

COMMISSION DECISION

of 10 March 2004

concerning the non-inclusion of atrazine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance

(notified under document number C(2004) 731)

(Text with EEA relevance)

(2004/248/EC)

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 2003/119/EC ⁽²⁾, and in particular the third and the fourth subparagraphs of Article 8(2) thereof,

Having regard to Commission Regulation (EEC) No 3600/92 of 11 December 1992 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 concerning the placing of plant protection products on the market ⁽³⁾, as last amended by Regulation (EC) No 2266/2000 ⁽⁴⁾, and in particular Article 7(3A)(b) thereof,

Whereas:

- (1) Article 8(2) of Directive 91/414/EEC provided for the Commission to carry out a programme of work for the examination of the active substances used in plant protection products which were already on the market on 25 July 1993. Detailed rules for the carrying out of this programme were established in Regulation (EEC) No 3600/92.
- (2) Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member States for the implementation of Commission Regulation (EEC) No 3600/92 ⁽⁵⁾, as last amended by Regulation (EC) No 2230/95 ⁽⁶⁾, designated the active substances which should be assessed in the framework of Regulation (EEC) No 3600/92, designated a Member State to act as rapporteur in respect of the assessment of each substance and identified the producers of each active substance who submitted a notification in due time.
- (3) Atrazine is one of the 89 active substances designated in Regulation (EC) No 933/94.
- (4) In accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92, the United Kingdom, being the designated rapporteur Member State, submitted on 11 November

1996 to the Commission the report of its assessment of the information submitted by the notifiers in accordance with Article 6(1) of that Regulation.

- (5) On receipt of the report of the rapporteur Member State, the Commission undertook consultations with experts of the Member States as well as with the main notifier Syngenta as provided for in Article 7(3) of Regulation (EEC) No 3600/92.
- (6) The Commission organised a tripartite meeting with the main data submitter and the rapporteur Member State for this active substance on 6 June 2003.
- (7) The assessment report prepared by the United Kingdom has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. This review was finalised on 3 October 2003 in the format of the Commission review report for atrazine.
- (8) The dossier and the information from the review were also submitted to the Scientific Committee for Plants. The Committee was asked to comment on the aspects of possible contamination of groundwater by atrazine. In its opinion ⁽⁷⁾, the Scientific Committee on Plants did not accept the reported calculations of the environmental concentrations in groundwater. The Committee is also of the opinion that available monitoring data does not demonstrate that concentrations of atrazine or its breakdown products will not exceed 0,1 µg/l in groundwater and it expects that for soils with pH above six concentrations of atrazine and its breakdown products will not exceed 0,1 µg/l.
- (9) Assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing atrazine satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. In particular available monitoring data were insufficient to demonstrate that in large areas concentrations of the active substance and its breakdown products will not exceed 0,1 µg/l in groundwater. Moreover it cannot be assured that continued

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 325, 12.12.2003, p. 41.

⁽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 on specific questions from the Commission concerning the evaluation of atrazine in the context of Council Directive 91/414/EEC — SCP/ATRAZINE/002-Final — adopted on 30 January 2003.

use in other areas will permit a satisfactory recovery of groundwater quality where concentrations already exceed 0,1 µg/l in groundwater. These levels of the active substance exceed the limits in Annex VI to Directive 91/414/EEC and would have an unacceptable effect on groundwater.

- (10) Atrazine should therefore not be included in Annex I to Directive 91/414/EEC.
- (11) Measures should be taken to ensure that existing authorisations for plant protection products containing atrazine are withdrawn within a prescribed period and are not renewed and that no new authorisations for such products are granted.
- (12) In the light of the information submitted to the Commission it appears that, in the absence of efficient alternatives for certain limited uses in certain Member States, there is a need for further use of the active substance so as to enable the development of alternatives. It is therefore justified in the present circumstances to prescribe, under strict conditions aimed at minimising risk, a longer period for the withdrawal of existing authorisations for the limited uses considered as essential for which no efficient alternatives appear currently to be available for the control of harmful organisms.
- (13) Any period of grace for disposal, storage, placing on the market and use of existing stocks of plant protection products containing atrazine allowed by Member States, should be limited to a period no longer than 12 months to allow existing stocks to be used in no more than one further growing season.
- (14) This Decision does not prejudice any action the Commission may undertake at a later stage for this active substance within the framework of Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances⁽¹⁾, as last amended by Regulation (EC) No 807/2003⁽²⁾.
- (15) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Atrazine shall not be included as active substance in Annex I to Directive 91/414/EEC.

Article 2

Member States shall ensure that:

1. authorisations for plant protection products containing atrazine are withdrawn by 10 September 2004;
2. from 16 March 2004 no authorisations for plant protection products containing atrazine are granted or renewed under the derogation provided for in Article 8(2) of Directive 91/414/EEC;
3. in relation to the uses listed in column B of the Annex, a Member State specified in column A may maintain in force authorisations for plant protection products containing atrazine until 30 June 2007 provided that it:
 - (a) ensures that such plant protection products remaining on the market are relabelled in order to match the restricted use conditions;
 - (b) imposes all appropriate risk mitigation measures to reduce any possible risks in order to ensure the protection of human and animal health and the environment; and
 - (c) ensures that alternative products or methods for such uses are being seriously sought, in particular, by means of action plans.

