

European Commission **Peer Review Programme**



Paraquat
Volume 3

Annex B

ADDENDUM

**to the Draft Assessment Report and Proposed Decision of the
United Kingdom prepared in the context of the possible inclusion
of the above active substance in Annex I of Council Directive
91/414/EEC**

Summary, Scientific Evaluation and Assessment

7 February 2003

WARNING: This document forms part of an Evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

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Addendum to the draft assessment report- paraquat

B.6.12.2 Intakes by humans

Acute risk assessment for paraquat

When the original monograph for paraquat was written and submitted to the Commission the acute risk assessment methodology had not been finalised. At that time an ARfD was not established for paraquat either by the rapporteur or as a result of ECCO consideration.

Based on the available data it has been proposed that the ARfD is set at 0.005 mg/kg bw based on the NOAEL in the 90 day dog study and a 100 fold assessment factor. This is presented in PSD's Addendum to the draft assessment report, dated 18 November 2002.. It is noted in that Addendum that this value is possibly conservative.

An acute dietary risk assessment conducted using the proposed ARfD is provided below.

The basis for this risk assessment is on the highest residues found in residue trials of representative crops evaluated in the monograph. In all cases residues above the limit of determination were not detected unless fallen fruit were sampled. Fallen fruit would not be utilised commercially and therefore the consumer will not be exposed to these higher residues.

The UK acute intake model has been used.

Table 1 Short term intakes - National Estimate of Short Term Intake (NESTI)

Commodity	Highest residue (mg/kg)	STMR (mg/kg)	Variability factor	NESTI for Adult	NESTI for Toddler
Apples	0.01	0.01	7	0.0001	0.0006
Cucumber	0.03	0.03	7	0.0003	0.001
Grapes	0.01	0.01	5	0.0001	0.0005
Melon	0.03	0.03	5	0.0008	0.0031
Oranges	0.02	0.02	7	0.0003	0.0016
Peaches	0.01	0.01	7	0.0001	0.0006
Plums	0.01	0.01	7	0.0001	0.0003
Potato	0.01	0.01	7	0.0003	0.001
Sweetcorn	0.05	0.05	1	0.0002	0.0004
Olives	0.05	0.05	1	<0.0001	0.0001
Strawberry	0.01	0.01	1	<0.0001	0.0001

Conclusion

It can be seen from Table 1 above that there are no exceedences of the ARfD. It can be concluded that there are safe uses of paraquat.

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