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EU-Beurteilungsbericht Bentazon
Rechtliche Regelungen der Europäischen Union
zu Pflanzenschutzmitteln und deren Wirkstoffen
Band D 10

Review Report Bentazon
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 10

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Inhalt / Contents

Vorwort / Preface

Richtlinie 2000/68/EG der Kommission

Commission Directive 2000/68/EC

Review Report 7585/VI/97-final

Summary Report of the Meeting of the Standing Committee on Plant Health held on
13 July 2000

Opinion of the Scientific Committee on Plants, 8 December 2000

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
70/2000	D7: Prohexadion-calcium	Frankreich France
71/2000	D8: Metsulfuron-methyl	Frankreich France
73/2000	D9: Esfenvalerat	Portugal Portugal

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 10. Heft dieser Reihe (Band D10) enthält nicht die Hintergrunddokumente A, B und C des Beurteilungsberichtes. Diese können bei Bedarf bei der BBA eingesehen oder für die Wirkstoffe, für die Deutschland Berichtersteller ist, ebenfalls beim Saphir Verlag gegen Erstattung der Unkosten bezogen werden. Für Bentazon war Deutschland Berichtersteller.

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

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

Preface

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

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

The Federal Biological Research Centre makes available review reports as reports from the Federal Biological Research Centre for Agriculture and Forestry, Volume D of the series "Legal Regulations of the European Union for Plant Protection Products and their Active Substances" via Saphir Verlag against reimbursement of expenses. The present 10th report belonging to this series (Volume D10) 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 bentazone Germany acted as Rapporteur Member State.

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

Report	Legal Regulations of the European Union for Plant Protection Products and their Active Substances
35/97	Volume A: Directive 91/414/EEC and respective Protocols (3 rd Edition, date: 1 November 1997)
68/2000	Volume B: Regulations and Protocols regarding the Evaluation of Active Substances (4 th Edition, date: 1 July 2000)
	Volume C: <i>In Progress</i>

RICHTLINIE 2000/68/EG DER KOMMISSION

vom 23. Oktober 2000

zur Aufnahme des Wirkstoffs Bentazon in Anhang I der Richtlinie 91/41/EWG des Rates 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⁾, insbesondere auf Artikel 6 Absatz 1 und Artikel 8 Absatz 2 Unterabsatz 4,

in Erwägung nachstehender Gründe:

- (1) Mit der Verordnung (EWG) Nr. 3600/92 der Kommission⁽³⁾, zuletzt geändert durch die Verordnung (EG) Nr. 2266/2000⁽⁴⁾, wurden die Durchführungsbestimmungen für die erste Stufe des Arbeitsprogramms gemäß Artikel 8 Absatz 2 der Richtlinie 91/414/EWG (im Folgenden „die Richtlinie“ genannt) erlassen. Gemäß vorgenannter Verordnung wurde mit der Verordnung (EG) Nr. 933/94 der Kommission⁽⁵⁾, zuletzt geändert durch die Verordnung (EG) Nr. 2230/95⁽⁶⁾, die Liste der Wirkstoffe in Pflanzenschutzmitteln festgelegt, die im Hinblick auf ihre mögliche Aufnahme in Anhang I der Richtlinie zu bewerten sind.
- (2) Gemäß Artikel 5 Absatz 1 der Richtlinie ist ein Wirkstoff in Anhang I aufzunehmen, wenn angenommen werden kann, dass weder die Anwendung von Pflanzenschutzmitteln, die diesen Wirkstoff enthalten, noch deren Rückstände schädliche Auswirkungen auf die Gesundheit von Mensch und Tier oder auf das Grundwasser bzw. unannehmbare Auswirkungen auf die Umwelt haben werden.
- (3) Ein solcher Wirkstoff kann für einen Zeitraum von höchstens zehn Jahren in Anhang I aufgenommen werden.
- (4) Die Auswirkungen von Bentazon auf die menschliche Gesundheit und auf die Umwelt wurden gemäß den Bestimmungen der Verordnung (EWG) Nr. 3600/92 für eine Reihe von vom Antragsteller vorgeschlagenen Anwendungen geprüft. Deutschland wurde gemäß der Verordnung (EG) Nr. 933/94 über die Festsetzung der Wirkstoffe von Pflanzenschutzmitteln und die Bestimmung der Bericht erstattenden Mitgliedstaaten zur Durchführung der Verordnung (EWG) Nr. 3600/92 zum Bericht erstattenden Mitgliedstaat ernannt und hat der Kommission am 13. November 1996 den betreffenden Bewertungsbericht und die Empfehlung gemäß Artikel 7 Absatz 1 Buchstabe c) der Verordnung (EWG) Nr. 3600/92 übermittelt.

- (5) Der Bewertungsbericht wurde von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses für Pflanzenschutz geprüft. Diese Prüfung wurde am 13. Juli 2000 in Form des Prüfungsberichts der Kommission für Bentazon abgeschlossen.
- (6) Die Unterlagen und die aus der Prüfung hervorgegangenen Informationen wurden auch dem Wissenschaftlichen Ausschuss „Pflanzen“ zur Stellungnahme vorgelegt. In seiner Stellungnahme⁽⁷⁾ hat der Wissenschaftliche Ausschuss „Pflanzen“ bestätigt, dass der Wirkstoff ohne unvermeidbares Risiko verwendet werden kann. Die Mitgliedstaaten sollten jedoch die mögliche Auswaschung in das Grundwasser in besonders anfälligen Gebieten und in Reiskulturen bewerten.
- (7) Aufgrund der Bewertungen kann davon ausgegangen werden, dass den betreffenden Wirkstoff enthaltende Pflanzenschutzmittel die Anforderungen gemäß Artikel 5 Absatz 1 Buchstaben a) und b) der Richtlinie, insbesondere hinsichtlich der geprüften Anwendungen, erfüllen. Der betreffende Wirkstoff sollte daher in Anhang I aufgenommen werden, damit in allen Mitgliedstaaten die etwaige Erteilung, Änderung bzw. Rücknahme der Zulassung von Pflanzenschutzmitteln, die Bentazon enthalten, in Übereinstimmung mit der Richtlinie erfolgen kann.
- (8) Gemäß Artikel 8 Absatz 2 der Richtlinie stellen die Mitgliedstaaten nach der Aufnahme eines Wirkstoffs in Anhang I sicher, dass die Zulassungen von Pflanzenschutzmitteln, die diesen Wirkstoff enthalten, innerhalb eines vorgeschriebenen Zeitraums erteilt, widerrufen bzw. geändert werden. In Artikel 4 Absatz 1 und Artikel 13 Absatz 1 der Richtlinie ist insbesondere festgelegt, dass ein Pflanzenschutzmittel nur zugelassen wird, wenn die Bedingungen in Zusammenhang mit der Aufnahme seiner Wirkstoffe in Anhang I sowie die einheitlichen Grundsätze gemäß Anhang VI auf der Grundlage von Unterlagen, die den Datenanforderungen nach Artikel 13 entsprechen, erfüllt sind.
- (9) Vor der Aufnahme ist eine angemessene Frist vorzusehen, um es den Mitgliedstaaten und interessierten Parteien zu ermöglichen, sich auf die sich daraus ergebenden neuen Anforderungen vorzubereiten. Nach der Aufnahme ist den Mitgliedstaaten eine angemessene Frist einzuräumen, um die Richtlinie umzusetzen und insbesondere bereits bestehende Zulassungen zu ändern oder zurückzuziehen bzw. neue Zulassungen gemäß den Bestimmungen der Richtlinie 91/414/EWG zu erteilen. Für die Einreichung und Bewertung der gemäß Anhang III für jedes Pflanzenschutzmittel vollständigen Unterlagen nach Maßgabe der einheitlichen Grundsätze von

⁽¹⁾ ABl. L 230 vom 19.8.1991, S. 1.

⁽²⁾ ABl. L 57 vom 2.3.2000, S. 28.

⁽³⁾ ABl. L 366 vom 15.12.1992, S. 10.

⁽⁴⁾ ABl. L 259 vom 13.10.2000, S. 27.

⁽⁵⁾ ABl. L 107 vom 28.4.1994, S. 8.

⁽⁶⁾ ABl. L 225 vom 22.9.1995, S. 1.

⁽⁷⁾ Stellungnahme des Wissenschaftlichen Pflanzenausschusses vom 2. Dezember 1999 betreffend die Aufnahme von Bentazon in Anhang I der Richtlinie 91/414/EWG über das Inverkehrbringen von Pflanzenschutzmitteln.

