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EU-Beurteilungsbericht Fenhexamid

Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen Band D 25

Review Report Fenhexamide
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 25

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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 25. Heft dieser Reihe (Band D 25) 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 Berichterstatter ist, ebenfalls beim Saphir Verlag gegen Erstattung der Unkosten bezogen werden. Für Fenhexamid war das Vereinigte Königreich Berichterstatter.

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

Heft	**Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen**
35/97	Band A: Richtlinie 91/414/EWG und diesbezügliche Protokolle (3. Auflage, Stand: 01. November 1997)
68/2000	Band B: Verordnungen und Protokolle zur Wirkstoffprüfung (4. Auflage, Stand 01. Juli 2000)
	Band C: *Wird zur Zeit bearbeitet*

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 25th report belonging to this series (Volume D 25) 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 fenhexamide the United Kingdom 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 (3rd Edition, date: 1 November 1997)
68/2000	Volume B: Regulations and Protocols regarding the Evaluation of Active Substances (4th Edition, date: 1 July 2000)
	Volume C: *In Progress*

RICHTLINIE 2001/28/EG DER KOMMISSION

vom 20. April 2001

zur Änderung des Anhangs I der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln zur Aufnahme des Wirkstoffs KBR 2738 (Fenhexamid)

DIE KOMMISSION DER EUROPÄISCHEN GEMEINSCHAFTEN —

gestützt auf den Vertrag zur Gründung der Europäischen Gemeinschaft,

gestützt auf die Richtlinie 91/414/EWG des Rates vom 15. Juli 1991 über das Inverkehrbringen von Pflanzenschutzmitteln [1], zuletzt geändert durch die Richtlinie 2001/21/EG der Kommission [2], insbesondere auf Artikel 6 Absatz 1,

in Erwägung nachstehender Gründe:

(1) Die Behörden des Vereinigten Königreichs haben am 8. Mai 1997 gemäß Artikel 6 Absatz 2 der Richtlinie 91/414/EWG (im Folgenden „die Richtlinie" genannt) einen Antrag von Bayer Plc. („der Antragsteller") auf Aufnahme des Wirkstoffs KBR 2738 (Fenhexamid) in Anhang I der Richtlinie erhalten.

(2) Gemäß Artikel 6 Absatz 3 der Richtlinie hat die Kommission in ihrer Entscheidung 98/398/EG [3] bestätigt, dass die für KBR 2738 (Fenhexamid) eingereichten Unterlagen grundsätzlich die an die Daten und Informationen gestellten Anforderungen des Anhangs II bzw. für ein Pflanzenschutzmittel, das diesen Wirkstoff enthält, diejenigen des Anhangs III der Richtlinie erfüllen.

(3) Gemäß Artikel 5 Absatz 1 der Richtlinie ist ein Wirkstoff für einen Zeitraum von höchstens zehn Jahren in Anhang I aufzunehmen, wenn angenommen werden kann, dass die Anwendung von diesen Wirkstoff enthaltenden Pflanzenschutzmitteln bzw. ihre Rückstände keine schädlichen Auswirkungen auf die Gesundheit von Mensch und Tier oder auf das Grundwasser bzw. keine unannehmbaren Auswirkungen auf die Umwelt haben werden.

(4) Die Auswirkungen von KBR 2738 (Fenhexamid) auf die menschliche Gesundheit und auf die Umwelt wurden gemäß Artikel 6 Absätze 2 und 4 der Richtlinie für die von dem Antragsteller vorgeschlagenen Anwendungen geprüft. In seiner Funktion als berichterstattender Mitgliedstaat hat das Vereinigte Königreich der Kommission am 15. Oktober 1998 einen Entwurf des Bewertungsberichts über den Wirkstoff übermittelt.

(5) Dieser Bewertungsbericht wurde von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses für Pflanzenschutz geprüft. Diese Prüfung wurde am 19. Oktober 2000 in Form des Beurteilungsberichts der Kommission für KBR 2738 (Fenhexamid) abgeschlossen. Falls der Beurteilungsbericht unter Berücksichtigung technischer und wissenschaftlicher Entwicklungen aktualisiert werden muss, sind auch die Bedingungen für die Aufnahme von KBR 2738 (Fenhexamid) in Anhang I der Richtlinie gemäß der Richtlinie zu ändern.

(6) Die Unterlagen und die aus der Prüfung hervorgegangenen Informationen wurden am 31. März 2000 dem Wissenschaftlichen Ausschuss „Pflanzen" zur Stellungnahme vorgelegt. Dieser Ausschuss hat seine Stellungnahme am 20. Juli 2000 im Sitzungsprotokoll (SCP/REPT/021 endg.) [4] abgegeben, aus dem hervorgeht, dass der Ausschuss keine Einwände hinsichtlich dieses Wirkstoffs erheben will. Der Ausschuss stellte auch fest, dass die nationalen Ermächtigungen ein besonderes Risikomanagement gemäß Anhang VI (Einheitliche Grundsätze) [5] der Richtlinie erfordern würden.

