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EU-Beurteilungsbericht Prohexadion-calcium

Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen Band D 7

Review Report Prohexadione-calcium
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 7

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Inhalt / Contents

Bereits erschienene Beurteilungsberichte / Already published Review Reports

Heft / Report	**Band / Volume** **Wirkstoff / Active Substance**	**Berichterstattender Mitgliedstaat** **Rapporteur Member State**
59/2000	D1: Fluroxypyr	Deutschland Germany
60/2000	D2: Azimsulfuron	Italien Italy
61/2000	D3: Kresoxim-methyl	Belgien Belgium
65/2000	D4: Azoxystrobin	Deutschland Germany
66/2000	D5: Spiroxamine	Deutschland Germany
69/2000	D6: Imazalil	Luxemburg Luxembourg

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 7. Heft dieser Reihe (Band D 7) 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 Prohexadion-calcium war Frankreich 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 7th report belonging to this series (Volume D 7) 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 prohexadione-calcium France acted as Rapporteur Member State.

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

Report	**Legal Regulations of the European Union for Plant Protection Products and their Active Substances**
35/97	Volume A: Directive 91/414/EEC and respective Protocols (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 2000/50/EG DER KOMMISSION

vom 26. Juli 2000

zur Aufnahme eines Wirkstoffs (Prohexadion-Calcium) in Anhang I der Richtlinie 91/414/EWG über das Inverkehrbringen von Pflanzenschutzmitteln

DIE KOMMISSION DER EUROPÄISCHEN GEMEINSCHAFTEN —

gestützt auf den Vertrag zur Gründung der Europäischen Gemeinschaft,

gestützt auf die Richtlinie 91/414/EWG des Rates vom 15. Juli 1991 über das Inverkehrbringen von Pflanzenschutzmitteln [1], zuletzt geändert durch die Richtlinie 2000/10/EG der Kommission [2], im folgenden „Richtlinie" genannt, insbesondere auf Artikel 6 Absatz 1,

in Erwägung nachstehender Gründe:

(1) Die französischen Behörden haben am 10. Februar 1994 gemäss Artikel 6 Absatz 2 der Richtlinie einen Antrag der BASF AG, im folgenden „Antragsteller" genannt, auf Aufnahme des Wirkstoffs Prohexadion-Calcium in Anhang I der Richtlinie erhalten.

(2) Gemäss Artikel 6 Absatz 3 der Richtlinie hat die Kommission in ihrer Entscheidung 96/520/EG [3] bestätigt, dass die für Prohexadion-Calcium 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 Prohexadion-Calcium 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 Frankreich der Kommission am 9. Juni 1998 den betreffenden Bewertungsbericht übermittelt.

(5) Der vorgelegte Bewertungsbericht wurde von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses für Pflanzenschutz geprüft. Diese Prüfung wurde am 16. Juni 2000 in Form des Prüfungsberichts der Kommission für Prohexadion-Calcium abgeschlossen. Der Bericht muss möglicherweise unter Berücksichtigung technischer und wissenschaftlicher Entwicklungen aktualisiert werden. In diesem Fall sind auch die Bedingungen für die Aufnahme von Prohexadion-Calcium in Anhang I der Richtlinie gemäss deren Artikel 6 Absatz 1 zu ändern.

(6) Die Unterlagen und die aus der Prüfung hervorgegangenen Informationen wurden am 26. November 1999 auch dem Wissenschaftlichen Pflanzenausschuss zur Stellungnahme vorgelegt. Dieser Ausschuss hat seine Stellungnahme am 6. Juni 2000 abgegeben.

(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 Prohexadion-Calcium 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 Prohexadion-Calcium und andere in Anhang I aufgeführte Wirkstoffe enthalten, kann auch eine längere Frist erforderlich sein.

(9) Es ist vorzuschreiben, dass die Mitgliedstaaten den endgültigen Prüfungsbericht (mit Ausnahme von vertraulichen Informationen im Sinne des Artikels 14 der Richtlinie) allen Betroffenen zur Einsicht zur Verfügung stellen oder zugänglich machen.

(10) Der Prüfungsbericht 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 nach Anhang II beziehen, die zwecks Aufnahme des Wirkstoffs in Anhang I der Richtlinie vorgelegt wurden.

(11) Die in dieser Richtlinie vorgesehenen Massnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz vom 16. Juni 2000 —

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

Prohexadion-Calcium wird hiermit gemäss dem Anhang der vorliegenden Richtlinie als Wirkstoff in Anhang I der Richtlinie 91/414/EWG aufgenommen.

