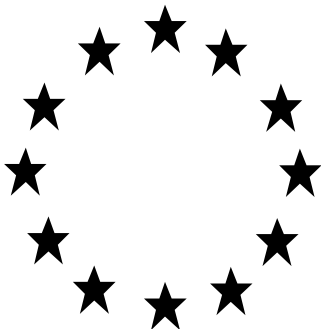
UK RAPPORTEUR MONOGRAPH

Council Directive 91/414/EEC
Regulation 3600/92



Paraquat

Volume 1

Report and Proposed Decision of the United Kingdom made to the European Commission under Article 7(1) of Regulation 3600/92

September 1996

CONTENTS

LEVEL 1

Paraquat

STATEMENT OF THE SUBJECT MATTER AND PURPOSE OF MONOGRAPH

1.1 Purpose for which the monograph was prepared

Council Directive 91/414/EEC established a review programme for all active substances on the Community market by 25 July 1993. This monograph on the review of paraquat has been prepared for submission to the Standing Committee on Plant Health to enable a decision to be made on the listing of paraquat on Annex I of the Directive 91/414/EEC.

1.2 Summary and assessment of the steps taken to collectively present the dossier

Confidential information - see Annex C (Volume 4)

1.3 Identity of the active substance.

Note: Information on notifiers other than Zeneca Agrochemicals is contained in section 1.6.1 (page 21) of this report and also in Annex C - confidential information - section C.1.4.1 (page 21).

1.3.1 Name and address of applicant for inclusion of the active in Annex I (Annex IIA 1.1)

Central address:	International Headquarters : ZENECA Agrochemicals Fernhurst Haslemere Surrey GU27 3JE United Kingdom
Telephone:	++ 44 1428 655602
Facsimile:	++ 44 1428 655949
Contact:	A R Cook

1.3.2 Common name and synonyms (IIA 1.3)

ISO: Paraquat
Paraquat dichloride

1.3.3 Chemical name (IIA 1.4)

IUPAC: 1,1'-dimethyl-4,4'-bipyridinium
CA: 1,1'-dimethyl-4,4'-bipyridinium (8 & 9 CI)

1.3.4 Manufacturer's development code number (IIA 1.5)

PP148

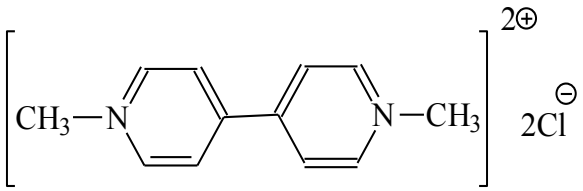
1.3.5 CAS, EEC and CIPAC numbers (IIA 1.6)

CAS No.	4685-14-7 (paraquat) 1910-42-5 (paraquat dichloride)
EEC No.	225-141-7 (paraquat) 217-615-7 (paraquat dichloride)
CIPAC No.	56 (paraquat)

1.3.6 Molecular and structural formula, molecular mass

Molecular formula	$C_{12}H_{14}N_2$ (paraquat) $C_{12}H_{14}Cl_2N_2$ (paraquat dichloride)
Molecular mass	186.3 (paraquat) 257.2 (paraquat dichloride)

Structural formula:



1.3.7 Manufacturer of the active substance (IIA 1.2)

Confidential information - See Annex C (Volume 4)

1.3.8 Method of manufacture (IIA 1.8)

Confidential information - See Annex C (Volume 4)

1.3.9 Specification of purity of the active substance (IIA 1.9)

Confidential information - See Annex C (Volume 4)

1.3.10 Identity of isomers, impurities and additives (IIA 1.10)

Confidential information - See Annex C (Volume 4)

1.3.11 Analytical profile of batches (IIA 1.11)

Confidential information - See Annex C (Volume 4)

1.4. Identity of the plant protection products

1.4.1 Identity of the plant protection product - Liquid Soluble Concentrate

1.4.1.1 Current, former and proposed trade names and development code numbers (IIIA 1.3)

Trade name: 'Gramoxone'

Code number: YF 7697A

1.4.1.2 Applicant and manufacturer of the plant protection product (IIIA 1.1, 1.2)

Note: Information on notifiers other than Zeneca Agrochemicals is contained in section 1.6.1 (page 21) of this report and also in Annex C - confidential information - section C.1.4.1 (page 21).

Applicant

Central address:	International Headquarters : ZENECA Agrochemicals Fernhurst Haslemere Surrey GU27 3JE United Kingdom
Telephone:	++ 44 1428 655602
Facsimile:	++ 44 1428 655949
Contact:	A R Cook

Manufacturer Confidential information - See Annex C (Volume 4)

1.4.1.3 Type of the preparation and code (IIIA 1.5)

The preparation is a liquid soluble concentrate (SL).

1.4.1.4 Function (IIIA 1.6, IIA 3.1)

Herbicide

1.4.1.5 Composition of the preparation (IIIA 1.4)

Confidential information - See Annex C (Volume 4)

1.4.2 Identity of the plant protection product - Water Dispersible Granule

1.4.2.1 Current, former and proposed trade names and development code numbers (IIIA 1.3)

Trade name: 'Weedol'

Code number: YF 7439B

1.4.2.2 Applicant and manufacturer of the plant protection product (IIIA 1.1, 1.2)

Note: Information on notifiers other than Zeneca Agrochemicals is contained in section 1.6.1 (page 21) of this report and also in Annex C - confidential information - section C.1.4.1 (page 21).

Applicant

Central address:	International Headquarters : ZENECA Agrochemicals Fernhurst Haslemere Surrey GU27 3JE United Kingdom
Telephone:	++ 44 1428 655602
Facsimile:	++ 44 1428 655949
Contact:	A R Cook

Manufacturer Confidential information - See Annex C (Volume 4)

1.4.2.3 Type of the preparation and code (IIIA 1.5)

The preparation is a water dispersible granule (WG).

1.4.2.4 Function (IIIA 1.6, IIA 3.1)

Herbicide

1.4.2.5 Composition of the preparation (IIIA 1.4)

Confidential information - See Annex C (Volume 4)

1.5 Uses of the plant protection products

1.5.1 Uses of the plant protection product - Liquid Soluble Concentrate

1.5.1.1 Field of use (IIIA 3.1, IIA 3.3)

Agriculture
Horticulture
Forestry
Viticulture

Amenity horticulture

Weed control on non-cultivated areas

Home garden

1.5.1.2 Effects on harmful organisms (IIIA 3.2, IIA 3.2)

Paraquat acts with great rapidity in the green parts of plants to produce disruption of the plant cells, leading to death and desiccation of the foliage. It is not translocated through plants, and its destructive action is restricted to the site of application. It is a non-selective herbicide with a broad spectrum of activity and is particularly effective against grass weeds.

1.5.1.3 Summary of intended uses (IIIA 3.3, 3.4, 3.7, IIA 3.4)

Annual and perennial weed control.

Table 1.5.1 Summary of notified uses - Liquid Soluble Concentrate

Crop /Situation	Country	Rate: (maximum per application) (kg a.s./ha)	Rate: (maximum per season) (kg a.s./ha)	Spray conc. (g a.s./hl)	No. of applications (maximum per season)	Spray interval (days)	Pre harvest interval in days
Alfalfa	Greece	1.0	-	200	-	-	
Alfalfa	Spain	0.6	-	200	-	-	
Apples	Portugal	1.1	-	440	-	-	
Apples	Spain	0.8	-	267	-	-	
Apples	Italy	1.0	3.0	100	3	-	30
Aquatic	Belgium	2.0	-	500	-		10
Aquatic	Spain	2.2	-	733	-	-	N/A
Aquatic	Spain	1.0	-	333	-	-	N/A
Around greenhouses, frames and pot standing areas	UK	0.6	-	300	-	-	N/A
Around greenhouses, frames and pot standing areas	UK	1.1	-	500	-	-	N/A
Around greenhouses, frames and pot standing areas	UK	1.7	-	500	-		N/A
Artichokes	Spain	0.6		200	-	-	
Asparagus	Belgium	0.8	-	200	-		
Asparagus	Netherlands	0.6	-	150	-	-	
Autumn use	Ireland	0.8	-	800	-	-	N/A
Autumn use	UK	0.8	-	800	-	-	N/A
Bananas	Portugal	1.1	-	440	-	-	
Bananas	Spain	0.6	-	200	-	-	
Before seedbed preparation	Netherlands	1.0	-	250	-		N/A
Blackberries	Netherlands	1.0	-	250	-	-	
Blackcurrants	Ireland	1.1	-	1100	-	-	
Blackcurrants	UK	1.1	-	1100	-	-	
Bulbs	Ireland	1.1	-	1100	-	-	N/A
Bulbs	UK	1.1	-	1100	-	-	N/A
Bush fruit	Ireland	1.1	-	1100	-	-	
Bush fruit	UK	1.1	-	1100	-	-	
Cabbages	Spain	0.6	-	200	-	-	
Canal banks	Italy	1.0	3.0	100	3	-	N/A
Cane fruit	Ireland	1.1	-	1100	-	-	
Cane fruit	UK	1.1	-	1100	-		
Citrus	Greece	1.1	2.0	250	2	-	
Citrus	Portugal	1.1	-	267	-	-	
Citrus	Spain	0.8	-	267	-	-	
Citrus	Italy	1.0	3.0	100	3	-	30
Clover	Belgium	0.6	-	300	-	-	N/A
Cotton	Greece	0.6	1.2	120	2		
Cotton	Greece	0.1	-	20	-	-	
Currant bushes	Netherlands	1.0	-	250	-	-	
Direct drilling	Ireland	1.7	-	1700	-	-	N/A
Direct drilling	Ireland	1.1	-	1100	-	-	N/A

