O. and Macdonald, I.	1989	Prolonged Toxicity of Fluroxypyr-1-Methyl Heptyl Ester to Rainbow Trout (<i>Salmo gairdneri</i>) (J9)	DE: The study has been submitted in 1995 in a national authorisation SE: The study has been used for authorisation in December 1991

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IIA, 8.2.1	Dill, D. C. and Bartlett, E. A.	1989	Fluroxypyr 1-Methylheptyl Ester: Evaluation of the Toxicity to the Bluegill (<i>Lepomis macrochirus Rafinesque</i>) (J7)	SE: The study has been used for authorisation in December 1991
IIA, 8.2.1	Sewell, I. G. and Bartlett, A. J.	1996	Fluroxypyr Pyridinol: Acute Toxicity to Rainbow trout (<i>Oncorhynchus mykiss</i>) (J260) owner: DowElanco Report No. 2911077	
IIA, 8.2.1	Weinberg, J. T., Richardson, C. H., Rick, D. L. and Piaseck, D. A.	1991	Fluroxypyr 1-Methylheptyl Ester: Evaluation of the acute toxicity to the Rainbow Trout (<i>Oncorhynchus mykiss Walbaum</i>) (J4) owner: DowElanco Report No. ES-DR-0186-1887-18	FR: The study has been used for authorisation January 1996 (09.01.96) SE: The study has been used for authorisation in December 1991
IIA, 8.2.1	Weinberg, J. T., Richardson, C. H., Rick, D. L. and Piaseck, D. A.	1991	Fluroxypyr: Evaluation of the acute toxicity to the Bluegill (<i>Lepomis macrochirus Rafinesque</i>). (J25) owner: DowElanco Report No. ES-DR-0170-8550	
IIA, 8.2.2	Douglas, M. T., Halls, R. W. S., Macdonald, I. A.	1989	The prolonged toxicity of Fluroxypyr acid to Rainbow trout (<i>Salmo gairdneri</i>) (J27)	DE: The study has been submitted in 1990 in a national authorisation FR: The study has been used for authorisation January 1996 (09.01.96) SE: The study has been used for authorisation in December 1991
IIA, 8.2.3	Ritter, A.	1989	Comments on the bioaccumulation study with 14C fluroxypyr-1 MHE. (J10)	SE: The study has been used for authorisation in December 1991
IIA, 8.2.4	Weinberg, J. T., Milazzo, D. P., Servinski, R. F. and Rick, D. L.	1989	Fluroxypyr, 1-methylheptyl ester: Evaluation of the acute toxicity to the Water Flea, <i>Daphnia magna straus</i> . (J13)	DE: The study has been submitted in 1995 in a national authorisation FR: The study has been used for authorisation January 1996 (09.01.96)

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IIA, 8.2.5	Wüthrich, V.	1993	Influence of Fluroxypyr 1-Methylester on the Reproduction of <i>Daphnia magna</i> under Flow-through conditions at pH 7. (J14)	DE: The study has been submitted in 1993 in a national authorisation
IIA, 8.2.5	Sewell, I. G. and Bartlett, A. J.	1996	Fluroxypyr Pyridinol: Acute Toxicity to <i>Daphnia magna</i> . (J261) owner: DowElanco Report No. 291/076	
IIA, 8.2.6	Cowgill, U. M. Milazzo, D. P. and Murphy, P. G.	1988	Five-day toxicity of fluroxypyr (DOWCO 433) to <i>Selenastrum capricornutum prinz</i> , a freshwater green alga. (J33)	FR: The study has been used for authorisation January 1996 (09.01.96)
IIA, 8.2.6	Hughes, J. S., Alexander, M. M.	1991	The toxicity of Fluroxypyr 1-Methylheptyl ester to <i>Selenastrum capricornutum</i> (J16)	DE: The study has been submitted in 1993 in a national authorisation SE: The study has been used for authorisation in December 1991
IIA, 8.2.6	Douglas, M. T., Bell, G., Macdonald, I. A.	1992	The algistatic activity of Fluroxypyr 1-Methylheptyl Ester, tech. (J15)	DE: The study has been submitted in 1993 in a national authorisation FR: The study has been used for authorisation January 1996 (09.01.96) SE: The study has been used for authorisation in December 1991
IIA, 8.2.7	Sewell, I. G. and Bartlett, A. J.	1996	Fluroxypyr Pyridinol: Algal Inhibition Test. (J262) owner: DowElanco Report No. 291/075	
IIA, 8.2.8	Cowgill, U. M. Milazzo, D. P. and Murphy, P. G.	1988	The Fourteen-day toxicity of Fluroxypyr (DOWCO 433) to <i>Lemna gibba</i> L. G-3 (Duckweed). (J35)	DE: The study has been submitted in 1989 in a national authorisation UK: The study has been used in 02/98 for a national authorisation.