[1] ABl. L 230 vom 19.8.1991, S. 1.
[2] ABl. L 57 vom 2.3.2000, S. 28.
[3] ABl. L 220 vom 30.8.1996, S. 19.

Artikel 2

(1) Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens 1. Januar 2001 nachzukommen.

(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 jedoch auf der Grundlage von Unterlagen, die die Anforderungen von Anhang III derselben Richtlinie erfüllen, für vorläufige Zulassungen von Pflanzenschutzmitteln, die Prohexadion-Calcium enthalten, bis zum 1. Januar 2002 verlängert.

(3) Bei Pflanzenschutzmitteln, die Prohexadion-Calcium 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 Aufnahme dieses anderen Wirkstoffes in den genannten Anhang I eine längere Umsetzungsfrist vorsehen.

(4) Die Mitgliedstaaten stellen den Prüfungsbericht (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.

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

Artikel 3

Diese Richtlinie tritt am 1. Oktober 2000 in Kraft.

Artikel 4

Diese Richtlinie ist an alle Mitgliedstaaten gerichtet.

Brüssel, den 26. Juli 2000

Für die Kommission

David BYRNE

Mitglied der Kommission

ANHANG

1. **Prohexadion-Calcium**

1. Identität: (IUPAC) Calcium 3,5-dioxo-4-propionylcyclohexancarboxylat

2. Zu erfüllende Bedingungen:

2.1. Der Wirkstoff muß eine Reinheit von mindestens 890 g/kg technisches Erzeugnis aufweisen.

2.2. Nur Verwendungen als Wachstumsregler dürfen zugelassen werden.

2.3. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 16. Juni 2000 abgeschlossenen Prüfungsberichts über Prohexadion-Calcium und insbesondere dessen Anlagen I und II zu berücksichtigen.

3. Aufnahme befristet bis: 1. Oktober 2010.

COMMISSION DIRECTIVE 2000/50/EC

of 26 July 2000

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Whereas:

(1) In accordance with Article 6(2) of the Directive, on 10 February 1994, France received an application from BASF AG, hereafter referred to as 'the applicant', for the inclusion of the active substance prohexadione-calcium 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 96/520/EC [3] that the dossier submitted for prohexadione-calcium 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 prohexadione-calcium, 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. France acting as nominated rapporteur Member State, submitted to the Commission on 9 June 1998 the draft assessment report concerned.

(5) 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 16 June 2000 in the format of the Commission review report for prohexadione-calcium. 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 prohexadione-calcium in Annex I to the Directive will also need to be amended pursuant to Article 6(1) of that Directive.

(6) The dossier and the information from the review were also submitted to the Scientific Committee for Plants for opinion on 26 November 1999. This Committee gave its opinion on 6 June 2000.

(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 prohexadione-calcium 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 prohexadione-calcium 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 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.

(11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health delivered on 16 June 2000,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 57, 2.3.2000, p. 28.
[3] OJ L 220, 30.8.1996, p. 19.

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 January 2001.

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 prohexadione-calcium to 1 January 2002.

3. However for plant protection products containing prohexadione-calcium 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 concerning the inclusion of this other active substance in Annex I to Directive 91/414/EEC.

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

5. When Member States adopt the measures, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The Member States shall lay down the procedure for such reference.

Article 3

This Directive shall enter into force on 1 October 2000.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 July 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX

1. **Prohexadione-calcium**

1. Identity: (IUPAC) Calcium 3,5-dioxo-4-propionylcyclohexanecarboxylate

2. Particular conditions to be fulfilled:

2.1. The active substance shall have a minimum purity of 890 g/kg.

2.2. Only uses as plant growth regulator may be authorised.

2.3. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on prohexadione-calcium, and in particular the Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 16 June 2000 shall be taken into account.

3. Expiry date of the inclusion: 1 October 2010.

EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH & CONSUMER PROTECTION

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

Prohexadione calcium

7475/VI/99-rev. 8

16 June 2000

FINAL

Review report for the active substance **prohexadione-calcium**

Finalised in the Standing Committee on Plant Health at its meeting on 16 June 2000 in view of the inclusion of prohexadione-calcium 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 prohexadione-calcium, made in the context of the work provided for in Articles 5 and 6 of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the French authorities received on 10 February 1994 an application from BASF AG, hereafter referred to as the applicant, for the inclusion of the active substance prohexadione-calcium in Annex I to the Directive. The French authorities indicated to the Commission on 4 January 1995 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 prohexadione-calcium 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 25 September 1995, 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 96/520/EC[1] of 14 June 1996 that these requirements were satisfied.