Table 1.5.1 Summary of notified uses - continued

Crop /Situation	Country	Rate: (maximum per application) (kg a.s./ha)	Rate: (maximum per season) (kg a.s./ha)	Spray conc. (g a.s./hl)	No. of applications (maximum per season)	Spray interval (days)	Pre harvest interval in days
Direct drilling	UK	1.7	-	850	-	-	N/A
Direct drilling	UK	1.1	-	1100	-	-	N/A
Ditch banks	Italy	1.0	3.0	100	3	-	N/A
Drainage channels	Italy	1.0	3.0	100	3	-	N/A
Fallow land	Ireland	1.1	-	1100	-	-	N/A
Fallow land	UK	1.1	-	1100	-	-	N/A
Field borders	Belgium	1.0	-	500	-	-	N/A
Field borders	Netherlands	1.0	-	250	-	-	N/A
Field headlands	Ireland	1.1	-	1100	-	-	N/A
Field headlands	UK	1.1	-	1100	-	-	N/A
Flower bulbs	Netherlands	1.0	-	250	-	-	N/A
Footpaths	UK	0.6	-	300	-	-	N/A
Footpaths	UK	1.1	-	500	-	-	N/A
Footpaths	UK	1.7	-	500	-	-	N/A
Forestry	Ireland	1.1	-	1100	-		N/A
Forestry	UK	1.1	-	1100	-	-	N/A
Forget-me-not grown for seed	Netherlands	0.6	-	150	-	-	N/A
Gooseberries	Ireland	1.1	-	1100	-	-	
Gooseberries	UK	1.1	-	1100	-	-	
Grass grown for seed	Netherlands	1.0	-	100	-	-	N/A
Grassland	Netherlands	1.0	-	100	-	-	N/A
Grassland renovation	Netherlands	0.6	-	150	-	-	N/A
Hardy ornamentals	Ireland	1.1	-	1100	-	-	N/A
Hardy ornamentals	UK	1.1	-	1100	-	-	N/A
Hazelnuts	Italy	1.0	2.0	100	2	-	30
Hazelnuts	Italy	1.0	2.0	100	2	-	40
Hops	Belgium	0.8	-	400	-	-	N/A
Hops	Ireland	1.1	-	1100	-	-	
Hops	UK	1.1	-	1100	-	-	
Horticulture	Portugal	1.1	-	440	-	-	
Industrial sites	Spain	1.0	-	333	-	-	N/A
Industrial situations	UK	0.6	-	300	-	-	N/A
Industrial situations	UK	1.1	-	500	-	-	N/A
Industrial situations	UK	1.7	-	500	-	-	N/A
Inter-row	Belgium	0.8	-	400	-	-	
Inter-row	Netherlands	1.0	-	100	-	-	
Killing grassland before ploughing	Ireland	0.8	-	800	-	-	N/A
Killing grassland before ploughing	UK	0.8	-	400	-	-	N/A
Lettuce	Spain	0.6	-	200	-	-	
Lucerne	Belgium	0.4	-	200	-	-	N/A

Table 1.5.1 Summary of notified uses - continued

Crop /Situation	Country	Rate: (maximum per application) (kg a.s./ha)	Rate: (maximum per season) (kg a.s./ha)	Spray conc. (g a.s./hl)	No. of applications (maximum per season)	Spray interval (days)	Pre harvest interval in days
Lucerne	Belgium	0.6	-	300	-	-	N/A
Maize	Greece	0.6	1.2	120	2	-	
Maize	Netherlands	0.6	-	200	-	-	
Maize	Spain	0.6	-	200	-	-	
Minimal cultivation	Ireland	0.8	-	800	-	-	N/A
Minimal cultivation	Ireland	1.7	-	1700	-	-	N/A
Minimal cultivation	UK	0.8	-	800	-	-	N/A
Minimal cultivation	UK	0.8	-	400	-	-	N/A
Minimal cultivation	UK	1.7	-	850	-	-	N/A
Non-crop areas	Portugal	2.2	-	880	-		
Nurseries	Portugal	1.1	-	440	-	-	
Nuts	Italy	1.0	2.0	100	2	-	40
Olives	Greece	1.0	2.0	250	2	-	
Olives	Portugal	1.1	-	440	-	-	
Olives	Spain	0.8	-	267	-	-	
Olives	Italy	1.0	2.0	100	2	-	30
Olives	Italy	1.0	2.0	100	2	-	40
Orchards	Belgium	1.0	-	500	-	-	
Orchards	Netherlands	1.0	-	250	-	-	
Ornamental shrubs	Belgium	1.0	-	500	-		N/A
Pasture renewal	Portugal	1.6	-	640	-		
Pasture renovation	Belgium	1.0	-	500	-	-	
Peaches	Portugal	1.1	-	440	-	-	
Peaches	Spain	0.8	-	267	-		
Pears	Portugal	1.1	-	440	-	-	
Pears	Spain	0.8	-	267	-	-	
Pears	Italy	1.0	3.0	100	3	-	30
Peppers	Spain	0.6	-	200	-	-	
Permanently uncropped areas	Netherlands	1.0	-	250	-	-	N/A
Plantations	Ireland	1.1	-	1100	-	-	N/A
Plantations	UK	1.1	-	1100	-	-	N/A
Plums	Spain	0.8	-	267	-	-	
Poa pratensis grown for seed	Netherlands	0.4	-	100	-	-	N/A
Potatoes	Belgium	1.0	-	500	-	-	
Potatoes	Netherlands	1.0	-	250	-	-	N/A
Potatoes	Ireland	1.1	-	1100	-	-	N/A
Potatoes	Portugal	1.1	-	440	-	-	
Potatoes	Spain	0.6	-	200	-		
Potatoes	UK	1.1	-	1100	-	-	N/A
Pre-emergence	Belgium	0.8	-	400	-	-	N/A
Pre-emergence	Spain	0.8	-	267	-	-	N/A
Pre-planting	Belgium	0.8	-	400	-	-	N/A

Table 1.5.1 Summary of notified uses - continued

Crop /Situation	Country	Rate: (maximum per application) (kg a.s./ha)	Rate: (maximum per season) (kg a.s./ha)	Spray conc. (g a.s./hl)	No. of applications (maximum per season)	Spray interval (days)	Pre harvest interval in days
Pre-planting or pre-emergence	Netherlands	0.6	-	150	-	-	N/A
Pre-sowing	Belgium	0.8	-	400	-	-	N/A
Pre-sowing	Greece	0.4	-	80	-	-	
Railways	Spain	1.0	-	333	-	-	N/A
Raspberries	Netherlands	1.0	-	250	-	-	
Raspberries	Ireland	1.1	-	1100	-	-	
Raspberries	UK	1.1	-	1100	-	-	
Roadsides	Spain	1.0	-	333	-	-	N/A
Roadsides	Italy	1.0	3.0	100	3	-	N/A
Rose beds	UK	0.6	-	300	-	-	N/A
Rose beds	UK	1.1	-	500	-		N/A
Rose beds	UK	1.7	-	500	-	-	N/A
Row crops	Ireland	1.1	-	1100	-	-	
Row crops	UK	1.1	-	1100	-	-	
Rye grown as a cover crop	Netherlands	1.0	-	250	-	-	N/A
Rye or barley cover in flower bulb growing	Netherlands	1.0	-	250	-	-	N/A
Seed bed preparation	Italy	1.0	-	100	-	-	N/A
Seed potatoes	Netherlands	1.0	-	250	-		N/A
Senescent crops	Netherlands	0.8	-	800	-	-	N/A
Shrubberies	UK	0.6	-	300	-	-	N/A
Shrubberies	UK	1.1	-	500	-	-	N/A
Shrubberies	UK	1.7	-	500	-	-	N/A
Spring cleaning of winter growth on ploughed or cultivated land	Ireland	0.8	-	800	-	-	N/A
Spring cleaning of winter growth on ploughed or cultivated land	UK	1.1	-	1100	-		N/A
Stone fruit	Italy	1.0	2.0	100	2	-	30
Strawberries	Belgium	0.6	-	300	-	-	N/A
Strawberries	Netherlands	0.6	1.2	150	2	-	
Strawberries	Ireland	1.1	-	1100	-	-	
Strawberries	UK	1.1	-	1100	-	-	
Sugar beet	Greece	0.6	1.2	120	2	-	
Sugar beet	Spain	0.6	-	200	-		
Temporarily uncropped land	Netherlands	1.0	-	250	-	-	N/A
Temporarily uncropped land	Ireland	1.1	-	1100	-	-	N/A
Temporarily uncropped land	UK	1.1	-	1100	-	-	N/A
Temporarily uncultivated land	Belgium	1.0	-	500	-	-	N/A

Table 1.5.1 Summary of notified uses - continued

Crop /Situation	Country	Rate: (maximum per application) (kg a.s./ha)	Rate: (maximum per season) (kg a.s./ha)	Spray conc. (g a.s./hl)	No. of applications (maximum per season)	Spray interval (days)	Pre harvest interval in days
Tomatoes	Spain	0.6	-	200	-	-	
Top fruit	Greece	1.0	2.0	250	2	-	
Top fruit	Ireland	1.1	-	1100	-	-	
Top fruit	UK	1.1	-	1100	-	-	
Transplanting bed preparation	Italy	1.0	-	100	-	-	N/A
Tree and shrub nurseries	UK	0.6	-	300	-	-	N/A
Tree and shrub nurseries	UK	1.1	-	500	-	-	N/A
Tree and shrub nurseries	UK	1.7	-	500	-	-	N/A
Tree bases	UK	0.6	-	300	-	-	N/A
Tree bases	UK	1.1	-	500	-	-	N/A
Tree bases	UK	1.7	-	500	-		N/A
Vegetables	Greece	0.6	1.2	120	2	-	
Vines	Greece	1.0	2.0	250	2	-	
Vines	Ireland	1.1	-	1100	-	-	
Vines	Portugal	1.1	-	440	-	-	
Vines	Spain	0.8	-	267	-	-	
Vines	UK	1.1		1100	-	-	
Vines	Italy	1.0	3.0	100	3	-	30
Windbreaks	Belgium	1.0	-	500	-	-	N/A
Windbreaks	Netherlands	1.0	-	250	-	-	N/A

1.5.1.4 Information on authorisations in EU Member States (IIIA 12.1)

Table 1.5.1.3 Authorisations and Registrations in the EU - Liquid Soluble Concentration

COUNTRY	TYPE OF AUTHORISATION	CROPS/USES	AUTHORISATION DETAILS
Belgium	Full Approval	Agriculture/Horticulture - pre-sowing/pre-planting uses - pre-emergence uses - early post-emergence uses (broadcast) - post-emergence uses (inter-row) Forestry - inter-row Weed control on non-cultivated areas Other (specialist uses) - hop stripping - sucker control (strawberries) - aquatic use - post-harvest uses (asparagus, clover, alfalfa) - dormancy (clover, alfalfa)	Gramoxone 2 Paraquat SL 200g/l Reg. No. 6753/B Reg. from. 15/2/1994 Reg. Exp. 14/9/1996
Eire	Full Approval	Agriculture/Horticulture - pre-sowing/pre-planting uses - pre-emergence uses - early post-emergence uses (broadcast) - post-emergence uses (inter-row) Forestry - pre-sowing/pre-planting uses - pre-emergence - inter-row Weed control on non-cultivated areas Other (specialist uses) - hop stripping - sucker control (strawberries) - dormancy (raspberries)	Gramoxone 100 Paraquat SL 200 g/l Reg. No. 90694 Reg. From 1985 Reg. Exp. unlimited
Greece	Full Approval	Agriculture/Horticulture - post-emergence uses (inter-row) - pre-sowing/pre-planting uses - pre-harvest uses (cotton) Other (specialist uses) - dormancy/post-harvest uses (alfalfa, clover)	Gramoxone Paraquat SL 200 g/l Reg. No. 7038/21-5-84 Reg. from 12/1992 Reg. Exp. 31/12/1996

