# COMMISSION DIRECTIVE 2003/112/EC
## of 1 December 2003
## amending Council Directive 91/414/EEC to include paraquat as an active substance
**(Text with EEA relevance)**

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 2003/84/EC [2], and in particular Article 6(1) thereof,

Whereas:

(1) 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], establishes a list of active substances of plant protection products to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes paraquat.

(2) For paraquat, 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 range of uses proposed by the notifier. Pursuant to Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member State for the implementation of Commission Regulation (EEC) No 3600/92 [5], as last amended by Regulation (EC) No 2230/95 [6], the United Kingdom was designated as rapporteur Member State. The United Kingdom submitted the relevant assessment reports and recommendations to the Commission on 31 October 1996 in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(3) This assessment report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 3 October 2003 in the format of the Commission review report for paraquat.

(4) The report on paraquat and further information were also submitted to the Scientific Committee for Plants. The Committee was asked to comment on the relevance for consumers and operators of the ocular and pulmonary changes, which were observed in the long-term rat study, on the risk for operators, taking into particular account potential inhalatory and dermal exposure, on potential long-term effects to soil-dwelling organisms, and on the risks the intended uses might pose to reproducing birds and hares. In its opinion [7], the Scientific Committee concluded that neither the pulmonary lesions observed in animals after oral administration of paraquat nor the systemic effects on the eye, observed in rats and not in other species, are relevant to the risk assessment for operators and consumers. Based on the field exposure studies, corroborated by information on health surveys on operators, the Committee found that when paraquat is used as a plant protection product as recommended under prescribed good working practices, its use does not pose any significant health risk for the operators. The Committee also noted that uses at recommended field rates are unlikely to pose a significant risk to soil-dwelling organisms. However, a more detailed appraisal of the likely effects of paraquat on the rate of degradation of organic material in soil was requested in view of remaining uncertainty. This information was subsequently delivered and evaluated by the rapporteur Member State. Furthermore, the Scientific Committee concluded that available studies

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 247, 30.9.2003, p. 20.
[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 regarding the evaluation of paraquat in the context of Council Directive 91/414/EEC; SCP/PARA/002 adopted on 20 December 2001.

indicate a hazard to ground-breeding birds but further information on realistic exposures is needed for a definitive assessment of the risk. This information was subsequently provided and the evaluation within the Standing Committee on the Food Chain and Animal Health concluded that there are several situations where exposure to ground-nesting birds is negligible. However, there are also scenarios where exposure may occur. The evaluation within the Standing Committee on the Food Chain and Animal Health concluded that the risk would be acceptable, provided appropriate risk-mitigation measures are applied. Finally, the Scientific Committee concluded that paraquat may be expected to cause lethal and sublethal effects for hares, but the available data are inadequate to estimate the proportion of hares affected. The views of the Scientific Committee were taken into consideration when drafting this Directive and the review report. The evaluation within the Standing Committee on the Food Chain and Animal Health concluded that the risk would be acceptable if appropriate risk-mitigation measures were applied.

(5) It has appeared from the various examinations made that there are uses of plant protection products containing paraquat which may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, provided appropriate risk-mitigation measures and restrictions are applied. It is therefore appropriate to include paraquat in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive. However some uses of plant protection products containing paraquat pose an unacceptable risk and should therefore not be authorised. Moreover, it is considered appropriate to ensure that Member States impose that the notifier and any other authorisation holder of paraquat establish a stewardship programme particularly for operator safety, and that they report to the Commission yearly on incidences of operator health problems as well as possible impacts on hares. This should enable a verification of whether the risk-mitigation measures imposed by Member States really limit the possible risks for operators and hares to an acceptable level, and, if appropriate, a re-evaluation, in line with scientific progress, of the properties and potentially related risks to humans and the environment.

(6) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(7) After inclusion, Member States should be allowed a reasonable period within which to implement the provisions of Directive 91/414/EEC as regards plant protection products containing paraquat, and, in particular, to review existing authorisations to ensure that the conditions regarding those active substances set out in Annex I to Directive 91/414/EEC are satisfied. A longer period should be provided for the submission and assessment of the complete dossier of each plant protection product in accordance with the uniform principles laid down in Directive 91/414/EEC.

(8) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

*Article 2*

Member States shall adopt and publish by 30 April 2005 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 May 2005.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

*Article 3*

1. Member States shall review the authorisation for each plant protection product containing paraquat to ensure that the conditions relating to those active substances set out in Annex I to Directive 91/414/EEC are complied with. Where necessary and by 30 April 2005 at the latest, they shall amend or withdraw the authorisation.

2. Member States shall, for each authorised plant protection product containing paraquat as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC, by 31 October 2004 at the latest, re-evaluate the product in accordance with 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 to that Directive. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC. Where necessary and by 31 July 2008 at the latest, they shall amend or withdraw the authorisation.

*Article 4*

Member States shall ensure that the authorisation holders report at the latest on 31 March 2008 on the effects of risk-mitigation measures to be applied through a stewardship programme and the implementation of advances in paraquat formulations. Member States shall submit this information without delay to the Commission.

The Commission shall submit to the Standing Committee on the Food Chain and Animal Health a report on the application of the present Directive indicating whether the requirements for Annex I inclusion continue to be satisfied and may propose any amendment, including if necessary the withdrawal from Annex I, to the present Directive that it deems necessary to comply with its provisions.

*Article 5*

This Directive shall enter into force on 1 November 2004.

*Article 6*

This Directive is addressed to the Member States.

Done at Brussels, 1 December 2003.

*For the Commission*
David BYRNE
*Member of the Commission*

*ANNEX*

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EEC

| No | Common name, identification numbers | IUPAC name | Purity [1] | Entry into force | Expiration of inclusion | Specific provisions |
|---|---|---|---|---|---|---|
| '75 | Paraquat<br>CAS No 4685-14-7<br>CIPAC No 56 | 1,1'-dimethyl-4,4'-bipyridinium | 500 g/l (expressed as paraquat dichloride) | 1 November 2004 | 31 October 2014 | Only uses as herbicide may be authorised.<br>The following uses must not be authorised:<br>— knapsack and handheld applications in home gardening, neither by amateur nor by professional users,<br>— use via broadcast air-assisted application equipment,<br>— ultra low volume applications.<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on paraquat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2003, shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of:<br>— operators, in particular for knapsack and handheld applications,<br>— ground-nesting birds. Where use scenarios indicate the potential for exposure of eggs a risk assessment should be conducted and, where appropriate, risk mitigation applied,<br>— aquatic organisms. Conditions of authorisation should include risk-mitigation measures, where appropriate,<br>— hares. Where use scenarios indicate the potential for exposure of hares, a risk assessment should be conducted and, where appropriate, risk mitigation applied.<br>Member States shall ensure that the authorisation holders report at the latest on 31 March each year until 2008 on incidences of operator health problems and impact on hares in one or more representative areas of use, which should be supplemented by sales data and a survey of use patterns, so that a realistic picture of the toxicological and ecological impact of paraquat can be obtained.<br>Member States must ensure that technical concentrates shall contain an effective emetic. Liquid formulations shall contain an effective emetic, blue/green colorants and stenching or other olfactory alerting agent or agents. Other safeners, such as thickeners, may also be included.<br>In doing so they shall take account of the FAO specification. |

[1] Further details on identity and specification of active substance are provided in the review report.'