(7) Die Bewertungen haben ergeben, dass davon ausgegangen werden kann, dass den betreffenden Wirkstoff enthaltende Pflanzenschutzmittel im Allgemeinen die Anforderungen gemäß Artikel 5 Absatz 1 Buchstaben a) und b) und Absatz 3 der Richtlinie erfüllen, insbesondere hinsichtlich der geprüften und im Bericht der Kommission behandelten Anwendungen. Daher sollte der betreffende Wirkstoff in Anhang I aufgenommen werden, damit die Zulassung von Pflanzenschutzmitteln mit dem betreffenden Wirkstoff in allen Mitgliedstaaten gemäß den Bestimmungen der Richtlinie gewährt werden kann.

(8) Nach der Aufnahme ist den Mitgliedstaaten eine angemessene Frist einzuräumen, um die Bestimmungen der Richtlinie über Pflanzenschutzmittel, die KBR 2738 (Fenhexamid) enthalten, umzusetzen und insbesondere innerhalb dieser Frist bereits bestehende vorläufige Zulassungen zu überprüfen bzw. vor Ablauf der Frist neue Zulassungen gemäß der Richtlinie zu erteilen. Für Pflanzenschutzmittel, die KBR 2738 (Fenhexamid) und andere in Anhang I aufgeführte Wirkstoffe enthalten, kann auch eine längere Frist erforderlich sein.

(9) 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.

(10) 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.

[1] ABl. L 230 vom 19.8.1991, S. 1.
[2] ABl. L 69 vom 10.3.2001, S. 17.
[3] ABl. L 176 vom 20.6.1998, S. 34.
[4] Protokoll der 21. Sitzung des Wissenschaftlichen Ausschusses „Pflanzen" vom 20. Juli 2000 in Brüssel.
[5] ABl. L 265 vom 27.9.1997, S. 87.

(11) Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz vom 19. Oktober 2000 —

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

Die Tabelle in Anhang I der Richtlinie 91/414/EWG wird geändert, indem der Eintrag bezüglich KBR 2738 (Fenhexamid) in den Anhang der vorliegenden Richtlinie aufgenommen wird.

Artikel 2

(1) Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens 1. August 2001 nachzukommen. Sie unterrichten die Kommission unverzüglich davon.

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

(2) Hinsichtlich der Bewertung und Entscheidungsfindung gemäß den einheitlichen Grundsätzen von Anhang VI der Richtlinie 91/414/EWG wird der in Absatz 1 festgesetzte Zeitraum jedoch auf der Grundlage von Unterlagen, die die Anforderungen von Anhang III derselben Richtlinie erfüllen, für vorläufige Zulassungen von Pflanzenschutzmitteln, die KBR 2738 (Fenhexamid) enthalten, bis zum 1. August 2002 verlängert.

(3) Bei Pflanzenschutzmitteln, die KBR 2738 (Fenhexamid) zusammen mit einem anderen in Anhang I der Richtlinie 91/414/EWG aufgeführten Wirkstoff enthalten, wird der Zeitraum gemäß Absatz 1 jedoch insoweit verlängert, als die Vorschriften der Richtlinie über die Änderung des genannten Anhangs I eine längere Umsetzungsfrist vorsehen, um den Wirkstoff in den Anhang aufzunehmen.

(4) Die Mitgliedstaaten stellen den Beurteilungsbericht für KBR 2738 (Fenhexamid) (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 3

Diese Richtlinie tritt am 1. Juni 2001 in Kraft.

Artikel 4

Diese Richtlinie ist an alle Mitgliedstaaten gerichtet.

Brüssel, den 20. April 2001

Für die Kommission

David BYRNE

Mitglied der Kommission

ANHANG

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

Nr.	Gebräuchliche Bezeichnung, Kennnummern	IUPAC-Bezeichnung	Reinheit (1)	Inkrafttreten	Aufnahme befristet bis	Besondere Bedingungen
„13	Fenhexamid CAS-Nr. 126833-17-8 CIPAC-Nr. 603	N-(2,3-dichloro-4-hydroxyphenyl)-1-ethylcyclohexancarboxamid	≥ 950 g/kg	1. Juni 2001	31. Mai 2011	Nur Verwendungen als Fungizid dürfen zugelassen werden. Bei der Entscheidungsfindung gemäß den einheitlichen Grundsätzen müssen die Mitgliedstaaten insbesondere die möglichen Auswirkungen auf Wasserorganismen berücksichtigen und sicherstellen, dass die Zulassungsbedingungen gegebenenfalls Maßnahmen zur Risikobegrenzung enthalten. Der Beurteilungsbericht wurde vom Ständigen Ausschuss für Pflanzenschutz am 19. Oktober 2000 abgeschlossen.