Table 1.5.1.3 Authorisations and Registrations in the EU - continued

COUNTRY	TYPE OF AUTHORISATION	CROPS/USES	AUTHORISATION DETAILS
Italy	Full Approval	Agriculture/Horticulture - pre-sowing/pre-planting uses - post-emergence uses (inter-row) Weed control on non cultivated areas	Gramoxone Paraquat SL 200 g/l Reg. No. 0629 Reg. from 15/11/1988 Reg. Exp. date unlimited
Italy	Full Approval	Agriculture/Horticulture - pre-sowing/pre-planting uses - post-emergence uses (inter-row) Weed control on non cultivated areas	Gramoxone W Paraquat SL 200 g/l Reg. No. 0625 Reg. from 15/11/1988 Reg. Exp. date unlimited
Netherlands	Full Approval	Agriculture/Horticulture - pre-sowing/pre-planting uses - pre-emergence uses - early post-emergence uses (broadcast) - post-emergence uses (inter-row) - pre-harvest uses (potatoes) Weed control on non cultivated areas Other (specialist uses) - sucker control (strawberries) - post-harvest uses (asparagus, grasses for seed) - spot treatments (grasses for seed)	Gramoxone Paraquat SL 200 g/l Reg. No. 6019 N Reg. from 19/3/1993 Reg. Exp. 1/12/1999
Portugal	Full Approval	Agriculture/Horticulture - pre-sowing/pre-planting uses - pre-emergence uses - early post-emergence uses (broadcast) - post-emergence uses (inter-row) Forestry - inter-row Weed control on non cultivated areas	Gramoxone 2000 Paraquat SL 200 g/l Reg. No. 1901 Reg. from 16/12/1994 Reg. Exp. 16/12/1995

Table 1.5.1.3 Authorisations and Registrations in the EU - continued

COUNTRY	TYPE OF AUTHORISATION	CROPS/USES	AUTHORISATION DETAILS
Spain	Full Approval	Agriculture/Horticulture - pre-emergence uses - post-emergence uses (inter-row) Weed control on non cultivated areas Other (specialist uses) - aquatic use - dormancy/post-harvest uses (alfalfa)	Gramoxone Extra N Paraquat SL 200 g/l Reg. No. 15761/98 Reg. from 21/1/1993 Reg. Exp. 31/1/1998
Spain	Full Approval	Agriculture/Horticulture - pre-emergence uses - post-emergence uses (inter-row) Weed control on non cultivated areas Other (specialist uses) - aquatic use - dormancy/post-harvest uses (alfalfa)	Violan Paraquat SL 200 g/l Reg. No. 14283/97 Reg. from 20/4/1992 Reg. Exp. 30/4/1997
United Kingdom	Full Approval	Agriculture/Horticulture - post-emergence uses (inter-row) Forestry - inter-row Weed control on non cultivated areas	Dextrone X Paraquat SL 200 g/l Reg. No. 00687 Reg. from 19/10/1990 Reg. Exp. 18/11/2000
United Kingdom	Full Approval	Agriculture/Horticulture - pre-sowing/pre-planting uses - pre-emergence uses - early post-emergence uses (broadcast) - post-emergence uses (inter-row) Forestry - pre-sowing/pre-planting uses - pre-emergence uses - inter-row Weed control on non cultivated areas Other (specialist uses) - hop stripping - sucker control (strawberries) - dormancy (raspberries)	Gramoxone 100 Paraquat SL 200 g/l Reg. No. 06674 Reg. from 24/4/1992 Reg. Exp. date unlimited

1.5.2 Uses of the plant protection product - Water Dispersible Granule

1.5.2.1 Field of use (IIIA 3.1, IIA 3.3)

Home Gardening (for the purposes of notification).

In certain Member States professional/commercial uses of this product are registered. These have been included and considered to ensure completeness.

1.5.2.2 Effects on harmful organisms (IIIA 3.2, IIA 3.2)

Contact action.

Paraquat is not translocated in plants.

1.5.2.3 Summary of intended uses (IIIA 3.3, 3.4, 3.7, IIA 3.4)

Annual and perennial weed control.

Table 1.5.2 Summary of notified uses - Water Dispersible Granule

Crop/ Situation	Country	Rate (maximum per application) (kg a.s./ha)	Rate (maximum per season rec.) (kg a.s./ha)	Spray conc. (g as /hl)	No. applications per season (rec. range max. given)	Spray interval days	Pre harvest interval (days)
Apples	Italy	0.875	2.625	88	3	-	30
Around roses and shrubs	UK	0.838	0.838	-	1	-	N/A
Around sheds and Greenhouses	UK	0.838	0.838	-	1	-	N/A
Between plants in flower beds	UK	0.838	0.838	-	1	-	N/A
Between rows in the vegetable garden	UK	0.838	0.838	-	1	-	-
Canal banks	Italy	0.875	2.625	88	3	-	N/A
Citrus	Italy	0.875	2.625	88	3	-	30
Ditch banks	Italy	0.875	2.625	88	3	-	N/A
Drainage channels	Italy	0.875	2.625	88	3	-	N/A
Ground clearance before autumn or spring digging	UK	0.838	0.838	-	1	-	N/A
Hazelnuts	Italy	0.875	1.75	88	2	-	30
Hazelnuts	Italy	0.875	1.75	88	2	-	40
Hedges	UK	0.825		-		-	N/A
Killing old lawns before re-sowing or re-turfing	UK	0.838	0.838	-	1	-	N/A
Olives	Italy	0.875	1.75	88	2	-	30
Olives	Italy	0.875	1.75	88	2	-	40
Paths, drives and patios	UK	0.838	0.838	-	1	-	N/A
Pears	Italy	0.875	2.625	88	3	-	30
Roadsides	Italy	0.875	2.625	88	3	-	N/A

Table 1.5.2 Summary of notified uses - continued

Crop/ Situation	Country	Rate (maximum per application) (kg a.s./ha)	Rate (maximum per season rec.) (kg a.s./ha)	Spray conc. (g a.s./hl)	No. applications per season (rec. range max. given)	Spray interval days	Pre harvest interval (days)
Seed bed preparation	Italy	0.875	0.875	88	1	-	N/A
Steps	UK	0.838		-		-	N/A
Stone fruit	Italy	0.875	1.75	88	2	-	30
Transplanting bed preparation	Italy	0.875	0.875	88	1	-	N/A
Uncultivated areas	UK	0.838	0.838	-	1	-	N/A
Under hedges and along fences	UK	0.838	0.838	-	1	-	N/A
Vines	Italy	0.875	2.625	88	3	-	30

1.5.2.4 Information on authorisations in EU Member States (IIIA 12.1)

Table 1.5.2.3 Authorisations and Registrations in the EU - Water Dispersible Granule

COUNTRY	TYPE OF AUTHORISATION	CROPS/USES	AUTHORISATION DETAILS
Belgium	Full Approval	Agriculture/Horticulture - pre-sowing/pre-planting uses - pre-emergence uses - early post-emergence uses (broadcast) - post-emergence uses (inter-row) Forestry - Inter-row Weed control on non cultivated areas Home Gardening Other (specialist uses) - hop stripping - sucker control (strawberries) - aquatic use - post-harvest uses (asparagus)	Pardi Diquat + Paraquat SG 25 + 25 g/kg Reg. No. 5433 Reg. from 27/7/1994 Reg. Exp. 25/7/1995
Eire	Full Approval	Home Gardening	Weedol Diquat + Paraquat SG 25 + 25 g/kg Reg. No. 91530 Reg. from 1985 Reg. Exp. date unlimited
Italy	Full Approval	Agriculture/Horticulture - pre-sowing/pre-planting uses - post-emergence uses (inter-row) Weed control on non cultivated areas	Weedol Granulare Diquat + Paraquat SG 25 + 25 g/kg Reg. No. 0582 Reg. from 15/11/1988 Reg. Exp. date unlimited
United Kingdom	Full Approval	Home Gardening	Weedol Diquat + Paraquat SG 25 + 25 g/kg Reg. No. 06863 Reg. from 26/1/1989 Reg. Exp. 1996

1.6 Additional information on the subject matter and purpose of the monograph

1.6.1 Notifiers other than Zeneca Agrochemicals

Sections 1.3-1.5 refer to the dossier submitted by Zeneca Agrochemicals. The evaluation and risk assessment of this review primarily refers to the dossier submitted by Zeneca Agrochemicals.

The supporting dossiers submitted by the notifiers other than Zeneca were limited and primarily based on published information which, in general, contained an insufficient level of detail for regulatory purposes. These data have been considered in the review but not necessarily included in the evaluation and risk assessment unless they provide additional relevant information to that submitted by Zeneca Agrochemicals.

Information on the notifiers other than Zeneca together with an assessment of their submissions is contained in Section C.1.4.1 of Annex C - Confidential Information.

1.6.2 Zeneca Agrochemicals dossier - Good Agricultural Practise

As part of the submission by Zeneca Agrochemicals the company provided the following information in relation to Good Agricultural practise.

It was confirmed that the following uses were not being defended within the European Union:

- Desiccation of potato haulm
- Desiccation of cotton
- Aquatic weed control
- Application rates in excess of 1.1 kg paraquat/ha

The following 'worse case' Good Agricultural Practise was defined by the company as follows:

- The maximum single application rate for uses other than home garden use is 1.1 kg paraquat/ha/application (this is represented by the formulated product 'Gramoxone')

- The maximum single application rate for home and garden use is 0.838 kg paraquat/ha/application (this is represented by the formulated product 'Weedol')

- The maximum total annual application rate is 2.2 kg paraquat/ha/annum

- The typical single application rate for uses other than home garden was defined by the company as 0.6-0.8 kg paraquat/ha/application (this is represented by the formulated product 'Gramoxone')

LEVEL 2

Paraquat

OVERALL CONCLUSIONS

2.1 Identity

All points of Annex IIA and IIIA Section 1 have been addressed and the information supplied is acceptable.

2.2 Physical and chemical properties

Paraquat is a bipyridinium herbicide derived from pyridine. It may be formulated as a soluble concentrate or water dispersible granules. The active substance is very water soluble and is of low volatility. Accelerated storage stability data submitted for the soluble concentrate formulation were satisfactory, but the water dispersible granules showed evidence of caking on storage. Further information on shelf life of both preparations and clarification of the flowability of the granular preparation is required.

2.3 Details of uses and further information

Information supplied adequately addresses methods for handling the active substance and plant protection product. Further information on storage properties with respect to the container are required.

At Member State level it must be considered whether a resistance management strategy for the use of paraquat in perennial crops needs to be developed. This is in order to prevent resistance to paraquat developing in certain weeds following long-term, repeated use. The addition of suitable label warning statements may be necessary.