[1] OJ No L220, 30.08.1996, p.19.

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

France submitted to the Commission on 9 June 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 prohexadione-calcium in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States on 22 June 1998 as well as to BASF AG being the sole applicant on 1 July 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 ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from September 1998 to January 1999.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 18 May 1999.

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 in September 1999 and was finalised in the meeting of the Standing Committee on 16 June 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 separate consultation. The results of this consultation were reported in the meeting of the Committee, which took place on 6 June 2000 [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 **00/50/EC** concerning the inclusion of prohexadione-calcium in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing prohexadione-calcium 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 prohexadione-calcium 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 prohexadione-calcium containing plant protection product for which Member States will grant or review the authorisation.

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[2] SCP/REPT/019-final

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

Plant growth regulator winter wheat and barley

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

4. Specific conclusions which are highlighted in this evaluation

4.1 Residues of prohexadione calcium 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 1 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This low intake value reflects the current limited use pattern for this active substance.

4.2 Exposure of operators, workers and bystanders

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

4.3 Environment

The review has 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.

5. Identity and Physical/chemical properties

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

The active substance shall have a minimum purity of 890 g/kg technical product.

The review has established that for the active substance notified by the applicant (BASF 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 on short term basis by Member States in relation to the granting of authorisations of plant protection products containing prohexadione-calcium

On the basis of the proposed and supported uses, no particular issue has been identified which require particular condition of use to be applied at the level of annex I inclusion

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 prohexadione-calcium 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.

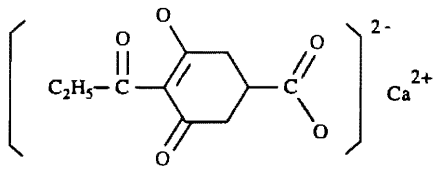
10. Updating of this review report

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 prohexadione-calcium in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

PROHEXADIONE CALCIUM

Common name (ISO)	Prohexadione-calcium
Chemical name (IUPAC)	Calcium 3,5-dioxo-4-propionylcyclohexanecarboxylate
Chemical name (CA)	Cyclohexanecarboxylic acid, 3,5-dioxo-4-(1-oxopropyl)-,ion (1-), calcium,calcium salt (9CI)
CIPAC No	567
CAS No	127277-53-6
EEC No	Not allocated
FAO SPECIFICATION	Not allocated
Minimum purity	890 g/kg
Molecular formula	$C_{10}H_{10}O_5Ca$
Molecular mass	250.26
Structural formula	

Melting point	> 360 °C
Boiling point	Not required
Appearance	White fine powder - no odour (purity 96.6 %) yellow brown powder - sweet smell odour (purity 91.9 %)
Relative density	1.44 at 22 °C (purity 96.6%) as density
Vapour pressure	$1.335 \cdot 10^{-5}$ Pa at 25 °C $1.737 \cdot 10^{-5}$ Pa at 20 °C
Henry's law constant	$1.9 \cdot 10^{-5}$ Pa·m^3·mol^{-1}
Solubility in water	At 20 °C, purity 96,6 %: pH 5 (buffer) : 1602 mg/l pH 7 (buffer) : 786 mg/l pH 9 (buffer) : 665 mg/l pH 6.5 (water) : 174 mg/l
Solubility in organic solvents	At 20°C: acetone : $4 \cdot 10^{-5}$ g/l at 20 °C toluene : $4 \cdot 10^{-6}$ g/l dichloromethane : $4 \cdot 10^{-6}$ g/l hexane : < $3 \cdot 10^{-6}$ g/l methanol : $1 \cdot 10^{-3}$ g/l ethyl acetate : < $1 \cdot 10^{-5}$ g/l
Partition co-efficient (log P_{OW})	- 2.90 at 20 °C, pH 7
Hydrolytic stability (DT_{50})	pH 9: 89 d at 22 °C pH 7: 21 d pH 5: < 5 d
Dissociation constant	pKa : 5,15
Quantum yield of direct photo-transformation in water at λ >290 nm	$2.89 \cdot 10^{-4}$ mol · einstein^{-1} at pH 7 $6.5 \cdot 10^{-4}$ mol · einstein^{-1} at pH 4
Flammability	Not flammable
Explosive properties	Not explosive
UV/VIS absorption (max.)	in water : λ max : 273 nm (ε = 15400 l·mol^{-1}·cm^{-1}) shoulder 234 nm (ε = 3145 l·mol^{-1}·cm^{-1}) No absorbance > 290 nm
Photostability (DT_{50})	≈ 4 d