(1) Weitere Einzelheiten hinsichtlich der Identität und Spezifikation des Wirkstoffs sind dem Beurteilungsbericht (Dok. 6497/VI/99 Rev. 2) zu entnehmen."

COMMISSION DIRECTIVE 2001/28/EC

of 20 April 2001

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include KBR 2738 (fenhexamid) 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 [1], as last amended by Commission Directive 2001/21/EC [2], 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') the United Kingdom received on 8 May 1997 an application from Bayer plc ('the applicant') for the inclusion of the active substance KBR 2738 (fenhexamid) in Annex I to the Directive.

(2) In accordance with the provisions of Article 6(3) of the Directive the Commission confirmed in its Decision 98/398/EC [3] that the dossier submitted for KBR 2738 (fenhexamid) 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) In accordance with Article 5(1) of the Directive, an active substance should be included in Annex I for a period not exceeding 10 years if it may be expected that neither the use of, or residues from, plant protection products containing the active substance will have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment.

(4) For KBR 2738 (fenhexamid), the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of the Directive, for the uses proposed by the applicant. The United Kingdom acting as nominated rapporteur Member State, submitted a draft assessment report concerning the substance to the Commission on 15 October 1998.

(5) That assessment report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. The review was finalised on 19 October 2000 in the format of the Commission review report for KBR 2738 (fenhexamid). If the review report has to be updated to take account of technical and scientific developments, the conditions for the inclusion of KBR 2738 (fenhexamid) in Annex I to the Directive will also need to be amended in accordance with the Directive.

(6) The dossier and the information from the review were submitted to the Scientific Committee on Plants for opinion on 31 March 2000. This Committee has given its opinion on 20 July 2000 in the minutes of the meeting (SCP/REPT/021 final) [4] where it was stated that the Committee did not wish to raise any issues with regard to this active substance. The Committee also noted that national authorisations would involve specific risk management in line with Annex VI [5] (Uniform principles) of the Directive.

(7) It has appeared from the various examinations made that plant protection products containing the active substance concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a), (b) and (3) of the Directive, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include the active substance concerned in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing the active substance concerned can be granted in accordance with the provisions of the said Directive.

(8) After inclusion, a reasonable period is necessary to permit Member States to implement the provisions of the Directive on plant protection products containing KBR 2738 (fenhexamid) and in particular to review, within this period, existing provisional authorisations or to grant, by the end of this period at the latest, new authorisations in accordance with the provisions of the Directive. A longer period may also be required for plant protection products containing KBR 2738 (fenhexamid) and other active substances included in Annex I.

(9) It is appropriate to provide that the finalised review report (except for confidential information in the meaning of Article 14 of the Directive) is kept available or made available by the Member States for consultation by any interested parties.

(10) 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 those principles 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.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 69, 10.3.2001, p. 17.
[3] OJ L 176, 20.6.1998, p. 34.
[4] Minutes of the 21st meeting of the Scientific Committee on Plants, Brussels, 20 July 2000.
[5] OJ L 265, 27.9.1997, p. 87.

(11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health delivered on 19 October 2000,

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 KBR 2738 (fenhexamid) 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 August 2001. They shall forthwith inform the Commission thereof.

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.

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 existing provisional authorisations of plant protection products containing KBR 2738 (fenhexamid) to 1 August 2002.

3. However for plant protection products containing KBR 2738 (fenhexamid) together with another active substance which is in Annex I to Directive 91/414/EEC, the period referred to in paragraph 1 is extended to the extent that a longer implementation period is provided for by the provisions laid down in the Directive amending Annex I to Directive 91/414/EEC to include the substance in the Annex.

4. Member States shall keep available the review report for KBR 2738 (fenhexamid) (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 3

This Directive shall enter into force on 1 June 2001.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 April 2001.

For the Commission

David BYRNE

Member of the Commission

ANNEX

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

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'13	(fenhexamid) CAS No 126833-17-8 CIPAC No 603	N-(2,3-dichloro-4-hydroxyphenyl)-1-methyl-cyclohexanecarboxamide	≥ 950 g/kg	1 June 2001	31 May 2011	Only uses as a fungicide may be authorised. In decision making according to the Uniform Principles Member States must pay particular attention to the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. Date of Standing Committee on Plant Health at which the review report was finalised: 19 October 2000

(1) Further details on identity and specification of active substance are provided in the review report (doc. 6797/VI/99 rev. 2).'

EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH & CONSUMER PROTECTION

Directorate E - Public, animal and plant health
Unit E1 Legislation relating to crop products and animal nutrition

Fenhexamid
6497/VI/99-rev. 2
19 October 2000

FINAL

Review report for the active substance **fenhexamid**

Finalised in the Standing Committee on Plant Health at its meeting on 19 October 2000 in view of the inclusion of fenhexamid 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 fenhexamid, 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 authorities of the United Kingdom received on 8 May 1997 an application from Bayer AG, hereafter referred to as the applicant, for the inclusion of the active substance fenhexamid in Annex I to the Directive. Authorities of the United Kingdom indicated to the Commission on 16 December 1997 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 fenhexamid 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 18 February 1998, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 98/398[1] of 2 June 1998 that these requirements were satisfied.

[1] OJ No L 176, 26.06.1998, p.34.

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 the United Kingdom 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.

The United Kingdom submitted to the Commission on 15 October 1998 the report of its detailed scientific examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of fenhexamid in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States as well as to Bayer AG being the sole applicant on 15 October 1998.

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

- Identity and physical /chemical properties, analytical methods;
- Fate and behaviour in the environment;
- Eco-toxicology;
- 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 to October 1999.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 14 March 2000.

The dossier, draft assessment 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 in March 2000, and was finalised in the meeting of the Standing Committee on 19 October 2000.

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

These documents were also submitted to the Scientific Committee for Plants for a separate consultation on 30 March 2000. The results of their examination were reported in the minutes of the plenary meeting which took place on 20 July 2000.(SCP/REPT/021 – final)[2]).

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 **2001/28EC** concerning the inclusion of fenhexamid in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing fenhexamid 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 fenhexamid 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 fenhexamid containing plant protection product for which Member States will grant or review the authorisation.

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

[2] Minutes of the twenty first meeting of the Scientific Committee on Plants, Brussels, 20 July 2000.

- Fungicide for uses on fruit and vegetables

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

4. Specific conclusions which are highlighted in this evaluation

4.1 Residues of fenhexamid in foodstuffs

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 5.4%, of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This low intake value reflects the current use pattern for this active substance.

4.2 Exposure of operators, workers and bystanders

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

4.3 Ecotoxicology

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

5. Identity and Physical/chemical properties

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

The active substance shall have a minimum purity of $\geq$ 950 g/kg technical product.

The review has established that for the active substance notified by the applicant (Bayer AG), 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 by Member States in relation to the granting of authorisations of plant protection products containing fenhexamid

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and timely (within 12 months at the latest) attention from the Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- impact on aquatic organisms

Member States must pay particular attention to the risks to aquatic organisms. The Member States should apply appropriate risk mitigation measures when granting or reviewing existing authorisations.

8. List of studies to be generated

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

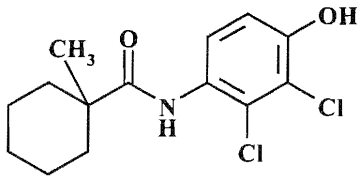
10. Updating of this review report

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 fenhexamid in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

KBR 2738 (FENHEXAMID)

Common name (ISO)	Fenhexamid
Chemical name (IUPAC)	N-(2,3-dichloro-4-hydroxyphenyl)-1-methylcyclohexanecarboxamide
Chemical name (CA)	N-(2,3-dichloro-4-hydroxyphenyl)-1-methyl-cyclohexanecarboxamide
CIPAC No	603
CAS No	126833-17-8
EEC No	Not allocated
FAO SPECIFICATION	Not allocated
Minimum purity	≥ 950 g/kg
Molecular formula	$C_{14}H_{17}Cl_2NO_2$
Molecular mass	302.2
Structural formula	

Melting point	153°C
Boiling point	Decomposition above 230 °C
Appearance	White powder, no characteristic odour
Relative density	1.34 at 20°C
Vapour pressure	1.91×10^{-6} to 2.58×10^{-6} Pa at 30 °C 4×10^{-7} Pa for 20 °C (extrapolated) 9×10^{-7} Pa for 25 °C (extrapolated)
Henry's law constant	20 °C pH 5: 9×10^{-6} Pa · m^3 · mol^{-1} pH 7: 5×10^{-6} Pa · m^3 · mol^{-1} pH 9: 3×10^{-7} Pa · m^3 · mol^{-1}
Solubility in water	pH 5: 14 mg/l at 20°C pH 7: 24 mg/l at 20°C pH 9: 412 mg/l at 20°C
Solubility in organic solvents	n-hexane < 0.1 g/l at 20 °C toluene 5.7 g/l at 20 °C dichloromethane 31 g/l at 20 °C 2-propanol 91 g/l at 20 °C 1-octanol 65 g/l at 20 °C polyethylene glycol (PEG) 110 g/l at 20 °C PEG + ethanol > 200 g/l at 20 °C acetone 160 g/l at 20 °C acetonitrile 15 g/l at 20 °C dimethylformamide > 200 g/l at 20 °C dimethylsulfoxide > 200 g/l at 20 °C
Partition co-efficient (log P_{ow})	P_{ow} log P_{ow} at 20 °C unbuffered 3300 3.52 pH 4 4200 3.62 pH 7 3200 3.51 pH 9 170 2.23
Hydrolytic stability (DT_{50})	stable at pH 5, 7 and 9 in aqueous buffer solutions.
Dissociation constant	pKa = 7.3
Quantum yield of direct photo-transformation in water at ε >290 nm	Φ = 0.083
Flammability	Not highly flammable; does not undergo spontaneous combustion
Explosive properties	Not explosive, however is dust-explosible and exhibits a lower explosible limit of 40 g/m^3
UV/VIS absorption (max.)	Peak maxima molar absorptivity [1000 cm^2/mol] 203 nm 41340 245 nm 10050 291 nm 2810
Photostability in water (DT_{50})	Experimental photolytic half-life in sterile aqueous buffered solution at 25±1 °C: 1.0 h. Environmental direct photolysis half-life: 11 d - >1 yr.