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 ⁸ on previous use in granting national authorisations
IIA, 8.2.8	Kirk, H. D. et al	1999	Phytotoxicological evaluation of Starane 180 (EF-1463) on exposed aquatic plant, duckweed <i>lemna gibba</i> L G-3. (J144) Dow Chemical Company DECO-HET-DR-0360-2082-001	
IIA, 8.3.2	Heimbach, U.	1990	Effects of Starane 180 (EF1018) on the Carabid Beetle (<i>Poecilus cupreus</i>) using WPRS/IOBC Standard Laboratory Methods. (J79)	DE: The study has been submitted in 1995 in a national authorisation FI: The study has been used for authorisation in April 1992 (22.4.1992) IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991
IIA, 8.3.2	Samsøe-Petersen, L.	1990	Effects of Tristar (EF838), XRD-535 (EF1020) and Starane 180 (EF1018) on the Staphylinid Beetle (<i>Aleochara bilineata</i>) using a Standard WPRS/IOBC Laboratory Method. (J80)	DE: The study has been submitted in 1995 in a national authorisation FI: The study has been used for authorisation in April 1992 (22.4.1992) IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991
IIA, 8.3.2	Heimann, D., Hof, A., Römbke, J., Vickus, P.	1992	Study of acute toxicity of STARANE 180 on <i>Pardosa spp. (Araneae)</i> (J82)	DE: The study has been submitted in 1995 in a national authorisation
IIA, 8.3.2	Mead-Briggs, M.	1996	A laboratory study to evaluate the side-effects of the herbicide fluroxypyr-BPE 400 EW (EF-1354) on the parasitic wasp <i>Aphidius rhopalosiphi</i> . (J118) GHE-P-4951	UK: The study has been used in 02/98 for a national authorisation.
IIA, 8.3.2	Miles, M.	1997	A laboratory test to evaluate the effects of Starane 2 EF-689 on the parasitic wasp <i>Aphidius rhopalosiphi</i> . (J141) Dow Elanco Europe GHE-P-6085	DE: The study has been submitted in 1998 in a national authorisation

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 ⁸ on previous use in granting national authorisations
IIA, 8.3.2	Bienert, U.	1997	Effects of Starane 2 (EF-689) on predatory mites <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the laboratory. (J142) GHE-P-6879	DE: The study has been submitted in 1998 in a national authorisation
IIA, 8.3.2	Riches, M. N.	1999	An extended laboratory study on barley seedlings test to assess the side effects of Starane 2 EF-689 on the parasitic wasp <i>Aphidius rhopalosiphi</i> . (J141A) Dow AgroSciences GHE-P-7880	DE: The study has been submitted in 1999 in a national authorisation
IIA, 8.3.6	Knowles, S. and Jenkins, W. R:	1991	Ready biodegradability of fluroxypyr-1-methylheptyl ester (Modified Sturm Test). (K39) GHE-P-2439	
IIA, 8.4.1	Rees, P. B.	1996	Fluroxypyr Methoxypyridine: Acute toxicity study in the earthworm (Artificial soil test) (J252)	
IIA, 8.4.1	Johnson, A. J.	1994	Fluroxypyr methyl heptyl ester: Acute toxicity (LC50) to the Earthworm (J86A) owner: DowEianco Report No. DWC 692/932394	
IIA, 8.4.2	Meinerling, M., Lührs, U.	1999	Effects of Starane 180 (EF-1463) on reproduction and growth of earthworms <i>eisenia fetida</i> (Savigny 1826) in artificial soil (J143) GHE-T-909	
IIA, 8.5	Forster, J.	1996	A laboratory assessment of the effects of fluroxypyr methoxypyridine on soil microflora respiration and nitrogen turnover according to BBA guideline VI 1-1 (1990). (J251)	
IIA, 8.7	Barnes, S. P.	1998	Starane 180 (EF-1463) activated sludge – Respiration inhibition test. (J145) Dow Chemical Company GHE-T-883	