2.4 Impact on human and animal health

2.4.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products

The absorption, distribution, metabolism and excretion of paraquat has been studied following single low (1mg paraquat/kg bw), single high (50mg paraquat/kg bw) or repeated low dose gavage administration in deionised water to rats. In all studies the absorption, as determined by extent of urinary excretion, was low (ca 10-20%), though what absorption there was occurred rapidly (within 6 hours). Results from single or repeat (14 daily doses) dosing at 1mg paraquat/kg bw showed excellent consistency, demonstrating that paraquat is unlikely to accumulate in the body. There was evidence of reduced absorption in males receiving 50mg paraquat/kg bw/d compared with 1mg/kg bw/d and an extension of the period of faecal excretion in both sexes at the higher dose. At the low dose, females excreted less of the dose in urine than males, this difference was not evident at the high dose. The organ having the highest concentration of paraquat 72 hours post dosing was the lung (ca 0.02µg equivalents/g after the low doses and ca 0.8 -1.1µg equivalents/g after the high dose). Total residues in the carcass and organs at 72 hours post dosing were <1% of the administered doses.

Evidence from published studies supports the above findings and indicates other species handle paraquat in a similar way to rats.

Analyses of urine and faeces for metabolites showed paraquat to undergo hardly any metabolism, with less than 1 % of the administered dose being excreted in the form of metabolites.

Dermal absorption data show that paraquat is poorly absorbed through human epidermis samples *in vitro* with 0.13% a 200g/l formulation and 0.44% of a 1:40 dilution being absorbed in 8 hours. These values are supported by the results of a human volunteer study.

It is proposed that the following values are used in performing operator exposure assessments:-

i) Systemic absorption from an oral dose - 10%
ii) Dermal penetration of concentrate - 0.13%
iii) Dermal penetration of dilution - 0.44%

No further ADME data are required for Annex I listing

Summary of mammalian toxicity

The dossier contained studies of an adequate standard to address all key aspects of the mammalian toxicity of technical paraquat dichloride.

Technical paraquat dichloride (33% w/w paraquat) is of moderate acute toxicity orally, low acute toxicity dermally and very toxic by inhalation. Lungs were identified as the key target organ following oral and inhalation exposure. In rabbits technical paraquat dichloride is a slight but persistent skin irritant and a moderate and persistent eye irritant. Technical paraquat dichloride produced no evidence of skin sensitising potential in guinea pigs when tested using a Maximisation protocol.

The short term toxicity of paraquat has been investigated in dietary studies in rats (13 weeks) and dogs (13 week, 1 year). Consistent findings were lung lesions (alveolar epithelial hyperplasia/alveolitis/chronic pneumonitis) and reduced body weight gain, with dogs the more sensitive species. Variations in haematology and clinical chemistry parameters were seen but were not consistent between studies or species. All 3 studies showed clear NOAELs with an overall short term NOAEL of 0.45mg/kg bw/d (15ppm) in the 1 year dog study, based on lung lesions at 30ppm and above.

The genotoxicity of paraquat dichloride has been investigated in a range of *in vitro* and *in vivo* assays. Negative results have been seen in 2 *in vitro* studies (UDS in primary rat hepatocytes and gene mutation in mouse lymphoma L5178Y cells without S9) and 4 *in vivo* studies (mouse micronucleus, rat bone marrow cytogenetics, rat liver UDS and a dominant lethal study in mice). Positive results were seen in an *in vitro* SCE assay in Chinese hamster lung cells ($\pm$S9), an *in vitro* cytogenetic assay in human lymphocytes ($\pm$S9), and in an *in vitro* gene mutation assay in mouse lymphoma cells in the presence of S9 - these findings were related to cytotoxic concentrations. The positive results *in vitro* indicate that

paraquat may have clastogenic and mutagenic potential in mammalian cells. It is possible that the positive results seen at cytotoxic concentrations were associated with the production of active oxygen species following saturation of detoxification systems such as catalase and would not be relevant to low level paraquat exposures. The *in vivo* studies show that any such potential was not expressed in the 4 *in vivo* assays performed. In the *in vivo* assays, paraquat dichloride was administered orally and while it is possible that the low absorption of orally administered paraquat may compromise the validity of the assay, there was evidence of cytotoxicity to the target tissue or toxicity to the test animals. It is concluded that paraquat dichloride does not present a genotoxic hazard *in vivo*.

Chronic toxicity/carcinogenicity (2 year dietary) studies have been performed in rats and mice. In neither study did paraquat produce significant increases in any tumour incidences. An apparent increase in lung adenomas and carcinomas in rats was not confirmed by a review of the slides though proliferative lesions of some form were confirmed at the top dose level. In the chronic **rat** study, ocular opacities were evident clinically at 75 and 150ppm and confirmed by ophthalmoscopy and histology; similar lesions were also present at the very end of the study (week 110) in the 25ppm groups. Testicular lesions, peripheral nerve degeneration and bile duct hyperplasia were seen at 75 and 150ppm. A consistent reduction in leukocyte count was noted in top dose males. The study fails to show a NOAEL but the ocular lesions present at the lowest dose level (25ppm; *ca* 1.2mg/kg bw/d) were consistent with an acceleration of typical ageing lesions, were not seen in any other studies and were not evident at the time when chronic studies are normally terminated (103 weeks). It is proposed that the lowest dose level is taken as a minimal effect level. [The applicant considers 25 ppm to be a NOAEL]. In the chronic **mouse** study, the kidney was found to be the target organ with tubular lesions evident at 125ppm and pelvic dilatation seen in males at 75 ppm and above. Alveolar hypercellularity present in 125ppm females was the only sign of pulmonary toxicity. There were no ocular lesions. A clear NOAEL of 12ppm (*ca* 1.5mg/kg bw/d) can be taken from this study.

Paraquat, as the technical material or the purified dichloride, has been tested for reproductive effects in a 3 generation study in rats and for developmental effects in rats (2 studies) and mice (2 studies). In the multigeneration study there were no adverse effects on reproduction at dose levels up to 150ppm in the diet. Maternal toxicity was evident at 150ppm (mortality, reduced weight gain in pregnancy, alveolar histiocytosis, lung discoloration & fibrosis) and 75ppm (alveolar histiocytosis). The NOAEL was 25ppm (*ca* 2.5mg/kg bw/d). In the rat developmental studies paraquat did not exhibit teratogenicity at maternally toxic dose levels (up to 10mg/kg bw/d) but mild foetotoxicity was evident at $\geq$4mg/kg bw /d. An overall NOAEL from the rat developmental studies is 3mg/kg bw/d. In the mouse developmental studies there was no overt teratogenicity at maternally toxic doses. A number of effects were seen at low or intermediate doses but with no dose response and the relationship to paraquat administration is unclear. Alterations in ossification (particularly the astragalus) and increases in minor abnormalities were seen consistently at dose levels above 7.5mg/kg bw/d. A clear NOEL from the mouse teratology studies is 1mg/kg bw/d and it is proposed that an overall NOAEL of 7.5mg/kg bw/d may be set.

There is no evidence indicating paraquat to have specific neurotoxicological or immunotoxicological effects

Data from accidental or deliberately exposed humans shows paraquat to be irritating to skin, eyes and nose. Toxic effects can be split into 3 classes depending on the level of exposure. An oral exposure of <20mg paraquat/kg bw is unlikely to produce anything other than transient effects; 20-40mg paraquat/kg bw is likely to produce death respiratory failure following initial liver and kidney damage; exposure of >40mg paraquat/kg bw is likely to produce death within 2 days due to multiple organ failure. These figures show humans to be more sensitive to paraquat than rats (LD50 *ca* 100mg paraquat/kg bw).

No further mammalian toxicology data are required for annex I listing

EC guidelines request a rabbit teratology study. As there is no evidence of overt teratogenicity in 4 rodent studies using doses up to those which increase mortality it is proposed that a rabbit teratology study is not warranted. This is further supported by the negative results from 3 rabbit teratology studies on the closely related compound diquat (JMPR 1993 report).

2.4.2 ADI

Paraquat was not carcinogenic nor directly toxic to reproduction. The dog was found to be more sensitive to the repeat dose effects of paraquat than either mice or rats. The NOAEL of 0.45mg/kg bw/d from the 1 year dog study is the appropriate value to use in deriving the ADI. This gives a margin of 2.5 with respect to the minimal effect level (eye lesions) in the chronic rat study (25ppm ;1.0-1.3mg/kg bw/d) and a margin of 2 with respect to the LOEL in the 1 year dog study (lung lesions). The eye lesions produced by paraquat appeared to be related to an acceleration of the normal ageing processes and were only evident at 25 ppm after 110 weeks of administration and were not evident at week 103 the usual limit of a chronic study. A safety factor of 100 is considered appropriate given the small margins between NOAELs and effect levels.

An ADI of 0 - 0.004mg paraquat ion/kg bw is proposed

[The applicant has proposed the same study, effects and safety factor as the basis for the ADI but uses a different value for paraquat intake (males and females combined) and rounds the value up, giving an ADI of 0.005mg/kg bw. The applicant's proposal is not supported by the paraquat intake figures for males presented in the study report. These differences are not considered to be critical in practice]

2.4.3 AOEL

There are no repeat dose inhalation or dermal studies on paraquat therefore systemic AOELs based on repeat dose dietary studies have been proposed.

a) Short term exposure

Paraquat was not directly toxic to reproduction in rats and mice. The dog is the most sensitive species to the general toxicological effects of paraquat and it is proposed that the NOAEL of 0.55mg/kg bw/d from the 13 week dog study is used to set the AOEL for short term exposure. At 1.6mg/kg bw/d lung lesions and weight gain reductions were evident, with severe toxicity present at 3mg/kg bw/d; therefore, a 100 fold safety factor is considered appropriate. An oral absorption figure of 10 % may be derived from the ADME studies.

A systemic AOEL (short term) of 0.0005mg paraquat ion/kg bw/d is therefore proposed.

[The applicant has proposed the same end points as the basis for the AOEL but has rounded up to give an NOAEL of 0.6mg/kg bw/d. The applicant has not taken absorption into account.]

b) Continuous exposure

Paraquat was not carcinogenic nor directly toxic to reproduction. The dog was found to be more sensitive to the effects of paraquat than mice or rats. The NOAEL of 0.45mg/kg bw/d from the 1 year dog study is the appropriate value to use in deriving the long term AOEL. This gives a margin of 2.5 with respect to the minimal effect level (eye lesions) in the chronic rat study and a margin of 2 with respect to the LOEL in the 1 year dog study (lung lesions). A safety factor of 100 is considered appropriate given the small margins between NOAELs and effect levels. An oral absorption figure of 10% may be derived from the ADME studies.

A systemic AOEL (long term) of 0.0004mg paraquat ion/kg bw/d is therefore proposed.