Anhang VI der Richtlinie ist ein längerer Zeitraum vorzusehen. Pflanzenschutzmittel, die mehrere Wirkstoffe enthalten, können jedoch auf der Grundlage der einheitlichen Grundsätze erst vollständig bewertet werden, wenn alle Wirkstoffe in Anhang I der Richtlinie aufgenommen sind.

- (10) Es ist vorzuschreiben, dass die Mitgliedstaaten den endgültigen Prüfungsbericht (mit Ausnahme von vertraulichen Informationen im Sinne des Artikels 14 der Richtlinie) allen Interessierten zur Einsicht zur Verfügung stellen oder zugänglich machen.
- (11) Der Prüfungsbericht ist erforderlich für die ordnungsgemäße Umsetzung bestimmter Teile der einheitlichen Grundsätze gemäß Anhang VI durch die Mitgliedstaaten, soweit sich diese Grundsätze auf die Bewertung der Angaben nach Anhang II beziehen, die zwecks Aufnahme des Wirkstoffs in Anhang I der Richtlinie vorgelegt wurden.
- (12) Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses für Pflanzenschutz —

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

- für Pflanzenschutzmittel, die Bentazon als einzigen Wirkstoff enthalten, auf vier Jahre nach dem Inkrafttreten dieser Richtlinie und
- für Pflanzenschutzmittel, die Bentazon und andere Wirkstoffe enthalten, die noch nicht in Anhang I der Richtlinie 91/414/EWG aufgenommen wurden, auf vier Jahre ab dem Zeitpunkt des Inkrafttretens der Richtlinie über die Aufnahme des letzten dieser Wirkstoffe in Anhang I.

(3) Die Mitgliedstaaten stellen den Prüfungsbericht (mit Ausnahme von vertraulichen Informationen im Sinne von Artikel 14 der Richtlinie 91/414/EWG) allen Interessierten zur Einsicht zur Verfügung oder machen ihn gegebenenfalls auf besonderen Antrag zugänglich.

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

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

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

Artikel 2

(1) Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens 31. Januar 2002 nachzukommen. Sie setzen die Kommission unverzüglich davon in Kenntnis. Gemäß den Bestimmungen der Richtlinie 91/414/EWG ändern oder widerrufen sie innerhalb dieses Zeitraums erforderlichenfalls insbesondere bestehende Zulassungen für Pflanzenschutzmittel, die Bentazon als Wirkstoff enthalten.

Artikel 3

Diese Richtlinie tritt am 1. August 2001 in Kraft.

Artikel 4

Diese Richtlinie ist an alle Mitgliedstaaten gerichtet.

Brüssel, den 23. Oktober 2000

Für die Kommission

David BYRNE

Mitglied der Kommission

ANHANG

Bentazon

1. Identität:

Gebrauchliche Bezeichnung: Bentazon

IUPAC-Bezeichnung: 3-isopropyl-(1H)-2,1,3-benzothiadiazin-4-(3H)-on-2,2-dioxid

2. Zu erfüllende Bedingungen:

2.1. Der hergestellte Wirkstoff muss eine Reinheit von mindestens 960 g/kg aufweisen.

2.2. Nur Verwendungen als Herbizid dürfen zugelassen werden.

2.3. Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss für Pflanzenschutz am 13. Juli 2000 abgeschlossenen Prüfungsberichts über Bentazon und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Bewertung sollten die Mitgliedstaaten:

— dem Grundwasserschutz besondere Aufmerksamkeit widmen;

3. Aufnahme befristet bis: 31. Juli 2011.

COMMISSION DIRECTIVE 2000/68/EC
of 23 October 2000

including an active substance (bentazone) 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⁾, and in particular Article 6(1) and the fourth subparagraph of Article 8(2) thereof,

Whereas:

- (1) Commission Regulation (EEC) No 3600/92 ⁽³⁾, as last amended by Regulation (EC) No 2266/2000 ⁽⁴⁾, laid down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC (hereinafter referred to as 'the Directive'). Pursuant to that Regulation, Commission Regulation (EC) No 933/94 ⁽⁵⁾, as last amended by Regulation (EC) No 2230/95 ⁽⁶⁾, laid down the list of active substances of plant protection products to be assessed, with a view to their possible inclusion in Annex I to the Directive.
- (2) In accordance with Article 5(1) of the Directive, an active substance should be included in Annex I if it may be expected that neither the use of, nor residues from, plant protection products containing that active substance will have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment.
- (3) Such an active substance may be included in Annex I for a period not exceeding 10 years.
- (4) For bentazone the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a number of uses proposed by the notifiers. Germany was designated as rapporteur Member State under Regulation (EC) No 933/94 laying down the active substances of plant protection products and designating the rapporteur Member State for the implementation of Regulation (EEC) No 3600/92. It submitted the relevant assessment report and recommendation to the Commission on 13 November 1996, in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.
- (5) The assessment report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. This review was finalised on

13 July 2000 in the format of the Commission review report for bentazone.

- (6) The dossier and the information from the review have also been submitted to the Scientific Committee for Plants for consultation. The Scientific Committee for Plants in its opinion ⁽⁷⁾ confirmed that the substance can be used without unacceptable risk but noted that Member States should assess the leaching potential to groundwater in particularly vulnerable locations and in rice cultures.
- (7) It has appeared from the assessments made that plant protection products containing the active substance concerned may be expected to satisfy in general the requirements laid down in Article 5(1)(a) and (b) of the Directive, in particular with regard to the uses which were examined. It is appropriate therefore to include the active substance concerned in Annex I, in order to ensure that in all Member States the granting, varying or withdrawing, as appropriate, of the authorisations of plant protection products containing bentazone can be undertaken in accordance with the provisions of the Directive.
- (8) Article 8(2) of the Directive provides that after inclusion of an active substance in its Annex I, Member States shall, within a prescribed period, grant, vary or withdraw, as appropriate, the authorisations of the plant protection products containing the active substance. In particular, Articles 4(1) and 13(1) of the Directive require that plant protection products are not authorised unless account is taken of the conditions associated with the inclusion of the active substance in Annex I and the uniform principles laid down in Annex VI on the basis of a dossier satisfying the data requirements laid down in its Article 13.
- (9) Before inclusion, a reasonable deadline is necessary to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion. Moreover, after inclusion, a reasonable period is necessary for the Member States to implement the Directive and in particular to vary or withdraw, as appropriate, existing authorisations or grant new authorisations in accordance with the provisions of Directive 91/414/EEC. A longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product in accordance with the uniform principles laid down in Annex VI to the Directive. For plant protection

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 57, 2.3.2000, p. 28.

⁽³⁾ OJ L 366, 15.12.1992, p. 10.

⁽⁴⁾ OJ L 259, 13.10.2000, p. 27.

⁽⁵⁾ OJ L 107, 28.4.1994, p. 8.

⁽⁶⁾ OJ L 225, 22.9.1995, p. 1.

⁽⁷⁾ Opinion of the Scientific Committee on Plants regarding the inclusion of bentazone in Annex I to Directive 91/414/EEC concerning the placing of plant protection products on the market (opinion expressed by the Scientific Committee on Plants on 2 December 1999).

products containing several active substances, the complete evaluation on the basis of the uniform principles can only be carried out when all the active substances concerned have been included in Annex I to the Directive.

- (10) 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.
- (11) 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.
- (12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

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

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

3. Member States shall keep available the review report (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.

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive, at the latest by 31 January 2002, and shall immediately inform the Commission thereof. In particular they shall, in accordance with the provisions of Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing bentazone as an active substance within such period.

Article 3

This Directive shall enter into force on 1 August 2001.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 23 October 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX

Bentazone

1. Identity:

Common name: bentazone

IUPAC name: 3-isopropyl-(1H)-2,1,3-benzothiadiazin-4-(3H)-one-2,2-dioxide

2. Particular conditions to be fulfilled:

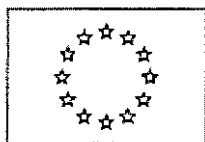
2.1. The active substance as manufactured shall have a purity of 960 g/kg.

2.2. Only uses as herbicide may be authorised.

2.3. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on bentazone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 13 July 2000 shall be taken into account. In this overall assessment Member States:

— must pay particular attention to the protection of groundwater.