APPENDIX II

END POINTS AND RELATED INFORMATION

FENHEXAMID

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid, > 97 % absorbed
Distribution:	Widely distributed into organs at low levels.
Potential for accumulation:	No potential for accumulation (0.1 % remaining after 48 hours).
Rate and extent of excretion:	Rapidly eliminated mainly in faeces (50 – 71 % in faeces, 16 – 33 % in urine in repeated low dose study within 72 hours).
Toxicologically significant compounds:	Parent and metabolites
Metabolism in animals:	Extensively metabolised, mainly conjugation and hydroxylation

Acute toxicity

Rat LD_{50} oral:	> 5000 mg/kg bw
Rat LD_{50} dermal:	> 5000 mg/kg bw
Rat LC_{50} inhalation:	> 5 mg/l (dust aerosol, nose only)
Skin irritation:	Non-irritant
Eye irritation:	Non-irritant
Skin sensitization (test method used and result):	Skin sensitiser (M & K study but not Buehler study)

Short term toxicity

Target / critical effect:	Liver, kidney (mice) and erythrocytes (dogs)
Lowest relevant oral NOAEL / NOEL:	500 ppm (18 mg/kg bw/day) in 1 year dog study or 1000 ppm (33 mg/kg bw/day) in 90-day dog study
Lowest relevant dermal NOAEL / NOEL:	1000 mg/kg bw/day in 21 day dermal study in the rabbit
Lowest relevant inhalation NOAEL / NOEL:	0.07 mg/l (approximately 20 mg/kg bw/day) in 28-day rat study, nose-only (high doses limited by high particle overload)

Genotoxicity

No genotoxic potential.

Long term toxicity and carcinogenicity

Target / critical effect:	Kidney (mice) at high doses.
Lowest relevant NOAEL:	800 ppm (250 mg/kg bw/day) in 2-year mouse study
Carcinogenicity:	No carcinogenic potential.

Reproductive toxicity

Target / critical effect - Reproduction:	Reduced pup weight at parentally toxic doses.
Lowest relevant reproductive NOAEL / NOEL:	500 ppm (38 mg/kg bw/day)
Target / critical effect - Developmental toxicity:	Slight fetal retardation, fetal body weight, delayed ossification and decreased placental weights at maternally toxic doses
Lowest relevant developmental NOAEL / NOEL:	100 mg/kg bw/day in rabbit developmental toxicity study

Delayed neurotoxicity

No evidence of neurotoxicity (acute neurotoxicity study provided).

Other toxicological studies

No data required.

Medical data

Limited data. New compound

Summary

	Value	Study	Safety factor
ADI:	0.2 mg/kg bw/day	52-week dog study	100
AOEL systemic:	0.3 mg/kg bw/d	13-week dog	100
AOEL inhalation:	Not required/ applicable		
AOEL dermal:	Not required/ applicable		
ARfD (acute reference dose):	Not allocated. Not considered necessary.		

Dermal absorption

18% for dilutions, 2 % for concentrate (from *in vivo* rat study).

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	17-21 % AR
Non-extractable residues after 100 days:	50-77 % AR
Relevant metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	None.

Supplemental studies

Anaerobic:	No data submitted; anaerobic conditions are unlikely for significant periods for the currently proposed crops.
Soil photolysis:	No significant photolysis observed.
Remarks:	None.