The Member State concerned shall inform the Commission on 31 December 2004, at the latest, on the application of this paragraph and in particular on the actions taken pursuant to points (a) to (c) and provide, on a yearly basis, estimates of the amounts of atrazine used for essential uses pursuant to this Article.

Article 3

Any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC, shall be as short as possible and:

- (a) for the uses for which the authorisation is to be withdrawn on 10 September 2004, shall expire not later than 10 September 2005;
- (b) for the uses for which the authorisation is to be withdrawn by 30 June 2007, shall expire not later than 31 December 2007.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 10 March 2004.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 33, 8.2.1979, p. 36.

⁽²⁾ OJ L 122, 16.5.2003, p. 36.

ANNEX

List of authorisations referred to in Article 2(3)

Column A	Column B
Member State	Use
Ireland	Maize, forestry
United Kingdom	Sweetcorn, forestry
Spain	Maize
Portugal	Maize



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Atrazine

SANCO/10496/2003-final

10 September 2003

Review report for the active substance atrazine

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
3 October 2003

*in support of a decision concerning the non-inclusion of atrazine in Annex I of Directive
91/414/EEC and the withdrawal of authorisations for plant protection products containing
this active substance*

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of atrazine, 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 2266/2000⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Atrazine 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, Ciba Geigy Limited (then Novartis, now Syngenta) on 23 July 1993, ACI International (on behalf of Sanachern International) on 30 July 1993, Oxon Italia S.p.A on 20 July 1993, Maktheshim Agan International on 20 July 1993, Industrial Kern Espagna on 26 July 1993, Helm AG on 23 July 1993, Calliope SA on 21 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 atrazine in Annex I to the Directive. Helm AG, B.V. Luxan and Calliope withdrew their notifications on 8 March 1995, 10 January 1995 and 17 July 1995, respectively.

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

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 259, 13.10.2000, p.27.

³ OJ No L 107, 28.04.1994, p.8.

2230/95⁽⁴⁾, designated the United Kingdom as rapporteur Member State to carry out the assessment of atrazine 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 atrazine this deadline was 30 April 1995.

Ciba Geigy Limited (then Novartis, now Syngenta), ACI International (on behalf of Sanachem International), Oxon Italia S.p.A and Maktheshim Agan International submitted each a dossier to the rapporteur Member State. Ciba Geigy was the main data submitter, with a dossier which did not contain substantial data gaps, taking into account the supported uses. ACI International (on behalf of Sanachem International), Oxon Italia S.p.A and Maktheshim Agan International did not submit complete dossiers. Information has furthermore been submitted by third parties, including the European Environmental Bureau and the World Wide Fund for Nature.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, the United Kingdom submitted on 11 November 1996 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of atrazine 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 atrazine from Ciba Geigy Limited (then Novartis, now Syngenta), on 05 February 1998.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report (monograph) to all the Member States on 09 December 1997, as well as to Ciba Geigy Limited (then Novartis, now Syngenta) being the main data submitter on 18 December 1997.

The Commission organised an intensive consultation of technical experts from a certain 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 ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from March to July 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 23 September 1998 for comments and further clarification.

⁴ OJ No L 225, 22.09.1995, p.1.

In accordance with the provisions of Article 6(4) of Directive 91/414/EEC concerning consultation in the light of a possible unfavourable decision for the active substance the Commission organised a tripartite meeting with the main data submitter and the rapporteur Member State for this active substance on 6 June 2003.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment 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 the Food Chain and Animal 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 March 2000 until May 2003, and was finalised in the meeting of the Standing Committee on 4 July 2003.

These documents were also submitted to the Scientific Committee for Plants for separate consultation. The report of this Committee was formally adopted on 30/01/2003 (SCP/ATRAZINE/002-Final⁵). The Committee was asked to comment on the aspects of possible contamination of groundwater by atrazine. In its opinion, the Committee did not accept the reported calculations of the environmental concentrations in groundwater. The Committee is also of the opinion that available monitoring data does not demonstrate that concentrations of atrazine or its breakdown products will not exceed 0.1 µg/l in groundwater and it expects that for soils with pH above 6 concentrations of atrazine and its breakdown products will not exceed 0.1 µg/l.

The present review report contains the conclusions of the 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.

⁵ Opinion of the Scientific Committee on Plants on specific questions from the Commission concerning the evaluation of atrazine in the context of Council Directive 91/414/EEC.

2. Purposes of this review report

This review report including the background documents has been developed and finalised in support of Decision 2004/248/EC⁶ concerning the non-inclusion of atrazine in Annex I to Directive 91/414/EEC.

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.

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

The overall conclusion of this evaluation, based on the information available and the proposed conditions of use, is that:

- **the information available is insufficient** to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC. In particular the available monitoring data were insufficient to demonstrate that in large areas concentrations of the active substance and its breakdown products will not exceed 0.1 µg/l in groundwater. Moreover it cannot be assured that continued use in other areas will permit a satisfactory recovery of groundwater quality where concentrations already exceed 0.1 µg/l in groundwater.

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general the requirements laid down in Article 5 (1) (a) and (b) of Council Directive 91/414/EEC.

⁶ OJ L78, 16.3.2004, p.53.