**SUMMARY REPORT
OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH
HELD ON 30 NOVEMBER 1999**

Extract

President : G. Del Bino

All Member States were present

1 Examination and possible opinion on a Draft Commission Directive concerning the inclusion of fluroxypyr in Annex I to Council Directive 91/414/EEC (7780/VI/98 rev. 11).

The Commission presented the Review report on fluroxypyr as finalised in document 6848/VI/98 rev 12. The Committee took note of the review report.

The following declaration was made by the Commission:

At the adoption of the Uniform Principles by Council in September 1997, the Council and the 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.”

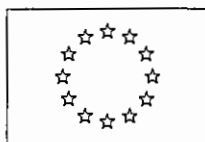
The Commission can for its part confirm its agreement with this declaration (subject to adequate adaptation of the deadline in the declaration).

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

Vote : unanimous favourable opinion.

The substance concerned is an “existing” active substances to be used as herbicide. The inclusion decision in Annex 1 will be subject to re-evaluation by November 2010.

A CHECCHI LANG
Director



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

SCIENTIFIC COMMITTEE ON PLANTS

**SCP/FLUROX/001-Final
4 June, 1999**

**OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS
REGARDING THE INCLUSION OF FLUROXYPYR
IN ANNEX 1 TO DIRECTIVE 91/414/EEC CONCERNING THE
PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET
SCIENTIFIC COMMITTEE ON PLANTS
(SCP/FLUROX/001-Final)**

(Opinion adopted by the Scientific Committee on Plants on 18 May 1999)

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

(SCP/FLUROX/001-Final)

(Opinion adopted by the Scientific Committee on Plants on 18 May 1999)

TERMS OF REFERENCE

The draft Commission Directive proposing the inclusion of fluroxypyr in Annex 1 to Directive 91/414/EEC¹ had been referred to the Scientific Committee on Plants for consultation with the following questions:

1. Is the environmental safety of the metabolites of fluroxypyr adequately addressed? Which metabolites are relevant?
2. Does the Committee confirm the conclusion of the peer review that the available data on the soil leaching behaviour of the parent and its metabolites are not sufficient to ensure the protection of ground water resources also for applications in autumn?

BACKGROUND

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

Fluroxypyr is a post-emergence herbicide against broad leaved weeds, acting similar to auxin-type herbicides in promoting cell elongation and interfering with RNA synthesis. Its current intended use is to control broad leaved weeds in cereals, maize, sorghum, pastures, amenity green, bulb onions, apple and olive orchards, and non-crop areas. The maximum rate of application per season is 0.4 kg active substance (as acid)/ ha (equivalent to 0.576 kg MHE / ha)

¹ OJ No L 230, 19.8.1991, p.1.

OPINION OF THE COMMITTEE

Question 1

**Is the environmental safety of the metabolites of fluroxypyr adequately addressed?
Which metabolites are relevant?**

a) Metabolites occurring

Fluroxypyr is applied as methyl-heptylester (MHE) which is rapidly hydrolysed to the corresponding acid (metabolite I). This is further degraded in relatively short time (few days) under aerobic conditions and at temperatures above 20 °C. Slower degradation occurs under anaerobic conditions or lower temperatures.

The following main metabolites have to be considered:

- Metabolite III (4-amino-3,5-dichloro-6-fluoro-2-methoxypyridine) is the main metabolite in soil where it occurs at levels of up to 38% of the applied radioactivity/dose. It does not occur in water/sediment systems.
- Metabolite II (4-amino-3,5-dichloro-6-fluoro-2-pyridinol) occurs in soil at levels of up to 18.7 %. Fate studies indicate that it may be stable in the top layer. Metabolite II is, however, clearly the main metabolite in water, with up to 62.4% under anaerobic and up to 44% under aerobic conditions. Metabolite II is (biologically) degraded further to metabolite IV:
- Metabolite IV (4-amino-3-chloro-6-fluoro-2-pyridinol), a minor metabolite in soil. In most water/sediment systems it occurs at levels less than 10%, but was detected under anaerobic conditions at up to 28.4%. Under aerobic conditions, it was detected at lower levels.
- Metabolite VI (4-amino-3,5-dichloro-6-fluoro-2- pyridinone) was only detected in two of 9 studies in water/sediment systems with 17 – 45%. The data provided suggest that it may occur in equilibrium with metabolite II. Further degradation is to metabolite IV.