[The applicant has not proposed a long-term AOEL]

2.4.4 Drinking water limit

No repeat dose toxicity studies on paraquat administered in the drinking water are available. The MAC has therefore been based on the ADI from repeat dose dietary studies (0-0.0045mg/kg bw/d; unrounded value). An additional safety factor of 10 has been applied to the ADI and a consumption rate of 2 litres/ day by a 60kg person assumed.

MAC = 0.0045/10 x 60 /2 = 0.013mg/l = **13µg/litre**

[The applicant has proposed a MAC of 15µg/l the differences are due to rounding of the ADI value]

2.4.5 Impact on human and animal health arising from exposure to the active substance or to impurities contained in it.

2.4.5.1 Operators, bystanders and workers

The range of products and application rates authorised across the European Union are broadly similar. 'Weedol' is a representative plant protection product for home gardening uses and 'Gramoxone' is a representative product for all agriculture, horticulture, forestry, viticulture, amenity and non-crop land uses. Stated application methods are, for Weedol - watering can fitted with a fine rose or dribble bar and for Gramoxone - conventional ground crop sprayer or knapsack sprayer.

Field crop sprayers

For field crop sprayers, the two UK models and the German model predict exposures of 20 - 100 times the short term AOEL if PPE is not worn.

For a worker wearing gloves only when mixing/loading the UK absorption rate model indicates exposure of 4 times the AOEL. For a worker wearing gloves when mixing/loading and during application the UK percent absorption model indicates exposure of about 40 times the AOEL. However, for a worker wearing gloves and RPE when mixing/loading and gloves, RPE, coverall and sturdy footwear during application, the German model indicates exposure approximately at the AOEL.

The model estimations of exposure generally exceed the AOEL. Therefore this triggers a requirement for appropriate measurements of operator exposure. Suitable measurements of operator exposure under representative or worse case situations have been submitted and these have been used in preference to assess operator risk.

In a study, conducted in the USA, 11 of 17 workers mixing/loading and applying paraquat over a full working day (using open cab/cabless tractor mounted sprayers in pecan orchards) had no detectable amounts of paraquat in the urine. The 6 workers with measurable amounts of paraquat absorption had exposures of 14 - 88 % of the AOEL. Clothing worn by the operators was long or short sleeved shirt, long trousers, baseball cap and boots. Some operators also wore gloves when mixing/loading.

Thus continued use of paraquat by field crop sprayers is acceptable and workers wearing coverall and gloves when mixing/loading and coverall, gloves, and boots during spray application should be adequately protected.

Section B 9.1.3 classifies the active substance and Gramoxone as a respiratory irritant in the light of nose bleeds in production plant workers and pesticide users (Section B 5.9.4) and states that inspiration of droplets is not expected. The operator exposure studies submitted support the conclusion that there is not a risk.

Knapsack sprayers

For use of knapsack sprayers, the UK and German models predict exposures of 20 - 100 times the short term AOEL if PPE is not worn.

For a worker wearing gloves when mixing/loading and during application the UK percent absorption model predicts exposure of 60 times the AOEL. However, for

a worker wearing gloves and RPE when mixing/loading and gloves, RPE, coverall, broad brimmed hat and sturdy footwear during application, the German model predicts exposures at about the AOEL.

The model estimations of exposure generally exceed the AOEL. Therefore this triggers a requirement for appropriate measurements of operator exposure. Suitable measurements of operator exposure under representative or worse case situations have been submitted and these have been used in preference to assess operator risk.

An operator exposure study conducted in a Sri Lankan tea plantation indicated exposures of 8 to 18 times the AOEL based on levels of potential dermal exposure (PDE). The measured levels of contamination are comparable to those predicted by the German model but are about 10 - 20 % of the exposure predicted by the POEM. One explanation for this maybe that POEM considers an operator spraying continuously for 6 hours whilst in the study workers were spot spraying for 6 hours.

Despite the measured PDE, paraquat was not detected (a limit of detection was not quoted) in the blood and urine of operators. A conservative assessment based on ½ LOD gave an estimate of exposure 2 times the AOEL.

Although operators were monitored over 5 days of spraying (each day involving about 6 hours spraying) they handled only small amounts of paraquat (about 226 g/day for mixer loaders and 45 g/day for spray men) because of the nature of the terrain and sparse weed infestation. In the UK much higher levels of paraquat may be handled/sprayed. However, the minimal clothing worn by operators may have countered the small amounts of paraquat handled. It is not clear how representative this study is of EU conditions but it does show that operators handling relatively small amounts of paraquat and wearing very little clothing (but maintaining a high standard of hygiene) could receive exposures of 2 times the AOEL.

For both mixer/loaders and spray operators, most of the measured exposure was on the hands, feet and legs. Assuming that a coverall, gloves and rubber boots provide 95% protection then an operator receiving a potential dermal exposure of 18 times the AOEL would be adequately protected.

Further reassurance can be drawn from a series of epidemiological investigations in countries in which the potential for worker exposure to paraquat is considerably greater than that within the European Union and which suggest that long-term use of 'Gramoxone' does not present a long-term risk to the health of spray operators. In each of these studies application was exclusively by means of knapsack sprayers in plantations in tropical areas where weed control is required throughout the year on a continuous basis.

Amateur use

The notifier states the use pattern for Weedol is likely to involve the householder applying small quantities of the product to limited areas on a few occasions per year. There are no models to estimate exposure from use of watering cans.

However, the UK percent absorption model does allow an estimate for use of a knapsack sprayer directed at a low level target. Although this model is not directly appropriate it does given an indication of the potential for exposure. The German model contains data on handling WG formulations and was therefore used to estimate exposure from mixing/loading.

It was assumed that an amateur spraying for 1 hour/day could spray 67 litres and treat 0.025 ha. The contents of approximately 15 sachets of Weedol (a fairly large number) would be required to treat such an area. Predicted exposure was at the AOEL for an unprotected operator (Table B 5.40).

Bystanders

If exposure of a bystander compared with an operator is proportional to the airborne material it is likely that exposure of bystanders outside the treatment area will not exceed the AOEL.

For the amateur user, exposure for an unprotected operator was below the AOEL. Bystander exposure is therefore not a concern.

Bystanders may potentially be present in the vicinity of the application site where the product is authorised and used for weed control in industrial situations or in municipal parks. However in such situations application will be in the form of directed (spot) treatments rather than as a broadcast application in order to avoid any possibility of the spray coming in to contact with non-target (ornamental) plants. Such applications may be made with a guarded or shielded sprayer and/or the application will be made close to the ground, thereby minimising any potential for off-target movement of the spray. Thus the potential for exposure even in a situation in which bystanders may conceivably be present is minimal.

Workers

The lack of volatility of paraquat dichloride precludes exposure by inhalation. There are no models to allow an estimate of dermal exposure from re-entry to treated crops or weeds. However, paraquat is fast-acting, rainfast and there is no requirement for the user to inspect (the desired effect is readily discernible from a distance) or to re-treat the weeds/crop shortly after application. Potential dermal exposure to foliar residues is therefore not a concern given the use pattern (application will usually be to relatively small weeds which will rapidly wilt and die following treatment) and poor dermal absorption of paraquat.

The notifier proposes a 24 hour re-entry period (until spray has dried) for professional products. However, it is not clear how the notifier intends that this should be enforced or why, if the product is considered rain fast after 10 minutes, a period of 24 hours is required. For amateur products the notifier proposes that a householder re-entry period is unnecessary but that children and pets be excluded until the spray has dried. The proposals are appropriate.

Recommendations

Paraquat be listed in Annex I. In view of the data on poisoning incidents (Section B.5.9.6), the following conditions and restrictions are proposed to reduce the risk of accidental/deliberate poisoning:

- All liquid formulations of paraquat should contain suitable alerting agents (dye and stench) to reduce the risk of accidental oral ingestion of the product.
- All solid formulations of paraquat should contain a suitable dye to reduce the risk of accidental oral ingestion of the product.
- All formulations of paraquat should contain an appropriate level of emetic, to increase the likelihood of emesis in case of significant accidental or deliberate oral ingestion.
- Member States should consider limiting, wherever practical and reasonable, availability and use of high-strength liquid formulations to *bona fide* agriculturalists, horticulturalists and professional users.

2.4.5.2 Consumers

Calculations of human consumer intakes have been carried out using either the established MRL or the highest residue found in supervised trials conducted according to the critical GAP. The calculated total TMDIs for adults, children and infants are all below the proposed ADI for paraquat of 0.004 mg/kg bw/day.

A further assessment of the potential dietary exposure will be necessary once additional residues data are available.

2.5 Methods of analysis

Methodology for the determination of paraquat cation is based on UV spectroscopy (technical material), ion pair chromatography (formulated preparation, water, milk and membrane filters for air sampling) or second derivative spectroscopy of a radical generated by alkaline sodium dithionite reduction (plants, animal tissues and soil).

The methodology was adequate for the determination of paraquat in technical active substance, plant protection products, plants soil and products of animal origin.

2.6 Definition of the residue

2.6.1 Definition of the residue relevant to MRLs

Residues in plants and products of animal origin should be defined as paraquat cation.

2.6.2 Definition of the residues relevant to the environment

In the light of all of the information relevant to the assessment of the environmental fate of paraquat the only soil residue of interest is paraquat itself.

2.7 Residues

The metabolism of paraquat was investigated in lettuce, carrots, soya and potatoes, by applying pyridine labelled [14C] paraquat to soil sown with lettuce and carrots and as a foliar treatment to soya and potatoes, just before harvest. On extraction and characterisation of the residues in the mature crops (lettuce and carrots were not extracted due to very low levels of total residues in the crops at maturity), one major component predominated paraquat, representing 89 - 94% of the total residue in the crops.

The metabolism and distribution in rotational crops was investigated in lettuce, wheat and carrots. The crops were grown in soil that had been treated with 2, 6 pyridine ring labelled [14C] paraquat. At harvest total [14C] residues in the immature wheat, wheat grain, wheat straw, wheat chaff, carrot tops, carrot roots and lettuce (expressed as parent equivalent) were all less than 0.01 mg/kg, for the crops planted 0, 30 and 120 days after application.

The metabolism and distribution in animals was investigated in a lactating goat and hens, by dosing the animals with 2,6 pyridine labelled [14C] paraquat. On extraction and characterisation of the milk, eggs and tissues, one major component predominated paraquat, representing 48 - 100% of the total radioactivity in the samples.

Based on the metabolism data submitted for a number of crops and domestic animals, residues in plants and products of animal origin should be defined as paraquat cation only.

Residues trials data which conform to the critical GAP in Northern and Southern Member States is given below and additional residues trials data required for evaluation at Member State level identified:

1. Fruit

1.1 Citrus fruit, tree nuts, pome fruit, stone fruit, other tree fruit, vine, cane fruit and hops

Extensive residues trials data are available to support the notified uses. As paraquat is used in weed control or in the control of suckers and is therefore unlikely to come into contact with the fruit, trials data generated on different tree fruits and grapes can be combined and used to support all the notified uses. The trials data submitted for various fruit trees and grapes indicated that residues in the fruit would be below the limit of determination (0.05 mg/kg), which is in line with the established EU MRLs. Therefore, due to the number of trials submitted no further residue trials data are required.