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	≤ 1 day; n=4; graphical estimation
DT_{90}lab (20 °C, aerobic):	1- 10 days; n=4; graphical estimation
DT_{50}lab (10 °C, aerobic):	Not required (due to short DT50 at 20 °C)
DT_{50}lab (20 °C, anaerobic):	Not relevant for current intended uses

Field studies (country or region)

DT_{50f} from soil dissipation studies:	None submitted, none required
DT_{90f} from soil dissipation studies:	None submitted, none required [half-lives < 1 day i lab studies]
Soil accumulation studies:	No data submitted, none required
Soil residue studies:	Not required

Remarks: e.g. effect of soil pH on degradation rate	None.

Adsorption/desorption

K_f / K_{oc}:	K_f 2.45-10.75 ml/g, K_{oc} 446-1226 ml/g (n=6)
K_d	Not applicable (Kf reported above)
pH dependence:	Adsorption decreases with increasing pH.

Mobility

Laboratory studies:

Column leaching:	No data submitted, not required.
Aged residue leaching:	No data submitted, not required.

Field studies:

Lysimeter/Field leaching studies:	No data submitted, not required.

Remarks:	None.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	No hydrolysis measured at pH 5,7, and 9 at 25°C within 30 days.
Relevant metabolites:	No hydrolysis measured at pH 5,7, and 9 at 25°C within 30 days.
Photolytic degradation:	DT_{50} 1.8 hours midday summer sunlight 40°N DT_{50} 4.7 hours summer sunlight Phoenix Arizona USA first order. DT_{50} modelled from quantum yield data 22 days -> 1 year.
Relevant metabolites:	M10 benzoxazole of fenhexamid, transient

Biological degradation

Readily biodegradable:	Relevant data not available.
Water/sediment study:	
DT_{50} water:	4-7 days 1st order n=2 r^2 =0.99-1
DT_{90} water:	15-23 days
DT_{50} whole system:	6-17 days 1st order n=2 r^2 =0.99-1
DT_{90} whole system:	21-57 days
Distribution in water / sediment systems (active substance)	Between 72 and 82% of the extractable fenhexamid present in the systems was in the water phase immediately after application. This had declined to 6 and 18% after 100 days. Max. 47% dissipated into sediment.
Distribution in water / sediment systems (metabolites)	No extractable metabolites were present at > 10% AR at any sampling time. Significant levels of non extracted residues were formed.
Accumulation in water and/or sediment:	Not applicable

Degradation in the saturated zone

Not applicable

Remarks:

None.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	1.91×10^{-6} to 2.58×10^{-6} Pa at 30 °C 4×10^{-7} Pa for 20 °C (extrapolated) 9×10^{-7} Pa for 25 °C (extrapolated)
Henry's law constant:	20 °C pH 5: 9×10^{-6} Pa · m^3 · mol^{-1} pH 7: 5×10^{-6} Pa · m^3 · mol^{-1} pH 9: 3×10^{-7} Pa · m^3 · mol^{-1}

Photolytic degradation

Direct photolysis in air:	not studied, not required
Photochemical oxidative degradation in air DT_{50}:	calculated using the 'Atkinson Method' first order 7.4 hours
Volatilisation:	from plant surfaces: not studied, not required from soil: not studied, not required

Remarks:	None.

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 > 5000 mg a.s./kg bw (rat and mouse)
Acute toxicity to birds:	LD50 > 2000 mg a.s./kg bw (*Colinus virginianus)*
Dietary toxicity to birds:	NOEC > 5000 ppm (*Colinus virginianus* and *Anas platyrhynchos*)
Reproductive toxicity to birds:	NOEC 2074 ppm (*Colinus virginianus*)
Short term oral toxicity to mammals:	500 ppm (18 mg/kg bw/day) in 1 year dog study or 1000 ppm (33 mg/kg bw/day) in 90-day dog study

Aquatic Organisms

Acute toxicity fish:	LC_{50}:(*Oncorhynchus mykiss*, 96-h) 1.34 mg/l
Long term toxicity fish:	NOEC (*Oncorhynchus mykiss*, 55-d)(time to swim up): 0.101 mg/l
Bioaccumulation fish:	BCF: whole fish 132-185
Acute toxicity invertebrate:	EC_{50}: (daphnid, 48-h) >18.8 mg/l
Chronic toxicity invertebrate:	NOEC (daphnid, 21-d): 1.0 mg/l
Acute toxicity algae:	EC_{b50}: 4.31 mg/l (*Raphidocellis subcapitata*)
Chronic toxicity sediment dwelling organism:	EC50 14.2 mg a.s./l; EC5 10 mg a.s./l (*Chironomus riparius*, 28-day static test)
Acute toxicity aquatic plants:	Not required.