APPENDIX II

END POINTS AND RELATED INFORMATION

PROHEXADIONE CALCIUM

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	About 80 % based on urinary excretion
Distribution:	Widely distributed
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	Rapidly excreted; about 80 % via urine and 20 % via faeces in 24 hours
Toxicologically significant compounds:	Parent compound
Metabolism in animals:	Hydrolysis, excreted essentially as free acid and glucuronide conjugates

Acute toxicity

Rat LD_{50} oral:	> 5000 mg/kg bw
Rat LD_{50} dermal:	> 2000 mg/kg bw
Rat LC_{50} inhalation:	> 4.21 mg/l
Skin irritation:	Non-irritant
Eye irritation:	Non-irritant
Skin sensitization (test method and result):	Non-sensitising (M & K)

Short term toxicity

Target / critical effect:	Kidney and hematotoxicity at high dose levels
Lowest relevant oral NOAEL / NOEL:	90-d rat: 1000 ppm (73 mg/kg bw/d) 1-year, dog: 20 mg/kg bw/d
Lowest relevant dermal NOAEL / NOEL:	No data, no study required
Lowest relevant inhalation NOAEL / NOEL:	No data, no study required

Genotoxicity

No genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect:	Kidney at very high dose levels
Lowest relevant NOAEL:	2-year, rat: 2000 ppm (94 mg/kg bw/d)
Carcinogenicity:	No carcinogenic potential

Reproductive toxicity

Target / critical effect - Reproduction:	Reduced pup weight at parental toxic doses
Lowest relevant reproductive NOAEL / NOEL:	500 ppm (35 mg/kg bw/d)
Target / critical effect - Developmental toxicity:	Embryo-/fetotoxicity at maternal toxic doses
Lowest relevant reproductive NOAEL / NOEL:	Rabbit: 100 mg/kg bw/d

Delayed neurotoxicity

Not relevant

Other toxicological studies

No data

Medical data

No data, new compound.

Summary

	Value	Study	Safety factor
ADI:	0.2 mg/kg bw	dog, 1 year study	100
AOEL systemic:	0.35 mg/kg bw/d	rat, multigeneration study	100
AOEL inhalation:	Not required		
AOEL dermal:	Not required		
ARfD (acute reference dose):	Not allocated (not necessary)		

Dermal absorption

No data, 10 % default value assumed

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	Ring labelled prohexadione 62.8 % (32 d)
Non-extractable residues after 100 days:	max. 27.6 % (4 d), 21 % (32 d)
Relevant metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	none (the acid form of prohexadione calcium (KI 2817) is considered as equivalent to the parent)

Supplemental studies

Anaerobic:	same as under aerobic condition
Soil photolysis:	no data provided, not required due to rapid biodegradation
Remarks:	Anaerobic degradation and photodegradation not significant under real conditions

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):

DT_{50lab} (20°C, aerobic):

	pH	OC (%)	DT50 (days)
Loamy sand	5.6	2.2	< 0.5
Clay loam	5.8	3.3	< 1
Sandy silt loam	5.3	2.3	< 0.5
Loamy sand	6.9	0.6	< 0.5

DT_{90}lab (20 °C, aerobic):

DT_{90lab} (20°C, aerobic):

	pH	OC (%)	DT90 (days)
Loamy sand	5.6	2.2	< 1
Clay loam	5.8	3.3	< 8
Sandy silt loam	5.3	2.3	< 2
Loamy sand	6.9	0.6	< 1

DT_{50}lab (10 °C, aerobic):

DT_{50lab} (10°C, aerobic):

	pH	OC (%)	DT50 (days)
Loamy sand	5.6	2.2	< 2
Clay loam	5.8	3.3	< 4
Sandy silt loam	5.3	2.3	< 8
Loamy sand	6.9	0.6	< 1

DT_{50}lab (20 °C, anaerobic):

DT_{50lab} (20°C, anaerobic):

< 4 d (same soils)

Field studies (country or region)

DT_{50f} from soil dissipation studies:	No data provided, not required
DT_{90f} from soil dissipation studies:	No data provided, not required
Soil accumulation studies:	Not relevant
Soil residue studies:	Not relevant