Positive residues were obtained for fruit placed on ground that had just been treated, to simulate the worse case of fruit falling on to treated ground. Although it is unlikely that positive residues would result in fruit falling on to treated ground, due to paraquat binding strongly to soil, potentially positive residues may result in fruit, thus leading to established EU MRLs being exceeded. Therefore either further residues trials data are required to ascertain the likely residues in fallen fruit and to amend the EU MRL according or the latest time of application is amended to ‘Before the end of flowering’ to ensure that an adequate period of time has past between the last application and the mature crop falling to the ground. For olives where paraquat is directly applied to the crop then, if this is indeed commercial practice, further residues trials data are required to amend the EU MRL accordingly.

1.2 Strawberry and bush fruit

Residues trials data are available from two trials which support the notified uses. As paraquat is used in weed control and is therefore unlikely to come into contact with the fruit, trials data generated on strawberries can be used to support all the notified uses. The trials data submitted for strawberries indicated that residues in the fruit would be below the limit of determination (0.01 mg/kg), which is in line with the established EU MRLs. Therefore, due to only two trials supporting the notified uses, additional residues trials data are required to confirm that residues are below the limit of determination.

2. Vegetables

2.1 Root vegetables (sugar beet, onion and potato)

Extensive residues trials data are available to support the notified uses. As paraquat is used in weed control and is therefore unlikely to come into contact with the crop, trials data generated on different root crops can be combined and used to support all the notified uses. The trials data submitted for various root crops indicated that residues in the root would be below the limit of determination (0.05 mg/kg), which is in line with the established EU MRLs. Therefore, due to the number of trials submitted no further residue trials data are required.

2.2 Fruiting vegetables (tomato and peppers)

Extensive residues trials data are available to support the notified uses. As paraquat is used in weed control and is therefore unlikely to come into contact with the fruit, trials data generated on different fruits can be combined and used to support all the notified uses. The trials data submitted for various fruit crops indicated that residues in the fruit would be below the limit of determination (0.03 mg/kg), which is in line with the established EU MRLs. Therefore, due to the number of trials submitted no further residue trials data are required.

2.3 Brassica, leafy, legume and stem vegetables

No relevant residues trials data were submitted, however as paraquat is used in weed control and is therefore unlikely to come into contact with the crops and strongly binds with soil, residues in the above crops would not be expected to be above the limit of determination. Therefore, only confirmatory residues trials data are required.

3. Pulses, Tea and Fungi

No NMS or SMS uses have been notified.

4. Cereals and oilseed (maize and sweetcorn)

Residues trials data are available from three trials which support the notified uses. As paraquat is used in weed control and is therefore unlikely to come into contact with the maize. The trials data submitted indicated that residues in the would be below the limit of determination (0.01 mg/kg), which is in line with the established EU MRLs. Therefore, due to only two trials supporting the notified uses, additional residues trials data are required to confirm that residues are below the limit of determination.

5. Fodder crops (alfalfa and clover)

No relevant residues trials data were submitted, however as paraquat is used in weed control and is therefore unlikely to come into contact with the crops and strongly binds with soil, residues in the above crops would not be expected to be above the limit of determination. Therefore, only confirmatory residues trials data are required.

EU MRLs have already been established for the use of paraquat on crops (see section B.6.13) and the residues data submitted, albeit lacking in some areas, support the levels set.

Data on the stability of residues during storage indicate that residues of paraquat are stable in prunes, tomatoes, potatoes, maize forage, maize grain and maize fodder for up to 12 months (only 6 months data submitted for prunes) following storage at -20°C.

Three studies were submitted and reported in the residues section (B.6.7). On processing the olives into oil (residues in treated olives were up to 10 mg/kg), residues in the oil were at, or in one case just above, the limit of determination (0.05 mg/kg) and residues in cake were up to 15 mg/kg.

No domestic animal feeding studies were submitted or required due to low intakes (see section B.6.12.1).

No rotational crop studies were submitted or required due to the study submitted in section B.6.2 indicating that residues in rotational crops would be below the limit of determination.

Calculations of human consumer intakes have been carried out using either the established MRL or the highest residue found in supervised trials conducted according to the critical GAP. The calculated total TMDIs for adults, children and infants are all below the proposed ADI for paraquat of 0.004 mg/kg bw/day.

A further assessment of the potential dietary exposure will be necessary once additional residues data are available.

2.8 Fate and behaviour in the environment

2.8.1 Fate and behaviour in soil

Clearly this part of the paraquat dossier submitted by the applicant is non-standard and is not performed in accordance with the data requirements stated in the Directive 91/414/EEC. However, the company states that the strong adsorption of paraquat to soil precludes paraquat fate and behaviour in soil being studied effectively by standard guideline methods. In addition it is stated that the soil microbial studies fulfil the scientific intent of demonstrating the intrinsic degradability of paraquat required by the guidelines. Thus, no additional information likely to be useful in assessing the route or rate of degradation, or sorption and mobility, of paraquat in soil would be obtained through any further conventional laboratory or field soil studies. The evaluator is in agreement with this position.

The strong adsorption of paraquat to soil greatly reduces the rate of formation of degradation products to amounts that would not be detectable using standard methods. In the absence of soil, paraquat appears to possess some intrinsic potential for biodegradability by a variety of soil micro-organisms, although this potential is very unlikely to be expressed in natural field soil situations because of the strong adsorption of paraquat to soil clay minerals and, to a lesser extent, to

soil organic matter. In addition, photodegradation on soil surfaces is very unlikely to be an important route for environmental dissipation of paraquat.

The long-term field soil dissipation/accumulation studies in the UK and USA indicated the existence of limited very slow dissipation following application, either at single high rates (dissipation study) or repeated annual normal rates (accumulation study). In the UK accumulation study, the DT_{50} was in the range of 7 to 8 years, whilst in the UK dissipation study, the DT_{50} value was considered to be of the order of 20 years. In the USA study, the DT50 value for the high-rate applications was of the order of 10 to 20 years. The assumption is that the dissipation consists of very slow degradation of the sorbed paraquat as it gradually becomes degraded and incorporated into normal soil components. The apparent differences in the DT50 values between the three long-term studies performed in the UK and USA probably result more from differences in methodology and sampling techniques, rather than any identifiable effect of soil type, climate etc. It is probably appropriate to state the field soil DT50 of paraquat obtained from these studies as being at least 7 years and not more than 20 years.

The field soil residue studies in six countries of Western Europe demonstrate that levels of paraquat in soil following application are probably less than those theoretically calculated, due at least partly to interception by weeds during application together with soil dissipation and/or photodegradation on plant surfaces between application and sampling.

In view of the unusually high soil adsorption potential of the compound, the soil sorption coefficients (both Kd and Koc) for paraquat based on the EPA guideline study with four soils or on the results from the field soil residue study in six countries, give some idea of the likely potential for sorption and mobility in soil. All results indicate that paraquat was very strongly adsorbed in all the soils tested. Thus, paraquat is assessed as completely immobile in all the soils tested. As expected, paraquat adsorption was found to increase with clay content. No correlation between paraquat adsorption and organic matter content was found. There was no evidence of any desorption of paraquat from the soils tested.

Whether it is possible to exceed the sorptive capacity of soils, leading to the potential for effects on sensitive crops, can be assessed from the monitoring information submitted from normal long term use in six countries. Despite repeated annual use, often at high rates and on low sorptive soils, detected residues only reached a fraction of the strong adsorption capacity of the soil. The available information therefore suggests that all soils have a considerable excess sorptive capacity following normal applications of paraquat.

In the light of all of the information relevant to the assessment of the environmental fate of paraquat the only soil residue of interest is paraquat itself. The assessment of predicted environmental concentration in soil (PECs) is therefore limited to consideration of the parent compound.

The maximum single application rate for agricultural field uses of paraquat is 1100 g/ha.

Calculation of PECs for home garden uses of paraquat is not appropriate as the use will be on a very small local scale and confined to various garden situations such as paths and vegetable plots. The discussion below is therefore limited to the agricultural field uses of paraquat.

Assuming a soil bulk density of 1.5 g/cm3 and even incorporation of chemical to 5 cm depth for application at the soil surface, an application of **1100 g paraquat/ha** will result in a **PEC_S of 0.73 mg paraquat/kg**. This is assuming an interception rate of 50%, (i.e. 50% of the chemical is lost on plant surfaces due to interception, prior to reaching the soil surface - as suggested in the Directive 91/414). For a foliar-acting herbicide such as paraquat there will always be plant interception and in many cases this will be substantial.

The above PECs is of course the initial one just after application. In the case of paraquat, any subsequent degradation or dissipation in the soil is so slow as to make estimating a PECs at time intervals after application very difficult and unlikely to provide meaningful results. In addition, as potential mobility is very low, significant movement of paraquat from the zone of application is unlikely. From all the submitted information, it appears that the residual paraquat remaining in the soil is not bio-available.

In fact, the degradation in soil has been shown to be so slow that estimation of PECs following multiple applications requires some assumptions concerning the likely degradation rate in soil. A worst-case situation would employ an assumption of no degradation or dissipation between successive applications of paraquat. Two applications within a year will result in higher concentrations up to a maximum of **1.46 mg/kg**. In the longer term PECs becomes more heavily dependent on the frequency of use of paraquat on a given area of land, the extent to which the land is cultivated (and residues are incorporated) and the rate of degradation of paraquat in soil.

Nevertheless, the company has submitted the following illustrations of calculated values for PEC_S corresponding to the repeated application of paraquat over the longer term. The company states that they are not expected to be typical values, but values arising from conservative assumptions about the use pattern and behaviour of paraquat. For these calculations, a multi-compartment, first-order model of paraquat degradation following application to soil has been used, since it fitted the behaviour of paraquat residues in long-term soil trials. A DT_{50} value of 20 years was used, along with the largest value from these trials of the parameter, a (= 0.0957), which gives the largest decrease of degradation rate over time. With these degradation parameters, the PEC_S for paraquat was calculated with the model following single paraquat applications of 600 or 800g paraquat/ha/year for 45 years, with 20% interception by plants for weed control uses of paraquat, a soil bulk density of 1.5 g/cm^3 and a long-term incorporation depth of 20 cm for the residues, accounting for mixing by cultivation and by biological activity (e.g. earthworm activity). Although the application rates chosen of 600 or 800g/ha are not the highest known, the company states that the chosen rates are likely to represent the mean over the long time span of the prediction, as the maximum rate will not be used every year.