3. Expiry date of the inclusion: 31 July 2011.



EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH & CONSUMER PROTECTION
Directorate E - Public, animal and plant health
Unit E1 Legislation relating to crop products and animal nutrition

Bentazone
7585/VI/97-final
30 November 2000

Final

Review report for the active substance **bentazone**

Finalised in the Standing Committee on Plant Health at its meeting on 13 July 2000
in view of the inclusion of bentazone in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of bentazone, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92⁽¹⁾ laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1972/99², has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Bentazone is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, BASF AG on 13 July 1993, AgriChem on 15 July 1993, Helm AG on 23 July 1993 and B.V. Luxan on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance bentazone in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94⁽³⁾, as last amended by Regulation (EC) No 2230/95⁽⁴⁾, designated Germany as rapporteur Member State to carry out the assessment of

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 244, 16.9.1999, p. 41.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

2230/95⁴), designated Germany as rapporteur Member State to carry out the assessment of bentazone on the basis of the dossiers submitted by the notifiers. In the same Regulation the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for bentazone this deadline was 30 April 1995.

BASF AG and AgriChem submitted each a dossier to the rapporteur Member State. BASF AG was the main data submitter, with a dossier which did not contain substantial data gaps. AgriChem did not submit a complete dossier. No information has furthermore been submitted by third parties.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Germany submitted on 16. October 1996 to the Commission the report of its examination, hereafter referred to as the draft report, including, as required, a recommendation concerning the possible inclusion of bentazone in Annex I to the Directive. Moreover, in accordance with the same provisions, the Commission and the Member States received also the summary dossier on bentazone from BASF AG, on 29 November 1996.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft report to all the Member States as well as to BASF AG and AgriChem, on 25 June 1997.

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

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

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, from September 1997 to January 1998.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 17 March 1998 for comments and further clarification.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on Plant Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from February 1999 to May 2000, and was finalised in the meeting of the Standing Committee on 13 July 2000.

⁴ OJ No L 225, 22.09.1995, p.1.

The present review report contains the conclusions of this final examination; given the importance of the draft report, the peer review report (i.e. full report) and the comments and 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 report of this Committee was formally adopted on 2 December 1999⁵).

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 2000/68/EC concerning the inclusion of bentazone in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing bentazone they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

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

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

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

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

The overall conclusion from the evaluation is that it may be expected that plant protection products containing bentazone 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

⁵ Opinion of the scientific Committee on Plants regarding the inclusion of bentazone in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Opinion expressed by the Scientific Committee on Plants on 2 December 1999).

91/414/EEC, for each bentazone containing plant protection product for which Member States will grant or review the authorisation.

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

- Herbicide (cereals, maize, rice, potatoes, pea, *Digitalis lanata*, poppy, flax, clover, yellow lilly, narcissi, flower seed cultivation (saponaria), pasture, grazing land, grass seed, turf, control of *Cyperus tuberosus* (several crops))

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

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 2.2 - 2.7 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

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

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and Physical/chemical properties

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

The active substance shall comply with the FAO specification and there seem not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report.

The review has established that for the active substance notified by the main data submitter BASF AG, none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, Germany is of the opinion, on the basis of the information currently available, that the substance notified by the other data submitter (AgriChem) differs significantly, in the meaning of Article 13(2) and (5) of the Directive, in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main data submitter. The substance notified by AgriChem has a minimum purity of 910 g/kg, which does not comply with the FAO specification.

5. Endpoints and related information

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

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing bentazone

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

Due to degradation and adsorption properties bentazone is considered to be mobile in soil.

- regarding the possibility of ground water contamination the review raised no concern if applications take place only once in spring or summer with not more than 1000 g bentazone/ha. However, it is recommended that risk assessment should be conducted at Member State level, in particular regarding use in rice cultivation, because the modelling scenarios and lysimeter/field studies presented by the notifier do not represent the full range of soil and climate. Member States should assess leaching potential in vulnerable locations, eg. sites with shallow groundwater, to determine whether further application pattern (crops, rates and timing) can be identified where groundwater contamination could be excluded.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of bentazone in Annex I under the current inclusion conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. This may particularly be the case for

- A degradation study at 10 °C for Nordic Member States
- Storage stability of residues

8. Information on studies with claimed data protection

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

9. Updating of this review report

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

APPENDIX I

Identity, physical and chemical properties

Bentazone

Common name (ISO)	Bentazone
Chemical name (IUPAC)	3-isopropyl-(1H)-2,1,3-benzothiadiazin-4-(3H)-one-2,2-dioxide
Chemical name (CA)	3-(1-methylethyl)-(1H)-2,1,3-benzothiadiazin-4-(3H)-one-2,2-dioxide
CIPAC No	366
CAS No	25057-89-0
EEC No	EINECS: 246-585-8
FAO SPECIFICATION	AGP: CP/ 307, (1994)
Minimum purity	960 ± 25 g/kg as given by FAO specification
Molecular formula	C ₁₀ H ₁₂ N ₂ O ₃ S
Molecular mass	240.3
Structural formula	

Melting point	BASF: 139 - 141 °C (99.8% pure)
Boiling point	No boiling or sublimation up to decomposition (gas evolution) point of 210 °C (99.8% pure).
Appearance	White (transparent) crystalline powder, odourless; (99.8% pure)
Relative density	BASF: 1.405 at 20 °C (99.8% pure)
Vapour pressure	$1.7 \cdot 10^{-4}$ Pa at 20 °C (100% purity)
Henry's law constant	$7.2 \cdot 10^{-5}$ Pa m ³ mol ⁻¹
Solubility in water	pH 3 : 490 mg/l at 20 °C -pH 7 : 570 mg/l at 20 °C
Solubility in organic solvents (at 20 °C)	All in g/l at 20 °C: n-heptane: $5 \cdot 10^{-3}$ toluene: 21 dichloromethane: 206 methanol: 1061 acetone: 1387 ethyl acetate: 582
Partition co-efficient (log P_{ow})	pH 5: 0.77 at 22 °C pH 7: - 0.46 at 22 °C pH 9: - 0.55 at 22 °C
Hydrolytic stability (DT₅₀)	In the pH range 5 to 9 at 25 °C tested bentazone is stable towards hydrolysis; not readily hydrolysed
Dissociation constant	pK _a : 3.28 at 24 °C
Quantum yield of direct photo-transformation in water at λ >290 nm	$4.38 \cdot 10^{-4}$ mol · Einstein ⁻¹
Flammability	Not classified as highly-flammable
Explosive properties	Not explosive when exposed to mechanical stress (shock and friction)
UV/VIS absorption (max.)	216 nm, 310 nm
Photostability (DT₅₀)	pH 5: 122 h at 25 °C pH 7: 93 h at 25 °C pH 9: 14 h at 25 °C

APPENDIX II

ENDPOINTS AND RELATED INFORMATION

Bentazone

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	high bioavailability, (about 90 %)
Distribution:	generally low residues; highest level in kidney
Potential for accumulation:	no potential for accumulation
Rate and extent of excretion:	rapid excretion (> 90 %, urine; 1 - 4 % faeces in 24 h)
Toxicologically significant compounds:	parent compound
Metabolism in animals:	10 % metabolised; parent compound predominantly excreted and small amounts of metabolites 6-OH-bentazone and 8-OH-bentazone

Acute toxicity

Rat LD ₅₀ oral:	1400 - 1800 mg/kg bw
Rat LD ₅₀ dermal:	> 5000 mg/kg bw
Rat LC ₅₀ inhalation:	> 5.1 mg/l
Skin irritation:	non irritant
Eye irritation:	irritant
Skin sensitization (test method used and result):	sensitizer (M&K)

Short term toxicity

Target / critical effect:	Blood (prolonged blood coagulation time, diminished hematocrit , reduced haemoglobin); liver and kidney
Lowest relevant oral NOAEL / NOEL:	400 ppm (13 mg/kg bw/d), 1 year dog study,
Lowest relevant dermal NOAEL / NOEL:	1000 mg/kg bw/d, (21-day rabbit dermal study)
Lowest relevant inhalation NOAEL / NOEL:	not required

Genotoxicity

no genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect:

Impairment of blood coagulation; effects on liver and kidney

Lowest relevant NOAEL:

200 ppm (10 mg/kg bw/d), 24-month rat study

Carcinogenicity:

no carcinogenic potential

Reproductive toxicity

Target / critical effect - Reproduction.

reduced pup weight at parental toxic doses

Lowest relevant reproductive NOAEL / NOEL:

200 ppm (14 mg/kg bw/d), multi generation rat study

Target / critical effect - Developmental toxicity:

no teratogenic potential

Lowest relevant developmental NOAEL / NOEL:

100 mg/kg bw/d (rat)

Delayed neurotoxicity

no relevant effects

Other toxicological studies

8-OH and 6-OH-metabolites; less toxic than parent compound

Medical data

no concern

Summary

	Value	Study	Safety factor
ADI:	0.1 mg/kg bw/d	24-month rat feeding study	100
AOEL systemic:	0.13 mg/kg bw/d	1 year dog feeding study	100
AOEL inhalation:	not relevant		
ARfD (acute reference dose):	0.25 mg/kg	90-day rat feeding study	100

Dermal absorption

2 %

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

mineralization after 100 days:

6 - 9 % (90 d)
2 % (60d) (further study)

non-extractable residues:

44 - 74 % (90d)
80% (100d) (further study)

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

<10 % - no relevant major metabolites

Supplemental studies

Anaerobic:

Anaerobic aquatic soil metabolism: 87.7 % as in water and 5.5 % in sediment after 365 d

Soil photolysis:

< 10 % of applied radioactivity

Remarks:

none

Rate of degradation

Laboratory studies:

DT_{50lab} (20 °C, aerobic):

8 - 102 d (n=7), Ø 45 d

DT_{90lab} (20 °C, aerobic):

37 - 198 d (n=4), Ø 90 d

DT_{50lab} (10°C, aerobic):

161d (n=1) (graphical interpolation)

DT_{50lab} (20°C, anaerobic):

not possible to estimate

Field studies

(country or region):

DT_{50f} from soil dissipation studies:

Germany: 4 - 21 d (n=5), Ø 14 d
USA (California): 6 d (n=2)

DT_{90f} from soil dissipation studies:

Germany: 38 - 69d (n=5), Ø 53 d
USA (California): 20,21 d

Soil accumulation studies:

Not required

Soil residue studies:

Not required

Remarks:

e.g. effect of soil pH on degradation rate

Not observed

Adsorption/desorption

K_{oc} / K_{om} :

soil	pH	org.C	K_{oc}
loam	7.3	0.6	37
loamy sand	6.1	2.7	13
sand	6.8	0.5	47
clay	5.4	1.8	23
clay	7.7	2.9	13
clay	4.3	1.7	176
loamy sand	5.0	0.6	78
clay sediment (rice soil)	6.6	0.7	25

Mobility

Laboratory studies:

- Column leaching:

BBA standard soil 2.1: 58 - 100% as in percolate
 BBA standard soil 2.2: 61 - 100% as in percolate
 BBA standard soil 2.3: 56 - 100% as in percolate

- Aged residue leaching:

30 d ageing: 18 - 67 % bentazone ,7 % more polar products in percolate

Field studies:

Lysimeter/Field leaching studies:

Seven lysimeter studies in Germany (duration 2 or 3 years):
 application rates: 500-1500 g as/ha
 application frequency: one or two applications during study period (once a year) maximum concentrations: 0.027-0.178 µg/l
 average annual concentrations: 0.004-0.084 µg/l

Remarks:

none

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation :

pH 5: stable (25 °C)

pH 7: stable (25 °C)

pH 9: stable (25 °C)

Relevant major metabolites:

No major metabolites

Photolytic degradation:

DT50 (laboratory):

pH 5 : 122 h

pH 7 : 93 / 63 h

pH 9 : 14 h

Major metabolites:

3-isopropyl-2,3-dioxo-5-oxocyclo-penteno[d]1H-2,1,3-thiadiazin-4(3H)-one 6 carbonic acid (21 %) (pH 7)

DT50 (calculated): 3.6 d (March), 1.6 d (May)

pure water from close to the surface (0-1cm), stagnant water, geographic and climatic conditions of Germany (50th degree of latitude).

Biological degradation

Readily biodegradable:

not submitted

Water/sediment study:

DT₅₀ water:

62 and 69% as , respectively after 100 d (DT50 161 d)

DT₉₀ water:

not calculable

DT₅₀ whole system:

523 and 908 d, respectively

DT₉₀ whole system:

not calculable

Distribution in water / sediment systems (active substance)

Main portion in water phase

Distribution in water / sediment systems (metabolites)

N-Methylbentazone: only in water phase, max. 7.2 % and 12.5 %, respectively, after 30 d

Accumulation in water and/or sediment:

Not observed

Degradation in the saturated zone

Not required

Field or mesocosm studies:

Two applications to rice in Southeastern United States (intervall: 14 d)

Mississippi: DT50 (whole) 3.8 d

in water: 0.77 - 0.0005 kg as/ha after 76 d

in soil: 0.12 kg as/ha - <10 µg as/kg after 76 d

Louisiana: DT50 (whole) 3.8 d

in water: 1.1 kg as/ha - < 10 µg as/kg after 76 d in soil: 0.19 kg as/ha - < 10 µg as/kg after 76 d
--

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

1.7 x 10 ⁻⁴ Pa (20 °C, 100 % purity)

Henry's law constant:

7.2 x 10 ⁻⁵ Pa m ³ mol ⁻¹
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Photolytic degradation

Direct photolysis in air:

DT50 (laboratory): pH 5 122h, pH 7 93/63h, pH 9 14 h

Photochemical oxidative degradation in air (DT₅₀):

2.1 h (Atkinson estimation)

Volatilisation:

From plant surfaces: no data
From soil: no data

Remarks:

none

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals

LD50: 500 mg/kg bw (NOEL =1800 ppm, 4 wk subchronic rat study)

Long term oral toxicity to mammals.

Lowest reproductive NOAEL: 200 ppm (multi generation rat study)

Acute toxicity to birds:

LD50: about 1140 mg/kg (Bobwhite quail)

Dietary toxicity to birds:

LC50: > 5000 ppm (Bobwhite quail and mallard duck)

Reproductive toxicity to birds:

NOEL: 800 ppm (Bobwhite quail and mallard duck)

Aquatic Organisms

Acute toxicity fish:

LC50: > 100 mg/l (*O. myciss*, 96 h)

Long term toxicity fish

NOEC > 48 mg a.s./l (*O. myciss*, 28 d, study with formulated product 'Basagran')

Bioaccumulation fish:

Not relevant, log P_{ow} < 3

Acute toxicity invertebrate:

EC50 64 mg/l (*D. magna*, 96 h)

Chronic toxicity invertebrate:

NOEC 120 mg a.s./l (*D. magna*, 21 d, study with formulated product 'Basagran')

Acute toxicity Higher aquatic plants

EC50 5.4 mg/l (*L. gibba*, 14 d)

Acute toxicity algae:

EC50 : 10.1 mg/l (*A. flos-aque*, 120 h)

Chronic toxicity sediment dwelling organism:

Not relevant

Honeybees

Acute oral toxicity:

> 200 µg a.s./bee

Acute contact toxicity:

> 200 µg a.s./bee

Other arthropod species

T. cacoeciae

Parasitization: 51 % effect on adults (2.633 kg a.s./ha, formulation 480 g/l)

T. pyri

Mortality: 7 % effects on protonymphs (0.960 kg a.s./ha, formulation 480 g/l);

Reproduction: 20 % effects

A. bilineata

Parasitization: no effect on adults/larvae (1.152 kg a.s./ha, formulation 480 g/l)

*B. lampros*Mortality: 4 % effect on adults
(1.920 kg a.s./ha, formulation 480 g/l)*P. cupreus*Mortality: no effect on adults
(2.655 kg a.s./ha, formulation 480 g/l)*C. carnea*Mortality/Fertility: no effect on larvae/adult
(2.655 kg a.s./ha, formulation 480 g/l)**Earthworms**

Acute toxicity:

LC50 > 870 mg a.s./kg dry weight substrate

Reproductive toxicity:

Not required

Soil micro-organisms

Nitrogen mineralization:

No effect up to 9.6 kg a.s./ha

Carbon mineralization:

No effect up to 9.6 kg a.s./ha

Appendix III

BENTAZONE

List of studies for which the main submitter has claimed data protection and which during the re-evaluation process were considered as essential for the evaluation with a view to Annex I inclusion¹.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
2.1; 2.2	Türk, W.	1994	Determination of the appearance, the melting point and thermal conversions of bentazone (PAI). BASF REG. DOC. #94/11115. CHE96-00126.	-
2.10	Sarafin, R.	1995	Photochemical oxidative degradation of Bentazon (QSAR Estimates). BASF 95/10642 ! STUDY NO. SA-95-01. LUF95-00179.	-
2.11; 2.15	Löffler, U.	1994	Safety characteristics of the active ingredient 51 929. BASF REG. DOC. #94/10977. CHE96-00135	-
2.3	Gückel, W.	1988	Determination of the vapour pressure of Bentazon. BASF Reg. Doc. #88/0111. LUF95-00078.	DE: The study has been submitted in 1988 in a national authorization
2.3	Travnicek, A.	1990	Henry's law constant for Bentazon. BASF Reg. Doc. #90/10374. LUF95-00079.	-
2.4	Kästel, R.	1993	Physical and chemical properties report for bentazone techn. BASF REG. DOC. #93/11290. CHE96-00128.	-
2.4	Türk, W.	1994	Determination of the odour of bentazone(PAI). BASF REG. DOC. #94/11193. CHE96-00129.	-
2.5	Türk, W.	1994	Spectra of bentazone (PAI). BASF REG. DOC. #94/11112. CHE96-00130.	-

¹ List based on a detailed analysis from RMS in its submission of 7 JULY 2000 (background document C).