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

No pH dependence

Adsorption/desorption

K_f / K_{OC}:

K_d

pH dependence:

Soil type	OC (%)	pH	Koc	slope
Loamy sand	2.2	5.6	166*	1.02
Clay loam	3.3	5.8	307*	1.04
Sandy silt loam	2.3	5.3	263*	1.01
Sandy loam	0.6	6.9	82	0.93

* value overestimated due to possible degradation

No pH dependence

Mobility

Laboratory studies:

Column leaching:

5 soils (sand 31-87 %, clay 3.5-21 %, OC 0.6-3.3 %, pH 5.8-6.9)

< 1 % of applied RA in CO_2 free leachates

29 % as KI 2817 (acid form) for one soil due to soil compaction and slower degradation under anaerobic condition

Aged residue leaching:

3 soils (13 hours incubation)

< 1 % of applied RA in CO_2 free leachates

Field studies:

Lysimeter/Field leaching studies:

No data provided, not required

Remarks:

No remarks

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	pH 5 (25° C) DT_{50} 4.4 d pH 7 (25° C) DT_{50} 65 d pH 9 (25° C) stable
Relevant metabolites:	KI 5376 : 91.6 % (pH 5), 24.1 % (pH 7)
Photolytic degradation:	Prohexadione calcium (pH 6.1) - dark : metabolite KI 5376 > 10 % - light : DT_{50} 4 d, Tricarballylic acid > 10 %
Relevant metabolites:	Acid form (KI 2817, pH 3.8) - same as for prohexadione calcium KI 5376 (pH 3.8) - dark : stable - light : Tricarballylic acid > 10 %

Biological degradation

Readily biodegradable:	No (according to OECD guideline 301B, 301D)
Water/sediment study:	
DT_{50} water:	< 2 d (acid form of prohexadione, graphic estimation)
DT_{90} water:	< 15 d (id.)
DT_{50} whole system:	< 2 d (id.)
DT_{90} whole system:	< 15 d (id.)
Distribution in water / sediment systems (active substance)	< 10 % in sediment
Distribution in water / sediment systems (metabolites)	< 10 % in both water and sediment mineralization : 76 – 84 % (100 d) non-extractable : 6 % (100 d)
Accumulation in water and/or sediment:	Not relevant

Degradation in the saturated zone

degradation in the saturated zone: not relevant

Remarks:

Leaching to the unsaturated zone not expected

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	$1.7 \cdot 10^{-5}$ Pa at 20 °C
Henry's law constant:	$1.9 \cdot 10^{-5}$ $Pa \cdot m^3 \cdot mol^{-1}$

Photolytic degradation

Direct photolysis in air:	No data provided, not required (no absorbance above 290 nm)
Photochemical oxidative degradation in air DT_{50}:	DT_{50} 31 h
Volatilisation:	from plant surfaces: no data provided
	from soil: no data provided

Remarks:	Low risk for air contamination

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 (rat) > 5 000 mg/kg b.w.
subchronic oral toxicity to mammals:	NOAEL (90-d, rat) = 1 000 ppm
Acute toxicity to birds:	LD50 (bobwhite quail) > 2 000 mg/kg b.w.
Dietary toxicity to birds:	LC50 (bobwhite quail) > 5 200 ppm LC50 (mallard duck) > 5 200 ppm
Reproductive toxicity to birds:	NOEC (Japanese quail) = 1 000 ppm

Aquatic Organisms

Acute toxicity fish:	LC50 (rainbow trout, bluegill sunfish 96 h): > 100 mg/l
Long term toxicity fish:	NOEC (rainbow trout, 28 d) = 100 mg/l
Bioaccumulation fish:	log P_{ow} = -2.9 (pH 7), no study
Acute toxicity invertebrate:	EC50 (daphnid, 48 h) > 100 mg/l
Chronic toxicity invertebrate	NOEC (daphnid, 21 d) = 100 mg/l
Acute toxicity algae:	EC50 (*S. capricornutum*,120 h) > 100 mg/l
Chronic toxicity sediment dwelling organism:	not required
Toxicity to aquatic plants	EC50 (*Lemna gibba, 14 d*) > 1.2 mg/l

Honeybees

Acute oral toxicity:	LD50 > 100 microg a.s./bee LD50 > 122 microg preparation [1]/bee
Acute contact toxicity:	LD50 > 100 microg a.s./bee

[1] mixture of 0.75 kg WG (10% w/w prohexadione calcium) + 1.0 l SL (46% w/v mepiquat-chloride)