Honeybees

Acute oral toxicity:	LD 50 > 102 µg a.s./bee
Acute contact toxicity:	LD 50 > 200 µg a.s./bee

Other arthropod species**

Typhlodromus pyri	-34.2 % i.e. no adverse effect (Dose: 1.0 kg as/ha) -33.2 % i.e. no adverse effect (Dose: 2.0 kg as/ha)
Aphidius rhopalosiphi	No significant effect
Aleochara bilineata	No significant effect
Coccinella septempunctata	Mortality 2.4% Larval emergence 119% of control (Dose: 0.3 kg as/ha) Mortality 5.2% Larval emergence147% of control (Dose: 0.6 kg as/ha)

** tested here with the formulated product 'Bayer UK 596', a water-dispersible granule containing 500 g fenhexamid/kg

Earthworms

Acute toxicity:	LC50 >1000 mg/kg NOEC 100 mg/kg
Reproductive toxicity:	No study reported. Not required

Soil micro-organisms

Nitrogen mineralization:	No adverse effect at rates equivalent to 1 kg as/ha and 10 kg a.s./ha
Carbon mineralization:	No adverse effect at rates equivalent to 1 kg as/ha and 10 kg a.s./ha

Appendix III

FENHEXAMID

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

B.2 Physical and chemical properties

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	Date of submission
IIIA, 2.7.1/01 (2.7.3)	Wirth, W	1999/ 05/31	Storage stability and shelf life MO-99-008916 non GLP unpublished [DPDB 85676]	1999/09/15
IIIA, 2.8.6.3	Hess, T.	1999/ 09/28	Attrition resistance of granules MO-99-0016902 non GLP unpublished [DPDB 95758]	2000/03/17

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	Date of submission
IIA, 4.1/12	Reubke, K J	1999/ 06/29	KBR 2738 Analytical method 2005-0007903-99E By products – HPLC external standard Bayer file no: 2005-0007903-99E non GLP, unpublished [DPDB 85511]	1999/06/09
IIA, 4.1/13	Reubke, K J	1999/ 09/02	Validation report V01.02-2005-0007903-E KBR 2738 DN technical impurities by HPLC external standard Bayer file no: V01.02-2005-0007903-E non GLP, unpublished [DPDB 85521 (95756)]	1999/06/09
IIA, 4.2.3	Weber, H	1999/ 10/28 ;1st adde-ndum 1999/ 11/11	Validation of an analytical method (Analogous to DFG Method 5) for the determination of residues of Fenhexamid (KBR 2738) in drinking and surface water. Bayer AG, BAY-9918V GLP, unpublished [DPDB 96368]	2000/04/04

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	Date of submission
IIA, 6.3	Ohs, P.	1999/ 03/10	Factors influencing the residue behaviour of pesticides in greenhouses Bayer AG, Bayer file no.: MR-140/99 non GLP, unpublished	
IIA, 6.3.2.2.1/ 05	Nüßlein, F	1998/ 12/11	Determination of residues of KBR 2738 50WG following spray applications in the field on grape in France and Germany Bayer files nos: RA-2182/98 (817112 identic. 1711-98,, 817120 identic. 1712-98, 817139 identic. 1713-98, 817147 identic. 1714-98) GLP, unpublished [DPDB 85531]	1999/06/09
IIA, 6.3.2.2.1/ 06	Nüßlein, F	1998/ 12/15	Determination of residues of KBR 2738 50WG following spray applications in the field on grape in France, Italy, Spain and Portugal Bayer files nos: RA-2183/98 (817155 identic. 1715-98,, 817163 identic. 1716-98, 817171 identic. 1717-98, 817198 identic. 1719-98) GLP, unpublished [DPDB 85538]	1999/06/09

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	Date of submission
IIA, 8.2.7/01	Heimbach, F	1999/ 11/16	Influence of KBR 2378 (tech.) on Development and Emergence of Larvae of *Chironomus riparius* in a Water-Sediment system Study no. E 416 1690 – 7 GLP, unpublished [DPDB 94270]	2000/01/19

DPDB = data protection database, Rapporteur's internal reference system

SUMMARY REPORT
OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH
HELD ON 19 OCTOBER 2000 IN BRUSSELS

President : G. Del Bino
All Member States were present.

Extract

1 **Examination and possible vote on a Draft Commission Directive Amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include KBR 2738 (fenhexamid) as an active substance** (SANCO/1835/2000 rev 4; Review Report 6497/VI/99-rev. 2).

The Commission presented the Review Report on fenhexamid in document 6497/VI/99-rev. 2. The Committee took note of the Review Report.

The following declarations were made:

The Netherlands: "The Dutch delegation is of the opinion that for national authorisations of fenhexamid it might be appropriate to use a long-term AOEL instead of the present short-term AOEL in the endpoint list of the review report."

Commission: Same declaration as under Point 4.

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

Vote : unanimous favourable opinion.

The measures on which the Committee has given its opinion are subject to the appropriate procedures for formal adoption by the Commission.