² Reports received from Member States at the date of finalisation of the present review report (not exhaustive)

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
2.6	Pawliczek, J.B	1987	Water solubility of bentazone. BASF REG. DOC. #87/0230. CHE96-00131.	-
2.7	Türk, W.	1993	Determination of the solubility of bentazone in organic solvents at 20° C. BASF REG. DOC. #93/11319. CHE96-00133.	-
2.8	Keller, W.	1986	Determination of the n-octanol/water partition coefficient of bentazone. BASF REG. DOC. #86/0450. CHE96-00134.	DE: The study has been submitted in 1994 in a national authorization
2.9	Redeker, J.	1985	Determination of the dissociation constant of Bentazon pure active ingredient. BASF 85/10109. WAS95-00115.	-
2.9	Sarafin, R.	1991	Bentazon - Determination of quantum yield. BASF 91/11271. WAS95-00108.	DE: The study has been submitted in 1992 in a national authorization
2.9; 7.2.1; 9.2	Ellenson, J.L.	1989	Isolation and identification of the major aqueous photolysis product of Bentazon: Final report. BASF 89/5139 / 89/0304. WAS95-00104.	-
2.9; 7.2.1; 9.2	Eswein, R.P. and Panek, E.J.	1986	Hydrolysis of Bentazon in pH 5, 7, and 9 solutions at 25°C. BASF Reg. Doc. #86/5018. WAS95-00101.	DE: The study has been submitted in 1992 in a national authorization
2.9; 7.2.1; 9.2	Eswein, R.P. and Panek, E.J.	1986	Photolysis of Bentazon in pH 5, 7, and 9 aqueous solutions at 25°C. BASF 86/5016. WAS95-00102.	DE: The study has been submitted in 1988 in a national authorization
2.9; 7.2.1; 9.2	Patel, J.R.	1988	¹⁴ C-Bentazon (BAS 351 H) aqueous photolysis at pH 7: Material balance and kinetics. BASF 88/5122. WAS95-00103.	-
2.9; 7.2.1; 9.2	Sarafin, R.	1991	Bentazon (BAS 351 ..H) absorption coefficients at pH 4, pH 7, and pH 9. BASF 91/10346. WAS95-00107.	DE: The study has been submitted in 1992 in a national authorization
3.9	Schenk, W.	1994	Possible procedures for the decontamination of water from bentazone. BASF REG. DOC. #94/10410. CHE96-00137.	-

¹ List based on a detailed analysis from RMS in its submission of 7 JULY 2000 (background document C).

² Reports received from Member States at the date of finalisation of the present review report (not exhaustive)

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
4.2.1	Cannizzaro R.	1974	Determination of bentazon, 8-hydroxy-bentazon, and 6-hydroxy bentazon residues in whole soybean plants of foliage and soybean grain. BWC Method No. 11A Analytical Development Corporation, Monument, Colorado; BWC Agric. Chem. Residue Laboratory, Parsippany, New Jersey, USA. BASF Reg. Doc. #74/5078. MET96-00007.	DE: The study has been submitted in 1976 in a national authorization
4.2.1	Cannizzaro, R.	1974	Determination of bentazon [3-isoprpyl-1H-2,1,3-benzothiadiazin-4-(3 H)-one 2,2-dioxide] and AIBA [2-Amino-N-Isopropyl-Benzamide] residues in cow and chicken tissues, BWC method no. 10. BASF 74/5086. MET96-00036.	-
4.2.1	Horten W.E., Huber R.	1977	Determination of bentazon, 8-hydroxy bentazon and 6-hydroxy bentazon residues in seed and pod vegetable (succulent and dry form) forage, hay, pods, and seeds. BWC Method No. 19A BWC Agric. Chem. Residue Laboratory, Parsippany, New Jersey, USA. BASF Reg. Doc. #77/5018. MET96-00006.	DE: The study has been submitted in 1991 in a national authorization
4.2.1	Keller W.	1981	Residues of Bentazon and 6-Hydroxy bentazon in milk following dietary administration to lactating goats. BASF Aktiengesellschaft, Limburgerhof, Germany. BASF Reg. Doc. #81/10068. MET96-00028.	DE: The study has been submitted in 1988 in a national authorization
4.2.1	Keller W.	1987	GLC Method for Residue Determinations of Bentazon, 8-Hydroxy -bentazon and 6-Hydroxy-bentazon in Chicken: Eggs, Muscle, Liver, Fat/Skin. BASF Method No. 276 BASF BASF Aktiengesellschaft, Limburgerhof, Germany. BASF Reg. Doc. #87/0497. MET96-00029.	-
4.2.1	Keller W.	1987	Bentazon-Accountability in Chicken Eggs, Muscle, Liver and Fat using BASF method No. 276. BASF Aktiengesellschaft, Limburgerhof, Germany. BASF Reg. Doc. #87/0495. MET96-00030.	-

¹ List based on a detailed analysis from RMS in its submission of 7 JULY 2000 (background document C).

² Reports received from Member States at the date of finalisation of the present review report (not exhaustive)

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
4.2.1	Keller, W.	1986	Determination of bentazon in cow milk. #BASF 86/0439. MET96-00037.	-
4.2.1	Keller, W.	1987	Bentazon-Accountability in rice forage, straw and grain, using BCH-method no. 20. BASF Aktiengesellschaft, Limburgerhof, Germany. BASF Reg. Doc. #87/0496. MET96-00018.	-
4.2.1	Offizorz P.	1994	Method validation - Determination of residues of bentazone in/on broad beans. RCC Umweltchemie GmbH & Co. KG, D-64374 Rossdorf, Germany. BASF Reg. Doc. #94/10190. MET96-00019.	-
4.2.1	Schwemmer B.A	1976	Determination of bentazon, 8-hydroxybentazon, and 6-hydroxy bentazon, in corn (forage, fodder, grain, cob, kernel plus cob and process fractions) and peanuts (forage, hay, nut, hull, nut plus hull and process fractions). BWC Method No. 21 BWC Agric. Chem. Residue Laboratory, Parsippany, New Jersey, USA. BASF Reg. Doc. #76/5061. MET96-00004.	-
4.2.1	Schwemmer B.A.	1976	Determination of bentazon, 8-hydroxybentazon and 6-hydroxy bentazon residues in rice forage, straw, grain, and process fractions: hulls, bran and white rice. BWC Method No. 20B BWC Agric. Chem. Residue Laboratory, Parsippany, New Jersey, USA. BASF Reg. Doc. #76/5065. MET96-00005.	DE: The study has been submitted in 1976 in a national authorization
4.2.1; 4.2.2; 4.2.3	Anonym, BASF Registration Group (GPE/R)	1977	Bentazon, 8-hydroxy-bentazon (metabolite A), 6-hydroxy-bentazon (metabolite B) Gaschromato-graphic determination in beans, peas, soil, peanuts, cereals, cucumbers, potatoes, linseed, corn, rice, soybean, water. BASF Method No. 118 BASF Aktiengesellschaft, Limburgerhof, Germany. BASF Reg. Doc. #77/10158. MET96-00002.	DE: The study has been submitted in 1990 in a national authorization

¹ List based on a detailed analysis from **RMS** in its submission of **7 JULY 2000** (background document C).