Other arthropod species

A. rhopalosiphi	E [1] = 0% (mortality; 1.79 kg preparation/ha) E = - 16% (reproduction; 1.79 kg preparation/ha)
T. pyri	E = 1.2% (mortality; 1.79 kg preparation/ha) E = - 27.5% (reproduction; 1.79 kg preparation/ha)
C. septempunctata	E = 12.3% (mortality, reproduction; 1.79 kg preparation/ha)
C. carnea	E = 5.7% (mortality, reproduction; 0.41 kg preparation/ha)
A. bilineata	E = - 2.5% (reproduction; 0.6 % [2] w/v preparation)
P. cupreus	E = 0 % (mortality, behaviour, food consumption; 1.79 kg preparation/ha)

[1] E = reduction of beneficial effect

[2] test concentration

Earthworms

Acute toxicity:	LC50 > 1 000 ppm (a.s.) LC50 = 432 ppm (preparation)
Reproductive toxicity:	no data

Soil micro-organisms

Nitrogen transformation:	preparation: effects < ± 25% (at 0.1 and 0.5 mg a.s./kg)
Carbon mineralization:	a.s.: effects < ± 25% (at 0.14 and 0.7 mg a.s./kg)

Appendix III

PROHEXADIONE CALCIUM

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

Annex II *Data and Information*

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Date of submission (d/m/y)
II A 2.28	O'Connor, J.	1994	BX-112: The behaviour on BX-112 in water, Addendum BASF - Reg.Doc. # BASF 94/10092 GLP or GEP : Y Not published	14.07.98
II A 2.29	Löffler, Dr.	1991	Final report for application to BBA : KIM 112 FW 114 BASF - Reg.Doc. # BASF 91/11956 GLP or GEP : Y Not published	14.07.98
II A 2.30	Gückel W.; Dr.	1992	Physical properties report for 285 342 (KIM 112) (Surface tension) BASF - Reg.Doc. # BASF 92/10304 GLP or GEP : Y Not published	14.07.98
II A 4.12	Perez R.; Truitt J.A.; Patel J.R.; Waitt G	1997	Method Validation - Determination of residues of Prohexadione-calicum and its metabolite despropionyl-prohexadione in soil using HPLC/UV detector BASF - Reg.Doc. # BASF 97/5038 GLP or GEP : Y Not published	29.12.1998
II A 4.13	Howell R.E.; Artz S.C.	1997	Method Validation - Analytical Method for the determination of residues of Prohexadione-calcium and its metabolite, despropionyl-prohexadione, in soil using HPLC/UV detection BASF - Reg.Doc. # BASF 97/5393 GLP or GEP : Y Not published	29.12.1998
II A 4.14	Mackenroth C.	1992	GC/MS Determination of Prohexadione-calcium in wheat (green matter, grain and straw) BASF - Reg.Doc. # BASF 92/12103 GLP or GEP : Y Not published	14.07.98
II A 4.15	O'Connor J.	1995	BX-112 : Method validation in soil - Final Report BASF - Reg.Doc. # BASF 95/11294 GLP or GEP : Y Not published	14.07.98

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 (d/m/y)
II A 4.16	Abdel-Baky S. ; Baumann S.	1997	Method of determination of BAS 125W and its metabolite in animal tissues, milk and apple commodities. BASF - Reg.Doc. # BASF 97/5034 GLP or GEP : Y Not published	14.07.98
II A 4.17	Zangmeister W.	2000	Validation of Analytical Method 459. Determination of BAS 125W (Reg.No.285342)in Air by HPLC-UV BASF-Reg.Doc.# BASF 2000/1000126 GLP or GEP : yes Not published	10.02.00
II A 5.37	Rossbacher R.; Kirsch H.	1995	Report on the Maximization test for the sensitizing potential of Prohexadione-calcium in guinea pigs BASF - Reg.Doc. # BASF 95/10028 GLP or GEP : Y Not published	14.07.98
II A 5.38	Rossbacher R.; Kirsch H.	1996	Amendment No. 1 to the Report on the Maximization test for the sensitizing potential of Prohexadione-calcium in guinea pigs BASF - Reg.Doc. # BASF 96/10211 GLP or GEP : Y Not published	14.07.98
II A 5.39	Inoue H.	1993	Amendment No. 1 to the Report Chronic feeding and oncogenicity study in rats with BX-112 technical BASF - Reg.Doc. # BASF 93/11350 GLP or GEP : Y Not published	14.07.98
II A 6.14	Steggles, H.A.	1993	Residues of prohexadione-calcium in winter barley following application of BAS 9054 2 W and BAS 083 00 W in the UK in 1992 BASF - Reg.Doc. # BASF 93/11345 GLP or GEP : Y Not published	14.07.98
II A 6.15	Gillis N.	1993	Determination of residues in cereals treated with BAS 9054 2 W and BAS 083 00 W during field trials conducted in Germany in 1992 BASF - Reg.Doc. # BASF 93/10748 GLP or GEP : Y Not published	14.07.98
II A 6.16	Miner C.	1994	Addendum to Report Volume 2 Metabolism BX-112: Adsorption, Distribution, metabolism and excretion study in the lactating goat BASF - Reg.Doc. # BASF 93/10118 GLP or GEP : Y Not published	14.07.98

