



Quintozene
5044/VI/97-rev. 4
13 July 2000

Review report for the active substance **quintozene**

Finalised in the Standing Committee on Plant Health at its meeting on **13 July 2000** in support of a decision concerning the non-inclusion of quintozene in Annex I to 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 quintozene, 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 1972/99⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Quintozenone 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, Uniroyal Chemicals Ltd. on 15 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 quintozene 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 Greece as rapporteur Member State to carry out the assessment of quintozene 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 quintozene this deadline was 30 April 1995.

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 244, 16.09.1999, p.41.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

Only Uniroyal Chemicals Ltd. submitted a dossier to the rapporteur Member State. B.V. Luxan did not submit a dossier. The dossier submitted by Uniroyal Chemicals Ltd. was not considered as complete.. No Information has been submitted by third parties.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Greece submitted on 1 December 1997 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 quintozene 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 quintozene from Uniroyal Chemicals Ltd., on 9 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 to all the Member States on 9 December 1997 as well as to Uniroyal Chemicals Ltd. 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, details of uses and further information, methods of analysis;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues;
- 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.

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 4 February 1999.

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 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 November 1999 to March 2000, and was finalised in the meeting of the Standing Committee on 13 July 2000.

The present review report contains the conclusions of this final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the

comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

2. Purposes of this review report

This review report including the background documents has been developed and finalised in support of Decision 2000/816/EC concerning the non-inclusion of quintozene 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

Uniroyal Chemicals, the main notifier of the substance, formally withdrew its support for quintozene within the EU Peer Review Programme and, therefore, no engagements are made to produce the necessary supplementary data.

Moreover the overall conclusion of this evaluation 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 with regard to the environmental fate and ecotoxicology of the substance and its main metabolite and with regard to certain data gaps concerning mammalian toxicology and residues.

Based on the information available and the proposed conditions of use it was concluded that a risk of non-target organisms exposed to quintozene cannot be excluded and that there are concerns on the persistence of the active substance and on the safety of operators and consumers. 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.