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4.2.1; 4.2.2; 4.2.3	Keller W.	1982	Bentazon, 8-hydroxy-bentazon (metabolite A), 6-hydroxy-bentazon (metabolite B) Gaschromatographic determination after methylation with methyl iodide and tetrabutylammonium hydroxide in cereals (forage, straw, grain), soybeans, rice, soil a. water. BASF Method No. 197 BASF Aktiengesellschaft, Limburgerhof, Germany. BASF Reg. Doc. #82/10033. MET96-00003.	DE: The study has been submitted in 1982 in a national authorization German translation
4.2.2	Gall D.E.	1989	Determination of Basagran (bentazon) in soil/sediment, SOP No.: LM-CAL-4072, Revision No.: 6. Enseco California Analytical Laboratory, West Sacramento, California, USA. BASF Reg. Doc. #89/10218. MET96-00021	DE: The study has been submitted in 1991 in a national authorization
4.2.2	Mackenroth C.	1993	Determination of 8-chloro-bentazon and bentazon in soil by gas chromatography. BASF Aktiengesellschaft, Limburgerhof, Germany. BASF Reg. Doc. #93/10351. MET96-00020.	DE: The study has been submitted in 1993 in a national authorization
4.2.2	Verrue K.A.	1988	Determination of Basagran (bentazon) in soil/sediment, SOP No.: LM-CAL-4072, Revision No.: 2. Enseco California Analytical Laboratory, West Sacramento, California, USA. BASF Reg. Doc. #88/10226. MET96-00022.	DE: The study has been submitted in 1992 in a national authorization
4.2.3	Keller W.	1984	Bentazon - Gaschromatographic determination after methylation with methyl iodide and tetrabutylammoniumhydroxide in water. BASF Aktiengesellschaft, Limburgerhof, Germany. BASF Reg. Doc. #84/10084. MET96-00024.	DE: The study has been submitted in 1987 in a national authorization
4.2.3	Keller W.	1998	Validation of Analytical Method No. 423 Determination of Bentazone residues in water Study plan no.: 46513 MET1999-18	-

¹ List based on a detailed analysis from **RMS** in its submission of **7 JULY 2000** (background document C).

² Reports received from Member States at the date of finalisation of the present review report (not exhaustive)

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
4.2.4	Sarafin R.	1993	Validation of Analytical Method 335 - Determination of Bentazon in Air by HPLC. BASF Aktiengesellschaft, Limburgerhof, Germany. BASF Reg. Doc. #93/10314. MET96-00027.	DE: The study has been submitted in 1993 in a national authorization
4.2.4	Sarafin R., Zangmeister W.	1993	Bentazon - High performance liquid chromatographical determination by means of UV detection in air. BASF Method No. 335 BASF Aktiengesellschaft, Limburgerhof, Germany. BASF Reg. Doc. #93/11587. MET96-00026.	DE: The study has been submitted in 1993 in a national authorization German translation
4.2.4	Sarafin, R.	1994	Further results for the validation of analytical method 335 determination of bentazon in air by HPLC. #BASF 95/10464. MET96-00035.	DE: The study has been submitted in 1995 in a national authorization
4.2.4	Scharf, J.	1995	Recovery of bentazon-sodium after elution from tenax - supplement to analytic method 335. #BASF 95/10673. MET96-00034.	DE: The study has been submitted in 1995 in a national authorization
6.1; 6.6	Hofmann, M.	1989	Plant uptake study with ¹⁴ C-bentazon in potatoes. BASF Aktiengesellschaft, Limburgerhof, Germany, 1989. BASF Reg. Doc. #89/10248. RIP95-00635.	-
6.1; 6.7	Ellenson, J.L.	1994	Metabolism of ¹⁴ C-BAS 351 H in potato tubers. BASF NVA, RTP, NC, USA, 1994. BASF Reg. Doc. #94/5106. RIP95-00636.	-
6.2; 6.4; 6.13	Kohl, W.	1995	The metabolism of [¹⁴ C]-8- hydroxybentazon in lactating goats. BASF Aktiengesellschaft, Limburgerhof, Germany, 1995. BASF Reg. Doc. #95/10062. RIP95-00643.	DE: The study has been submitted in 1995 in a national authorization
6.2; 6.4; 6.16	Hafemann, C.	1995	The metabolism of ¹⁴ C-6-OH-Bentazon in lactating goats. BASF Aktiengesellschaft, Limburgerhof, Germany, 1995. BASF Reg. Doc. #95/10011. RIP95-00645.	DE: The study has been submitted in 1995 in a national authorization

¹ List based on a detailed analysis from RMS in its submission of 7 JULY 2000 (background document C).

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6.5; 6.14	Stewart, J.	1992	Magnitude of the residues of bentazon and its metabolites in processing fractions of rice grain following treatment with BASAGRAN herbicide. BASF Corp, ARC, RTP, NC USA, 1992. BASF Reg. Doc. #92/5170. RIP95-00670.	-
6.9; 6.13	Giese, U.	1989	Characterization of residues in lactating goat after feeding with bound bentazon residues in rice straw. NATEC GmbH, Hamburg, Germany, 1989. BASF Reg. Doc. #89/0370. RIP95-00646.	DE: The study has been submitted in 1992 in a national authorization
7.1	Clark, J.R.	1989	Bentazon (BASAGRAN Herbicide) Field soil dissipation Summary report. BASF 89/5120 ! REPORT NO. E8934 BOD96-00176	DE: The study has been submitted in 1992 in a national authorization
7.1.1	Gottesbüren, B., Platz, K.	1999	Assessment whether field dissipation studies with Bentazone in Europe can be used to estimate transformation rates in soil BASF Reg.Doc.#99/10081	-
7.1.1	Hofmann, M.	1990	Determination of the DT50 of 14C-bentazon in a new lysimeter soil BASF Reg.Doc.# 90/10921	NL: Used for registration in 1998
7.1.1	Huber, R.	1999	Laboratory soil half-lives of Bentazon; proposal to accept a newly established median DT50 of 17.8 days, which is based on biologically active soils, and use this value for assessment and e.g. modelling purposes BASF DocID 1999/10335	-
7.1.1	Huber, R.	1999	Laboratory soil half-lives of Bentazon; proposal to accept a newly established median DT50 of 17.8 days, which is based on biologically active soils, and use this value for assessment and e.g. modelling purposes (Supplement to the publication) BASF Reg.Doc.#99/10409	-
7.1.1 9.1.1	Keller, W.	1996	Photoabbau von Bentazon im 500 l Ökoteich BASF Reg.Doc.# 96/10086	-
7.1.1 9.1.1	Keller, W.	1996	Photochemical degradation of bentazone in a 500 l eco-pond BASF Reg.Doc.# 96/11217	-

¹ List based on a detailed analysis from RMS in its submission of 7 JULY 2000 (background document C).

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7.1.1.2	Hesse, Schepers	1991	Prüfung des Abbauverhaltens von Bentazon im Boden unter Feldbedingungen. BASF 91/11243 ! BER.NR. 3246 BOD96-00122	DE: The study has been submitted in 1992 in a national authorization NL: Used for registration in 1998
7.1.1.2	Schepers, Hesse	1991	Prüfung des Abbauverhaltens von Bentazon im Feldversuch. BASF 91/11154 ! BER.NR. 3243 BOD96-00123	DE: The study has been submitted in 1992 in a national authorization NL: Used for registration in 1998
7.1.1.2	Seher	1999	Comparison of half-lives of bentazone determined in field experiments to half-lives in similar soils determined under laboratory conditions BASF Reg.Doc.#99/10688	-
7.1.1; 9.1.1	Evans, J.R., Jordan, J. and Anderson, S.E.	1994	Basagran herbicide dissipation in a rice paddy 1992 study: Final report. BASF 94/5151 WAS95-00112	-
7.1.1; 9.1	Keller, E.	1987	The aerobic soil metabolism of BAS 351 H (Bentazone). BASF Reg. Doc. #87/0415 BOD95-00264	DE: The study has been submitted in 1992 in a national authorization NL: Used for registration in 1998
7.1.1; 9.1	Wood, N.F.	1986	Photolysis of bentazone on soil. BASF Reg. Doc. #86/5017 BOD95-00265	NL: Used for registration in 1998
7.1.2	Seher	1999	Adsorption Study of 51929 (BAS 351 H) on lysimeter soils BASF Reg.Doc.#99/10685	-
7.1.2; 9.1	Huber, R.	1994	Bentazon - KA, KOC and 1/n values. BASF Reg. Doc. #94/10553 BOD95-00267	NL: Used for registration in 1998
7.1.3	von Götz, N.	1999	Risk assessment of groundwater contamination through application of Bentazone in rice BASF Reg.Doc.#99/10689	-
7.1.3.3	Gottesbüren, B.	1999	Standardisation of lysimeter studies with bentazone in the 'Speyrer Wald' soil to the conditions of the Dutch standard scenario BASF Reg.Doc.#99/10078	-
7.1.3; 9.1	Becker-Arnold, R.	1993	Outdoor lysimeter study with 14C-Bentazone in a BAS 351 32 H formulation. BASF 93/10189 BOD95-00269	NL: Used for registration in 1998

¹ List based on a detailed analysis from RMS in its submission of 7 JULY 2000 (background document C).