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 (d/m/y)
II A 6.17	Miner C.	1994	Second Amendment to Report Volume 2 Metabolism BX-112: Adsorption, Distribution, metabolism and excretion study in the lactating goat BASF - Reg.Doc. # BASF 93/10334 GLP or GEP : Y Not published	14.07.98
II A 6.18	Steginsky C.A.,et al.	1997	Metabolism of BAS 125 W in Egg-Laying White Leghorn Hens BASF - Reg.Doc. # BASF 97/5331 GLP or GEP : Y Not published	25.11.1998
II A 6.19	Mackenroth C.	1995	Investigation of the storage stability of Prohexadione-calcium in wheat - Test of storage stability in green matter, grain and straw BASF - Reg.Doc. # BASF 95/10624 GLP or GEP : Y Not published	25.11.1998
A II 6.20	Formenko J.	1996	PAM I Multiresidue Testing for BAS 125 W and its Metabolite BASF - Reg.Doc. # BASF 96/5196 GLP or GEP : Y Not published	13.11.98
A II 6.21	Nagai Y.; et al	1994	Metabolism of Prohexadione-calcium in rat Identification of Metabolites in uring and faeces BASF - Reg.Doc. # BASF 94/11272 GLP or GEP : Y Not published	17.11.98
A II 6.22	Burkey J.	1998	Prohexadione calcium use in pome fruits and peanuts ; plant/animal residue overview BASF – Reg.Doc.No.# BASF 98/5203 GLP or GEP : N Not published	15.01.99
A II 6.23	Patel J.R., Singh M., Oswald J.	1998	Metabolism of 14C-BAS 125W in apples. BASF-Reg.Doc.No.# BASF 97/5005 GLP or GEP : Y Not published	27.05.99
A II 7.15	O'Connor J.	1994	BX-112 : BBA Plant Protection Evaluation Degradation and Retention of pesticides in the water/sediment system BASF - Reg.Doc. # BASF 94/10949 GLP or GEP : Y Not published	14.07.98
A II 7.16	O'Connor J.	1994	BX-112 : The behaviour of BX-112 in water BASF - Reg.Doc. # BASF 94/10092 GLP or GEP : Y Not published	14.07.98
A II 7.17	Singh M.	1995	Hydrolysis of Prohexadione-calcium in aqueous media BASF - Reg.Doc. # BASF 95/5186 GLP or GEP : Y Not published	29.12.1998

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 (d/m/y)
A II 7.18	Wait G., et al	1997	Method Validation of BAS Analytical Method No. D 9512 HPLC Method for determination of Prohexadione-calcium (BAS 125 W) and Storage stability in aqueous media BASF - Reg.Doc. # BASF 97/5032 GLP or GEP : Y Not published	4.09.98
A II 8.11	Thompson S.G., Swigert J.P., Haughey D.W., Qiu J.	1997	BAS 125 W - A 14-day toxicity test with duckweed (Lemna gibba G3) BASF - Reg.Doc. # BASF 97/5016 GLP or GEP : Y Not published	18.03.1999