The resulting PEC_S values are given in company documentation for two different times, corresponding approximately to the period over which the product has currently been commercialised (35 years) and to the end of the period for which EU approval is currently being sought (45 years). In summary these values show that repeated applications of paraquat will result in PEC_S which are typically no more than approximately 3.8 or 5.1 mg/kg as a worst-case, depending on the application rate. Furthermore, the increase in PEC_S over the period for which approval is currently being sought is less than 1 mg paraquat/kg. The evaluator considers that this illustrative calculation by the company is interesting, but is unable to assess the importance to be attached to it, in the absence of other comparable data.

2.8.2 Fate and behaviour in water and sediment

This section of the paraquat dossier is more conventional than the previous section on soil, and satisfies the scientific intent of the data requirements of the Directive 91/414/EEC, even though not all the detailed requirements have been undertaken. However, further data generation is unlikely to provide any more meaningful information and is therefore not considered necessary.

Hydrolysis will not be a significant environmental degradation process for paraquat, particularly since in natural aquatic environments paraquat will very rapidly be adsorbed to suspended particulate matter or sediment.

It is possible that aqueous photolysis could be a more significant degradation process for paraquat in the aquatic environment. However in relatively shallow waters where sunlight could penetrate to most of the water volume, it is more likely that paraquat would rapidly partition to any available sediment or suspended particulate or plant material. In situations such as larger water bodies or lakes where there may be less available sorptive material, much of the volume would be inaccessible to sunlight. Thus, in conclusion, it is perhaps unlikely that paraquat will undergo significant environmental aqueous photodegradation. In addition, the slower photodegradation rate in the winter months, particularly in Northern Europe, is likely to limit the importance of photodegradation in the winter. For the Southern EU countries, aqueous photolysis of paraquat could remain a possibility, particularly in summer and in situations with little available sorptive material.

The aquatic dissipation study performed in two small shallow natural lakes shows that the primary route of dissipation of paraquat from natural water is through very rapid adsorption onto sediment, or by adsorption onto plant material and/or suspended particulate matter which ultimately all settle to the bottom of the lake or water course. Paraquat dispersion within and dissipation from water are both extremely rapid with difficulties in measuring these accurately. Substantial dissipation from the water had clearly taken place after a few hours, paraquat residue levels fell very quickly and to almost half the original concentration within 24 hours.

2.8.2.1 Groundwater

Paraquat is extremely strongly bound to soil and is clearly assessed as immobile. There is little or no possibility that paraquat will occur in groundwater as a result of leaching and the predicted environmental concentration in groundwater (PECgw) is zero.

2.8.2.2 Surface water

The use of paraquat on non-crop land or home garden use should not result in significant contamination of natural surface waters and the PECsw for such uses is assumed to be zero.

For the terrestrial agricultural weed control uses of paraquat, spray drift values can be used for the purpose of calculating PECsw. Where an agricultural chemical is applied to fields adjacent to surface waters there is a possibility of spray drift occurring. The prediction of the concentration which may occur in surface waters as a result of spray drift requires information on the use patterns which result in the highest single application rates. The maximum single application rate for field uses of paraquat is 1100 g/ha.

Dissipation of paraquat from the water column occurs very rapidly due principally to adsorption to plant material, suspended particulate matter and bottom sediments. In the event of repeated or multiple entry of paraquat occurring via spray drift, build-up of the amount of paraquat present in solution is not expected to occur; dissipation from the water column will be essentially complete before the next entry occurs. Maximum predicted environmental concentrations in surface waters following multiple entry of paraquat via spray drift are therefore assumed to be the same as for single entry.

Various guidelines exist for the estimation of spray drift into surface waters. Figures for drift derived from field measurements in Germany and published by the BBA will be used to estimate the PEC_{SW} figure. The maximum single application rate for field uses of paraquat is **1100 g/ha**. From the BBA publication, a drift value of **5.0% at 1 metre** for field crops is employed, together with **30 cm** depth of water. This gives a **PECsw value of 18.3 µg/litre**. This represents the initial paraquat concentration just after drift has occurred. However, the dissipation of paraquat from water to sediment occurs so rapidly that prediction of the time-course is difficult. It is assumed that the initial concentration will fall to essentially zero within a few days. An approximate DT_{50} of 1 day is assumed, using the results of the aquatic dissipation study. This gives actual **PEC_{sw} values of 9.2µg/litre after 1 day, falling to zero after 14 days**.

According to the company, paraquat is not intended for use in mist blowers and approval is not sought for such use. Specific approval is not being sought for aerial application within the context of the EU review of paraquat.

2.8.2.3 Sediment

The assessment below is somewhat speculative and is not required in the Directive 91/414/EEC, but due to the behaviour of paraquat in natural water/sediment systems, it has been included by the evaluator to provide a worst-case estimation of PECsed. The method employed is based on that used for the calculation of PECsoil. The calculation takes no account of paraquat which may, for example, be dissipated from surface waters by adsorption onto plant material.

Assuming a sediment bulk density of **1.5 g/cm^3**, complete and rapid partition of paraquat from water to sediment and even incorporation of chemical to **5 cm** depth of natural sediment, for transport by spray drift to the water surface (**5% of application rate**), a terrestrial application of **1100 g paraquat/ha** will result in a **PEC$_{sed}$ of 73.3 µg paraquat/kg**. This assumes that all of the paraquat transported by spray drift from the site of application to the water surface partitions directly to the sediment.

The above PECsed is of course the initial one following drift from the site of application. In the case of paraquat, any subsequent degradation or dissipation in the sediment is likely to be so slow as to make estimating a PECsed at time intervals after application very difficult and unlikely to provide meaningful results.

In fact, the degradation in sediment is likely to be so slow that estimation of PECsed following multiple applications requires some assumptions concerning the likely degradation rate in sediment. A worst-case situation would employ an assumption of no degradation or dissipation between successive applications of paraquat. Two applications within a year will result in higher concentrations up to a maximum of **ca. 0.15 mg/kg**. In the longer term PECsed becomes more heavily dependent on more speculative factors.

2.8.3 Fate and behaviour in air

Paraquat dichloride is fully ionised in aqueous conditions, very soluble in water, and has no measurable vapour pressure (i.e. less than 10^{-8} kPa at 25°C). In addition, it is of course highly sorbed to soil. Henry's Law Constant (H) is estimated to be less than 4×10^{-12} Pa m^{-3} mol^{-1}. Therefore no further studies are deemed necessary.

From the above consideration of relevant parameters, it is assumed that paraquat concentrations in air following application will be negligible. No further information is required at this time.

PECa is assumed to be zero.

2.9 Effects on non-target species

2.9.1 Effects on terrestrial vertebrates

i) Risk to mammals

Exposure to small mammals is likely to occur from either:

a) consumption of treated vegetation, including seed contaminated with paraquat residues
b) consumption of earthworms also contaminated with paraquat residues

a) Based on the EPPO vertebrate scheme, the expected initial residues on treated grass oversprayed at the maximum application rate of 1100 g as/ha is 123.2 mg as/kg. Therefore, a 3230 g hare consuming 500 g per day would consume 61.5 mg as/day. Using the above toxicity data and this consumption figure, a short term TER of 5 is produced. This is less than the Annex III of the Directive 91/414/EEC trigger of 100, and indicates that there should be further consideration of the risk. There is also concern regarding the exposure of hares to paraquat when grooming wet fur. In the 1960-70s there were several incidents in the UK where paraquat was implicated in the deaths of hares. As a result a precautionary warning phrase was added to the label of formulations approved for use in the UK to draw the users attention to the possible risk to hares. The exact cause of deaths of these hares has been questioned by the Notifier. They propose that European Brown Hare Syndrome caused the deaths.

The risk to hares from the use of paraquat is unclear, there is evidence that it can cause deaths, however there is also evidence that deaths previously thought due to paraquat may have been due to the 'European Brown Hare Syndrome'. Therefore, further suitable information on the risk of paraquat to hares (for example data on residues of paraquat on treated vegetation, the risk from grooming as well as data on the toxicity of paraquat to hares) is required before Annex I listing can be recommended.

Small mammals, for example wood mice (*Apodemus sylvaticus*), may be exposed to paraquat from the use on stubbles or on established pasture/grassland that has gone to seed. Exposure of wood mice to residues of paraquat may be via seeds present either in the seed head or on the ground. If it is assumed that an 18.5 g wood mouse consumes *Avena fatua* seeds which contained residues of 87 mg as/kg fresh weight of seed, then the corresponding acute TER would be 7.1. This is less than the Annex III trigger of 100 and requires further consideration. Wood mice tend to be opportunistic feeders, therefore if there is grain or seed available on the surface of the field, then they will consume it. Therefore, it is feasible that wood mice may consume treated seed in sufficient quantity in order to obtain an median lethal dose. Data from Section B.5.3 indicates that rats fed 100 ppm paraquat in the diet for 13 weeks showed no adverse effects. Therefore, on the basis of these data, the risk to small mammals, from the consumption of contaminated seed containing residues of 87 mg as/kg (i.e. ≅87 ppm) would be low.

b) Based on the EPPO earthworm scheme, the expected residues in soil at 1100 g as/ha (based on one application to bare soil and no significant degradation and crop interception (see Section B.7.3)) is 0.73 mg as/kg soil (assuming a soil depth of 5 cm and bulk density of 1.5 g/cm^3). If it is assumed that a 100 mg worm contains 30 mg of such contaminated soil, then it could contain approximately 0.02 µg as/worm, equivalent to 0.2 mg as/kg worm. Using the acute LD50 of 204 mg/kg the acute TER would be 467. This is greater than the trigger for unacceptable effects of 100 and indicates that the risk to small mammals via this route is acceptable.

ii) Risk to birds

On the basis of the acute oral toxicity data summarised in Section B.8.1.1, the LD50 of paraquat to birds may vary from 35 to 144 mg as/kg bw. None of the studies submitted were conducted to modern standards or reported to sufficient clarity to determine the exact nature of the test substance. Therefore, a reliable LD50 for paraquat cannot be obtained from these studies. However, in order to carry out the following risk assessment it is proposed to use the lowest LD50 calculated, i.e. 35 mg as/kg, which was obtained when the mallard duck was tested.

Five-day dietary studies were generally more reliable and reported LC50 figures of 698-2915 ppm for a range of species (see Section B.8.1.1). Therefore, the figure from the study using the Japanese quail, i.e. 698 ppm, will be used.

Exposure to birds is likely to occur from either:

a) consumption of treated vegetation, including seed contaminated with paraquat residues
b) consumption of earthworms also contaminated with paraquat residues
c) consumption of oversprayed insects contaminated with paraquat residues

a) Based on the EPPO vertebrate scheme, the expected initial residues on treated grass oversprayed at the maximum application rate of 1100 g as/ha is 123.2 mg as/kg. Therefore the short-term dietary TER, based on a dietary 8-day LC50 figure of 698 ppm as, would be 5.6. The acute oral TER, based on an acute oral LD50 of 35 mg as/kg bw was determined to be 0.95. The dietary and the acute TERs based on an application rate of 1100 g as/ha are less than the Annex III of the Directive 91/414/EEC trigger and indicate that there is a high risk to birds from this route of exposure.