Metabolites II and IV were microbially degraded further with DT_{90} 's² of 60-120 days (i.e., within one season) under aerobic conditions. All metabolites in water/sediment-systems occurred at higher levels in the water phase, indicating low adsorption to the sediment. The potential for accumulation in the sediment is very low.

b) Ecotoxicological relevance of metabolites

Soil

Metabolite III has been tested for its effects on earthworms and soil micro-organisms. For earthworms, an NOEC³ of 135 mg/kg was determined (LC_{50} ⁴ = 313 mg/kg) in the standard 14 day test (nominal concentrations). Although this is more toxic than the active ingredient itself, the trigger value for a reproduction study was not reached. The NOEC is by a factor of

² Disappearance time for 50/90% of compound

³ No observed effect concentration

⁴ Lethal concentration (50%)

1400 and more above the worst-case estimate for the concentration of metabolite III in soil which is based on the highest application rate of 400 g acid/ha, and assuming 100% going into the soil in spite of vegetation cover. The time-weighted average PEC⁵ values then range from 0.01 to 0.1 mg/kg, depending on soil type. For MHE, the initial PEC is 0.77 mg/kg.

With regard to possible effects on micro-organisms, concentrations of metabolite III equivalent to the highest intended application rate and to the five fold rate (0.132 and 0.66 mg metabolite III/kg, respectively) caused no significant effects on either microflora respiration or nitrogen turnover. Minor transient effects over the first 14 days of the test were observed on nitrogen turnover.

Metabolite II has not been tested on any soil organisms. It is structurally very similar to metabolite III and might therefore also be more toxic to soil organisms than the active substance. Since it may be stable under field conditions and remain in the biologically most important top soil layer, its environmental safety needs to be addressed by appropriate studies.

Water

Metabolite II as the main metabolite has been tested for its effects on algae, *Daphnia* and fish in the standard short-term tests. The resulting NOEC values of > 45 mg/L, > 49 mg/L and 29 mg/L, respectively, are approximately 100fold higher than the equivalent values for the active substance and the representative formulation, indicating that the metabolite II is far less toxic than the parent compound. The metabolite NOEC's are also by a factor of 300 – 450 above the worst-case (overspray situation) estimate for the initial environmental concentration of metabolite II in water. This is based on the highest application rate, assuming overspray of a pond of 30 cm depth. The highest TWA⁶ PEC value then is 0.042 mg/L. For MHE, the initial PEC is 0.19 mg/L. All this refers to dark conditions; under light there is a faster breakdown.

The structural difference between metabolites II and VI is minimal (a hydrogen atom shifting between 2 neighbouring positions), and it can reasonably be concluded that they occur in an equilibrium. The toxicity tests done nominally with metabolite II can therefore be regarded to cover metabolite VI as well.

No data are available on metabolite IV.

Question 2

Does the Committee confirm the conclusion of the peer review that the available data on the soil leaching behaviour of the parent and its metabolites are not sufficient to ensure the protection of ground water resources also for applications in autumn?

The Committee confirms this conclusion.

OVERALL CONCLUSION

⁵ Predicted environmental concentration

⁶ Time weighted average

The Committee can confirm the conclusion of the peer review that the use of fluroxypyr in autumn is not supported by the available data. The environmental safety of the relevant metabolites is not completely addressed: the safety of metabolite IV for aquatic organisms and of metabolite II for soil organisms needs to be addressed by further data.

ACKNOWLEDGEMENTS

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Environmental: Professor A Hardy (Chairperson), and Committee Members Dr H.G. Nolting and Professor A. Silva Fernandes and invited experts Professor V. Forbes and Drs J. Boesten, A. Carter, H. Köpp and T. Sherratt.

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