Annex III Data and Information

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Date of submission (d/m/y)
III A 2.4	Ziegler H.	1995	Storage stability of BAS 9054 4 W two year study - Analytical results BASF - Reg.Doc. # BASF 95/10365 GLP or GEP : Y Not published	14.07.98
III A 2.5	Kästel R.	1994	Storage stability Physical Properties Report for BAS 9054 4 W BASF - Reg.Doc. # BASF 94/10906 GLP or GEP : Y Not published	14.07.98
III A 2.6	Löffler U.	1998	Absence of explosivity risks and of oxidizing properties of the granular product BAS 9054 4 W BASF - Reg.Doc. # BASF 98/11204 GLP or GEP : N Not published	13.11.1998
III A 5.10	Ziegler H.	1992	Determination of Prohexadione-calcium in BAS 9054 4 W, Addendum BASF - Reg.Doc. # BASF 92/11552 GLP or GEP : N Not published	14.07.98
III A 7.30		1997	Data on exposure BASF - Reg.Doc. # BASF 97/11279 GLP or GEP : N Not published	14.07.98
III A 7.36		1998	Data on exposure BASF – Reg.Doc.# BASF 98/11335 : third amendment GLP or GEP : N Not published	11.12.98
III A 7.37	Wiemann C. ; Hellwing J.	1999	Tankmix (Kombinationspräparat mit BAS 083 00 W und BAS 125 10 W). Modified Buehler test (9 inductions) in guinea pigs. BASF – Reg. Doc. # BASF 99/10742 GLP or GEP : Y Not published	5.07.99
III A 9.15	Sarafin R.	1993	Laboratory Study on the Volatilization of Prohexadione-calcium after application of BAS 9054 4 W/BAS 083 00 W (Tank-mix) on soil and Plant Surfaces BASF - Reg.Doc. # BASF 93/11170 GLP or GEP : Y Not published	4.09.98

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 (d/m/y)
III A 10.11	Bühler A.	1999	Effect of the combination product BAS 08300W + BAS 905 42W on the predatory mite Typhlodromus pyri (Acari : Phytoseiidae) in an extended laboratory trial. BASF – Reg.Doc.# BASF 99/11938 GLP or GEP : Y Not published	20.12.99
III A 10.12	Schuld M.	1999	Tank-mix (combination product) of BAS 083 00W + BAS 905 42 W : toxicity to the Aphid Parasitoid, Aphidius rhopalosiphi (Hymenoptera, Braconidae) using an extended laboratory test. BASF- Reg.Doc. # BASF 99/11950 GLP or GEP : Y Not published	20.12.99

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

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

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

Extract

1 Examination and possible opinion on a Draft Commission Directive concerning the inclusion of prohexadione calcium in Annex I to Council Directive 91/414/EEC (SANCO/1005/2000).

The Commission presented the Review Report on Prohexadione Calcium in document 7475/VI/99-rev. 8. The Committee took note of the Review Report.

The following declarations were made:

Sweden: Since 1987, plant growth regulators are not allowed to be used in cereals in Sweden, except in rye for which there are no short straw (lodging resistant) varieties available at present. This regulation is based on a general restrictive national view on the use of all agrochemicals and is also in line with the Council Resolution of the 5th Environmental Action Programme. We also fear that allowing plant growth regulators may as a consequence indirectly increase the risk of nitrogen eutrophication.

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

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

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

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

Vote : favourable opinion by qualified majority. One MS abstained (SE).

The substance is a new active substance to be used as a growth regulator in cereals.

A CHECCHI LANG
Director

EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH & CONSUMER PROTECTION

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

SCIENTIFIC COMMITTEE ON PLANTS

SCP/REPT/019- FINAL
6 June 2000

MINUTES OF THE NINETEENTH MEETING OF THE SCIENTIFIC COMMITTEE ON PLANTS BRUSSELS, 17 MARCH 2000

(Extract)

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...

6. Progress reports on the following plant protection product dossiers referred to the Scientific Committee on Plants

...

6.4 Prohexadione calcium

This new active substance had been referred to the Committee without a specific question(s). The Committee had agreed a procedure for dealing with such cases which is outlined under item 4.2 of the minutes of the Seventeenth Plenary Report[1]. In such cases, the relevant review documentation would be submitted to the Committee for information and the period between meetings allowed for the Committee to react. Prohexadione calcium had been submitted to the Committee at its last meeting of 28 January 2000. The Committee reiterated its earlier statements that absence of comment should only be interpreted as an indication of no obvious reasons necessitating comment.

Following and 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 1 to Directive 91/414/EEC[2]. It was recognised that national authorisations would involve specific risk management in line with Annex VI[3] (Uniform Principles) of Directive 91/414/EEC.

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[1] http://europa.eu.int/comm/dg24/health/sc/scp/out57_en.html
[2] OJ No L 230, 09.08.1991, p.1., as corrected in OJ NoL 170, 25.6.1992, p.40
[3] OJ No L 265, 27.09.1997, p.87.

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