A CHECCHI LANG
Director

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/REPT/021-Final
20 July 2000

MINUTES OF THE TWENTY FIRST MEETING OF THE SCIENTIFIC COMMITTEE ON PLANTS BRUSSELS, 20 JULY 2000

Excerpt on Fenhexamid

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W:\WSTPRUEFUNG\WIRKSTOFFE\WN2\NAS___E-L\FENHEXAMID\HEFT 91\SCPOPINION.DOC

ATTENDANCE LIST

Members

Prof.	H. V. DAVIES	
Dr.	R. HANS	
Prof.	A. R. HARDY	(Chairman)
Prof.	S. O. KARENLAMPI	
Mr	H. KOEPP	
Dr.	O. MEYER	
Dr.	A. MORETTO	
Prof.	F O' GARA	(Vice-Chairman)
Prof.	K. SAVOLAINEN	
Prof.	A. M. S. SILVA FERNANDES	
Dr.	G. SPEIJERS	

Apologies

Dr.	M.-P. DELCOUR-FIRQUET	
Dr.	H. A. KUIPER	
Dr.	J. J. LEGUAY	
Prof.	M. MARONI	(Vice-Chairman)
Dr.	H. G. NOLTING	
Dr.	T. SHERRATT	

Invited Experts

-

Commission

Mr.	W. M. MAIER	Health and Consumer Protection, E1
Mr.	L. BRESLIN	Research, B11
Mr.	B. VERACHTERT	Research, B11

Secretariat

Mr.	M. WALSH	Health and Consumer Protection, C3
Mr.	J. FERRIERE	Health and Consumer Protection, C3
Ms.	S. VAN IMPE	Health and Consumer Protection, C3

1. Welcome, Apologies and Introductory Remarks

The Chairman, Professor A. Hardy opened the meeting and welcomed the members.

2. Adoption of the agenda

The agenda was adopted.
(Doc. SCP/AGENDA/021-Rev. 3)
(http://europa.eu.int/comm/food/fs/sc/scp/agenda_en.html - ag15)

3. Declaration of interests by Members

All members present confirmed that they had no conflict of interests to report relative to the items for discussion.

4. Adoption of the minutes of the Twentieth Plenary Meeting and matters arising (6 June 2000)

4.1 Adoption of the minutes of the Twentieth Plenary Meeting

The draft minutes were approved and are available as Document SCP/REPT/020-Final.

4.2 Matters arising

None.

5. Progress report on the following plant protection product dossiers referred to the Scientific Committee on Plants

5.12 Fenhexamid

No specific question was addressed to the Committee.

Following an exchange of views the Committee decided that there were no issues that it wished to raise regarding the active substance in the context of a possible inclusion in Annex I to Directive 91/414/EEC[1]. It was recognised that national authorisations would involve specific risk management in line with Annex VI[2] (Uniform Principles) of Directive 91/414/EEC.

The Committee reiterated its earlier statements that absence of comment should only be interpreted as an indication of no obvious reasons necessitating comment.

11. Other business

[1] OJ No L 230, 09.08.1991, p.1, at last amended by Directive 1999/80/EC (OJ No L 210 of 29.07.99 p. 13).
[2] OJ No L 265, 27.09.1997, p.87.

Date of next meeting:

The next meeting of the Committee will take place on 22 September 2000.

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

Heft 72, 2000: Pflanzenschutz im ökologischen Landbau – Probleme und Lösungsansätze. Drittes Fachgespräch am 2. November 1999 in Kleinmachnow. Unkrautregulierung im ökologischen Landbau. Bearbeitet von Dr. Bernhard Pallutt, 71 S.

Heft 73, 2001: EU-Beurteilungsbericht Esfenvalerat. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 9. Bearbeitet von Edelgard Adam und Elke Leske, getr. Zählung.

Heft 74, 2001: EU-Beurteilungsbericht Bentazon. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 10. Bearbeitet von Dr. Henning Bruno und Elke Leske, getr. Zählung.

Heft 75, 2001: EU-Beurteilungsbericht Triasulfuron. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 11. Bearbeitet von Dr. Henning Bruno und Elke Leske, getr. Zählung.

Heft 76, 2001: Pflanzenschutz im ökologischen Landbau – Probleme und Lösungsansätze. Viertes Fachgespräch am 6. Juni 2000 in Darmstadt. Azadirachtin und Pyrethrine. Bearbeitet von PD Dr. habil. Stefan Kühne, 90 S.

Heft 77, 2001: Liste der zugelassenen Pflanzenschutzmittel (Stand: 1. Januar 2001). Bearbeitet von Dr. Achim Holzmann, 84 S.

Heft 78, 2001: EU-Beurteilungsbericht Lambda-Cyhalothrin. Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen. Band D 12. Bearbeitet von Edelgard Adam und Elke Leske, getr. Zählung.

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