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7.1.3; 9.1	Hamm, R.T. und Becker-Arnold R.	1994	Freiland-Lysimeterstudie mit 14C- Bentazon in der Formulierung BAS 351 32 H. BASF 94/11024 BOD95-00270	DE: The study has been submitted in 1994 in a national authorization German translation NL: Used for registration in 1998
7.1.3; 9.1	Kurth, H.-H. und Hassink, J.	1994	Freiland-Lysimeterstudie mit BAS 351 32 H. BASF 94/10983 BOD95-00271	DE: The study has been submitted in 1994 in a national authorization NL: Used for registration in 1998
7.2.1	Hoek van der, E. and de Kreuk, J.F.	1987	Biodegradability of Bentazone according to OECD 301 B (Modified Sturm-Test). PROJECT NO. 17143 ! REPORT R 87/277 WAS96-00041	NL: Used for registration in 1998
7.2.1	Vonk, J.W. and van den Hoven, A.M.	1987	Adsorption of Bentazone to ditch-bottom sediment. PROJECT NO. 17859 ! REPORT R 87/315 WAS96-00042	NL: Used for registration in 1998
7.2.1; 9.2	Bieber, W.-D.	1994	Degradation of the test substance Bentazon in aerobic aquatic environment. BASF 94/11026 WAS95-00111	DE: The study has been submitted in 1994 in a national authorization NL: Used for registration in 1998
7.2.1; 9.2	Gerhardt, R. and Hamm, R.T.	1987	The anaerobic aquatic metabolism of Bentazon (BAS 351 H). BASF 87/0416 WAS95-00114	DE: The study has been submitted in 1993 in a national authorization NL: Used for registration in 1998
7.2.1; 9.2	Hamm, R.T.	1983	Aquatic degradation of 14C-Bentazone. BASF 83/10050 WAS95-00109	DE: The study has been submitted in 1988 in a national authorization German translation NL: Used for registration in 1998
7.2.1; 9	von Götz, N.	1997	Predicted environmental concentrations (PEC) of Bentazone in a rice field and adjacent water bodies BASF Reg.Doc.# 97/11232	-

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8.2	Hamm, R.T.	1987	Einfluß von Bentazon auf das Wachstum von <i>Pseudomonas putida</i> . BASF Aktiengesellschaft, Ludwigshafen, Germany WAT95-00497	DE: The study has been submitted in 1995 in a national authorization
8.2.1	Kirsch, P. and Munk, R.	1987	Report of the study of the acute toxicity Animal species: Rainbow trout (<i>Salmo gairdneri</i> Rich.). BASF Aktiengesellschaft, Ludwigshafen, Germany WAT95-00489	DE: The study has been submitted in 1995 in a national authorization
8.2.2	Kirsch, P. and Munk, R.	1988	Sublethal toxic effects on rainbow trout (<i>Salmo gairdneri</i> Rich.) of BAS 351 32 H (Basagran) BASF Aktiengesellschaft, Ludwigshafen, Germany WAT95-00492	DE: The study has been submitted in 1995 in a national authorization
8.2.5	Bias and Jatzek	1989	Determination of the longterm effects of Basagran BAS 351 32 H Charge 89-1 on the parthenogenetic reproduction rate of the waterflea <i>Daphnia magna</i> Straus. BASF Aktiengesellschaft, Ludwigshafen, Germany WAT95-00494	DE: The study has been submitted in 1995 in a national authorization
8.3.2	Kühner, C.	1994	Assessment of side effects of BAS 351 45 H on <i>Trichogramma cacoeciae</i> Marchal (Hym., Trichogrammatidae) as a representative of the mikrohymenoptera in the laboratory, Test on imagines, Test A. BASF Aktiengesellschaft, Ludwigshafen, Germany ANA96-00021	DE: The study has been submitted in 1995 in a national authorization
8.3.2	Kühner, C.	1994	Assessment of side effects of BAS 351 45 H on <i>Trichogramma cacoeciae</i> Marchal (Hym., Trichogrammatidae) as a representative of the mikrohymenoptera in the laboratory, Test on imagines, Test A. ANA96-00023 BASF Aktiengesellschaft, Ludwigshafen, Germany	DE: The study has been submitted in 1995 in a national authorization
8.3.2	Künast, C.	1993	Effects of BAS 351 45 H on the Lacewing <i>Chrysopa</i> (<i>Chrysoperla</i>) <i>carnea</i> (Chrysopidae, Neuroptera) in laboratory Trials. Test A. BASF Aktiengesellschaft, Ludwigshafen, Germany ANA96-00025	DE: The study has been submitted in 1995 in a national authorization

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8.3.2	Künast, Ch.	1989	Toxizitätstest an dem Laufkäfer Bembidion lampros. BASF Aktiengesellschaft, Ludwigshafen, Germany ANA96-00017	DE: The study has been submitted in 1995 in a national authorization
8.5	Hamm, R.T.	1988	Effect of BASAGRAN (BAS 351 32 H) on Soil Respiration. BASF Aktiengesellschaft, Ludwigshafen, Germany BMF95-00046	DE: The study has been submitted in 1990 in a national authorization
8.5	Hamm, R.T.	1987	Effect of bentazon (BAS 351 32 H) on the nitrification. BASF Aktiengesellschaft, Ludwigshafen, Germany BMF95-00047	DE: The study has been submitted in 1990 in a national authorization

¹ List based on a detailed analysis from **RMS** in its submission of **7 JULY 2000** (background document C).

² Reports received from Member States at the date of finalisation of the present review report (not exhaustive)

**SUMMARY REPORT
OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH
HELD ON 13 JULY 2000 IN BRUSSELS**

President : G. Del Bino

All Member States were present.

Extract

1 Examination and possible vote on a Draft Commission Directive concerning the inclusion of bentazone in Annex I to Council Directive 91/414/EEC (Directive Sanco/1552/2000 rev 2; Review Report 7585/VI/97-rev.4)

The Commission presented the Review Report on Bentazone in document 7585/VI/97-rev.4. The Committee took note of the Review Report.

The following declaration was made:

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

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

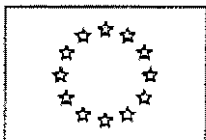
The Commission can for its part confirm its agreement with this declaration (subject to adequate adaptation of the deadline in the declaration).

The Commission subsequently presented the draft Commission Directive concerning the inclusion of Bentazone in Annex 1 to Council Directive 91/414/EEC.

Vote : favourable opinion by qualified majority (84 in favour, 3 abstain).

The substance is an existing active substance used as a herbicide.

A CHECCHI LANG
Director



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

SCIENTIFIC COMMITTEE ON PLANTS

SCP/BENTA/002-Final
8 December 1999

OPINION

OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE EVALUATION OF BENTAZONE IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

(Opinion expressed by the Scientific Committee on Plants on 2 December 1999)

**OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE
INCLUSION OF BENTAZONE IN ANNEX 1 OF DIRECTIVE 91/414/EEC¹
CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE
MARKET**

(Opinion expressed by the Scientific Committee on Plants on 2 December 1999)

TERMS OF REFERENCE

In the context of the possible inclusion of bentazone in Annex 1 to Directive 91/414/EEC, the Commission consulted the Scientific Committee on Plants and submitted for response the following questions:

- (1) Can the Committee comment on the assessment of the Rapporteur Member State on storage stability of the residues in crop samples and confirm the acceptability of the consumer dietary risk assessment?
- (2) Can it be confirmed that use scenarios exist which pose no unacceptable risk to groundwater?

BACKGROUND

Bentazone is an existing active substance in the context of Directive 91/414/EEC concerning the placing of plant protection products on the market and is being one of the active substances covered by the first stage of the work programme provided for under the Directive.

In order to complete its evaluation, the Scientific Committee on Plants had access to documentation comprising a monograph prepared by Germany as Rapporteur Member State and the recommendations of the ECCO² Peer Review Programme.

Bentazone is a widely used contact herbicide for the control of many broad-leaved plants and sedges in agriculture and horticulture and is taken up by foliage and root tissues of plants and is translocated acropetally in the xylem. Based on the data in Volume 1 of the monograph, application rates up to 2.88 kg/ha /season are intended. However, the Committee understands that the notifier BASF has proposed reductions in the application rates for spring and summer for the single treatment to a maximum of 1.5 kg bentazone /ha and for the double application scenario a maximum of 2 x 1 kg bentazone /ha (excluding rice). Autumn and winter authorised uses of bentazone were withdrawn in 1998 in The Netherlands and United Kingdom. BASF also proposed a reduction of the application rate in rice to 1.6 kg/ha and season.

In several plant metabolism studies the residue of concern was determined as bentazone and its metabolites 6-hydroxybentazone glycoside and 8-hydroxybentazone glycoside. The residue levels found in edible crop samples from supervised field trials were close to or below the limit of determination for the applied analytical methods. The Peer Review concluded that the stability of

¹ OJ No L 230, 19.8.91, p. 1.

² European Community Co-ordination

residues in crop samples stored prior to analysis must be addressed. The lack of residue stability tests covering the time of storage of samples between harvest and analysis had given rise to uncertainty of the reported residue data.

The Rapporteur Member State had concluded, on the basis particularly of the hydrolysis stability tests on bentazone and the metabolism studies, that the data provided was sufficient to establish an absence of a risk to consumer

With respect to fate and behaviour in soil, bentazone is a readily degradable compound with no accumulation potential. Furthermore, it does also not accumulate significantly in water and air. The Rapporteur Member State concluded with regard to the contamination of groundwater that there is no concern once applications take place only once in spring or summer with 1500 g bentazone /ha or twice in spring or summer with 1000 g bentazone/ha. However, the Peer Review meeting stressed a possible contamination of groundwater on the basis of monitoring data and missing data i.e. soil degradation studies for colder climates.

OPINION OF THE COMMITTEE

Question 1

Can the Committee comment on the assessment of the rapporteur MS on storage stability of the residues in crop samples and confirm the acceptability of the consumer dietary risk assessment ?

Assessment

Hydrolysis stability tests were only reported in the Monograph for the active substance bentazone; these tests show that bentazone is stable in the pH range 5 to 9 at 25 °C for 30 days.

Due to the fact that bentazone is rapidly metabolised in plants, the stability of the metabolites 6-hydroxybentazone glycoside and 8-hydroxybentazone glycoside have also to be considered. There were no hydrolysis tests for these metabolites reported by the Rapporteur Member State.

However, taking into account the severe conditions necessary to release 6-hydroxy- and 8-hydroxybentazone from its conjugates [i.e. methanolic hydrochloric acid, 90 min at 150° C], it can be assumed that the conjugates of these metabolites are also stable under the storage conditions of harvested samples at - 18 or - 20 °C.

The metabolism of bentazone using the radiolabelled active substance has been investigated in five different crops (monocotyledon and dicotyledon) with application rates comparable with Good Agricultural Practice (GAP). The extractable residues (including bentazone, 6-hydroxybentazone glycoside and 8-hydroxybentazone glycoside) in the plant parts relevant for consumers were very low (below 0.1mg/kg).

The calculation of the TMDI³ as presented to the Committee were performed for the WHO⁴ European diet and the German method [consumption data of a 4-6 year old girl, body weight 13.5

³ Theoretical Maximum Daily Intake

⁴ World Health Organisation

kg] using the proposed MRLs⁵, and for the crops for which no MRL could be proposed and also for crops without registered uses respectively, the sum of the lowest determination limits of bentazone and its metabolites were used.

The reported TMDI exhausts the ADI for 2.7% and 2.2% for the WHO European diet and the consumption data of a 4-6 year old girl respectively.

Conclusion

On the basis of the available information about the stability of bentazone and its metabolites and the result of the metabolism studies, the Committee concludes that the results from the supervised residue trials can be considered as plausible. The dietary intake calculations for adults and young children give similar results of 2 to 3% of the ADI⁶. The Committee confirms that the data provided show sufficient evidence that no risk for the consumer is to be expected.

Question 2

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

Assessment

The Committee considers that bentazone is a mobile substance under field conditions. This is confirmed by, for example, field leaching studies carried out in The Netherlands and in Sweden, although it must be emphasised that these studies were performed under autumn conditions using bare soil and in the case of the Netherlands' study a high groundwater table. The low K_{om} -values (n=13) ranged from 1.7 to 102 l/kg with a median of 14.6 also indicate a high mobility. There is a large amount of monitoring data for bentazone from different European countries which show bentazone residues in groundwater > 0.1 µg/l. Examples include, monitoring data for shallow groundwater in The Netherlands and in the United Kingdom and data from Sweden and Germany. For northern European countries specific data e.g. soil degradation studies conducted under colder climates are missing. A particular problem for groundwater contamination is the applications in rice paddy fields. After flooding, the fields can come in direct contact with the groundwater resulting in high bentazone concentrations in wells of a depth up to 20 m.

Model calculations conducted by the notifier show that use scenarios exist which demonstrate that groundwater concentrations do not exceed 0.1 µg/l. These are based on data from the PELMO and PESTLA leaching models, for example, assuming a $DT50_{lab}^7$ value of 18 days and a K_{om} value of 16, and it was shown that neither the annual average concentrations nor the maximum concentrations reached the 0.1 µg/l value. A PESTLA calculation with a $DT50_{field}$ value of 13 days and a K_{om} value of 7.7 also showed no exceedence of 0.1 µg/l for the maximum concentration.

This assessment is supported by the results of lysimeter studies and field leaching studies. In seven lysimeter studies conducted in Germany with application rates of 1 x 0.5, 1.0 or 1.5 kg/ha or 2 x 1.0 kg/ha it was shown that concentrations in the leachates never reached or exceeded 0.1 µg/l (averaged over one year).

⁵ Maximum Residue Limit

⁶ Acceptable Daily Intake

⁷ Disappearance time for first 50/90% of compound

Regarding the situation in Northern Europe, it must be taken into consideration that bentazone is applied in spring (May) and that the optimum conditions for degradation in soil are from May to July. The average temperatures for this time in Northern Europe are comparable to those of Northern Germany. The lysimeter studies carried out in the 'Sauerland' region in Germany show bentazone concentrations in leachates < 0.1 µg/l. The monthly average temperatures in this region in the May to July period is almost the same as in Jokioinen, Finland (Schmallenberg, Sauerland: 7.9, 11 and 17.9 °C respectively; Jokioinen: 7.1, 12.3 and 16.2 °C respectively). Therefore the lysimeter studies conducted in Schmallenberg may be considered in the context of other Northern European Countries. However the field degradation rate of bentazone is an important factor in determining leaching potential and groundwater contamination and the variability of degradation in different soil types should be taken into account.

Monitoring data in Germany showed the presence of bentazone in groundwater but it is possible to establish that such incidences were linked to misuse or accidents in product handling. Groundwater monitoring of 3547 wells carried out in 1996 showed 19 cases with concentrations >0.1 µg/l and in 1997 revealed 13 wells >0.1 µg/l out of 2365 sampled. Monitoring data of shallow groundwater and field leaching studies from The Netherlands, United Kingdom and Sweden show possible leaching of bentazone. The interpretation of these data is difficult. Reasons for the contamination could have been: autumn applications, applications on bare soil, high application rates, sandy soils, groundwater table about 1 m and macropore flow.

Conclusion

On the basis of the scenarios presented by the notifier it can be confirmed that use scenarios could exist which would pose no unacceptable risks to ground water.

The modelling scenarios and lysimeter/field studies presented by the notifier do not represent the full range of soil, climate and physico-chemical properties of the active substance. This is particularly relevant for the existing use on rice.

It is recommended that risk assessments should be conducted at Member State level, in particular regarding use in rice cultivation. Member States should assess leaching potential in vulnerable locations to determine whether the revised GAP i.e. reduced application rates and timing of application can achieve the desired result.

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