It is assumed that treated vegetation will become unpalatable to birds due to desiccation and hence unlikely to be consumed in large quantities. The initial residue predicted according to the EPPO risk assessment scheme is 123 mg as/kg grass, data from the reproduction study indicated that birds fed this concentration of paraquat in their food did not die or show adverse effects. It should also be noted that paraquat has not been implicated in any incidents reported to the UK Wildlife Incident Investigation Scheme when used in this situation. Therefore, the risk to grazing birds should be acceptable and no further data required.

Small birds will consume seeds that have either been treated as seeds still in the head, or as seeds on the ground. The Notifier has submitted data on the residues of paraquat on a range of seeds (i.e. *Avena fatua*, *Chenopodium album*, *Polygonum lapathilfolium* and *Sinapis arvensis*) following an application of 1 kg as/ha (i.e. 10% lower than the maximum application rate) (see Section B.8.10).

Small birds, for example chaffinches (*Fringilla coelebs*) will consume weed and cereal seeds. If all of this was as seeds containing the highest residue measured, i.e. 88 mg as/kg seed, then the resulting acute TER will be 1.6. Using dietary data the resulting TER would be 7.9. The dietary and the acute TERs are less than the Annex III of Directive 91/414/EEC triggers value of 10 and indicate that cage or semi-field trial are required. It should be noted that the above residue data were generated using an application rate 10% lower than the maximum authorised.

The above TERs are based on a worst case scenario. The above risk assessments only consider the initial residues on *Chenopodium album* and take no account of degradation, birds dehusking seeds, or birds eating a combination of treated seeds. However taking these factors into account indicates that the risk to small birds from this route of exposure should be acceptable.

Large seed eating birds, for example wood pigeons (*Columba palumbus*), may eat fallen seed, for example *Avena fatua*. Therefore using the maximum residues quoted above, i.e. 87 mg as/kg, and the resulting short term TER is 7.9 and acute TER would be 11.3. The acute and dietary risk to birds are below the appropriate Annex III trigger of 100 and indicates that further consideration of the risk is required.

It should be noted that the above risk assessment is based on a worst case example. If more refined exposure data are used, then the risk to large seed eating birds should be acceptable.

b) Based on the EPPO earthworm scheme, the expected residues in soil at 1100 g as/ha (based on one application to bare soil and no significant degradation and weed or crop interception (see Section B.7.3)) is 0.73 mg as/kg soil (using a soil depth of 5 cm and bulk density of 1.5 g/cm^3). If it is assumed that a 100 mg earthworm contains 30 mg of such contaminated soil, then it contain approximately 0.02 µg as/worm, equivalent to 0.2 mg as/kg worm. Therefore, the short-term TER, based on a dietary 8-day LC50 would be approximately 3500. Assuming a thrush's total daily food consumption was such contaminated earthworms, it would consume 0.004 mg as/bird, equivalent to 0.05 mg as/kg. Therefore the acute oral TER, based on an acute oral LD50 of 35 mg as/kg, would be approximately 700. Both these TERs are above the relevant Annex III of the Directive 91/414 trigger of 100, which indicates that no further data are required. Therefore, the acute risk to birds eating earthworms feeding from soil treated with paraquat is acceptable.

It was noted that paraquat is very persistent in soil with a half life measured in several years (see Section B.7.4). Using data based on several years usage of the active substance (see Section B.7.4), the acute TER was less than the trigger of 100. It was determined that due to the number of worms required in order to obtain a median lethal dose, the risk was acceptable.

c) Based on the EPPO vertebrate scheme, the expected initial residue on insects present in treated vegetation following an application of 1100 g as/ha is 31.9 mg as/kg small insects. Therefore, the short-term dietary TER, based on a dietary 8-day LC50 of 698 ppm as, would be 21.9.

According to Annex III of Directive 91/414/EEC, when a short term TER is greater than 10 but less than 100 then further consideration of the risk is required. Residue data from insects exposed to paraquat indicate that the likely highest residues would be 18 mg as/kg, therefore using this more realistic figure the short term TER is 39. Therefore, due to these factor the risk to small insect eating birds from this route of exposure is considered to be acceptable.

Assuming that a 11 g bluetit (*Parus caeruleus*) consumed its daily intake of 7.4 g wet weight of contaminated small insects (EPPO 1992), it would consume 0.24 mg as. Therefore, the acute oral TER, based on an acute oral LD50 of 35 mg as/kg would be 1.6. Data have been submitted on the residues of paraquat on insects. Using these data, the corresponding acute TER is 4.2. This is still less than the Annex III trigger of 10 and indicates that further data, for example a cage or semi-field trial are required. It should be noted that there have been no recorded incidents, where paraquat has been implemented in the death of small insectivorous birds in the UK.

Conclusion of the avian acute and short-term risk assessments

It was noted in the introduction to this risk assessment section that poor avian acute toxicity studies had been submitted and, as a result, it was not possible to set a reliable LD50. However, using the worst case figure from the data submitted, together with the available reliable dietary and exposure data, the risk to birds is considered to be acceptable. Therefore no further acute or short-term avian toxicity data are required.

d) Risk to bird reproduction

From the available data, it would appear that the reproductive success of birds may be affected by the use of paraquat during the breeding season. Therefore, it is proposed that the Notifier should conduct an appropriate study designed to assess the effects of paraquat on bird reproduction. The study should consider whether birds are likely to be exposed to residues of paraquat during the breeding season, and if so whether there are any significant effects at the application rate. This risk should be adequately addressed prior to paraquat being placed on to Annex I.

2.9.2 Effects on aquatic species

Acute risk

Section B.7.5 (table B.7.8) reports a surface water PEC of 0.018 mg as/l, assuming 5% drift at 1 m in to a 30 cm deep water body and application rate of 1100 g as/ha. Using this as the acute PEC using the active substance application rate and the available toxicity data, the TERs are 1677, 244 and 8.8 for fish, *Daphnia magna* and alga, respectively. Using data on the toxicity of the 200 g/l

SL formulation, the TERs for fish, *Daphnia magna* and alga are 461, 333 and 6.1 respectively. No data have been submitted regarding the toxicity of either the active substance, paraquat, or either SL or WG formulation to a suitable aquatic plant, e.g. *Lemna* spp. Therefore, a study should be submitted on the toxicity of paraquat to *Lemna* spp. Once this study is available, data using the most sensitive species (i.e. alga or *Lemna*) and an appropriate formulation should be generated for product re-registration, to enable the product to be classified correctly.
The TERs for algae are lower than the Directive 91/414/EEC Annex VI trigger 10 for unacceptable effects, indicating an acute risk to alga from the use of paraquat in 'arable/orchard' situations.

Paraquat has been reported to rapidly partition to the sediment ($\leq$ 1 day - see section B.7.4). Therefore, due to the rapid partitioning of paraquat into the sediment, it is considered feasible use a time weighed average PEC of 0.0062 mg as/l. Comparing this PEC with the above toxicity data, a TER of 26 is produced for algae. Using data on the toxicity of the formulation to algae, a TER of 17.7 is produced. These TERs , are above the Directive 91/414/EEC Annex VI trigger of 10 and indicate that the risk to alga from the use of this product is acceptable.

The use of paraquat on canal and ditchbanks was seen to pose a high acute risk with TERs for fish, *Daphnia magna* and alga of 90, 13.2 and 0.48 respectively. Data on the 200 g/l formulation indicated an even higher acute risk with TERs of 4.5, 3.3 and 0.06 for fish, *Daphnia magna* and alga respectively. The short half-life of paraquat in the natural water sediment system did not decrease the risk to aquatic life significantly and there was no suitable mesocosm study to indicate the effect of paraquat on the aquatic environment. Normally when a high risk to the aquatic environment is highlighted, then an appropriate restriction is applied. However, in this instance it is proposed that this specialised use be allowed to continue, pending the receipt and evaluation of a suitable mesocosm study which addresses the risk posed by such applications.

Chronic risk

Several 'chronic' studies were submitted, however of these only the one using the *Daphnia magna* over a 21-day period is considered sufficiently reliable for risk assessment purposes. This study indicated that the 21-day NOEC 252 mg as/l. Paraquat is unlikely to persist in the water phase of the aquatic environment, hence it is unlikely that aquatic life present in the water column will be exposed for a prolonged period to paraquat. However, when these chronic toxicity data were compared to a time-weighed PEC a TER in excess of 10000 was produced indicating a low risk to aquatic invertebrates from the active substance.

Risk to sediment dwelling organisms

Section B.7.4 reports that paraquat rapidly partitions into the sediment phase of natural water systems with a DT50 of less than 1 day. Therefore, paraquat entering water from spray drift may pose a risk to sediment dwelling organisms. Once present in the sediment paraquat is likely to persist (see Section B.7.5), therefore it is feasible that invertebrates present in the sediment may be exposed to paraquat for a prolonged period.

The total maximum amount of paraquat applied to any one crop in one year is approximately 2200 g as/ha for 'arable/orchard' uses, resulting in a possible concentration of 0.15 mg as/kg sediment. No data are available to indicate the toxicity of paraquat to sediment dwelling organisms. Usually an indication of the risk of an active substance to sediment dwelling organisms may be obtained if data on the Log Koc and chronic toxicity to *Daphnia magna* are available. No data are available on the Log Koc, therefore it is not possible to assess the risk. It is also considered inappropriate to use *Daphnia magna* data as a surrogate species as exposure may not be from pore water due to the binding of the active substance to the sediment. Hence, the risk may be from dietary exposure. Therefore, data should be generated using appropriate sediment concentrations (i.e. to simulate the range of spray drift application rates) and a suitable sediment dwelling organism, for example *Chironomid* spp so that the risk to sediment dwelling organisms can be determined.

Bioaccumulation

Paraquat would not be expected to bioaccumulate on the basis of a consideration of its chemical and physical properties, particularly its very high solubility in water and its low fat solubility together with its biological deactivation through strong adsorption to soil particles.

The octanol/water partition co-efficient (Log Pow) of pure paraquat dichloride is -4.5 at 20°C (see Annex II, Point 2.8). It is generally accepted that it is only in those cases where the octanol/water partition co-efficient (Pow) of the active substance exceeds 1,000 (Log Pow > 3) that a specific bioaccumulation study is justified, as only these chemicals have significant bioaccumulation potential. On this basis there is no reason to expect paraquat to bioaccumulate.

2.9.3 Effects on bees and other arthropod species

Honeybees are likely to be exposed to paraquat as the SL or WG formulation when applications are made when either the 'crop' is in flower or there are flowering weeds present in the crop.

The maximum application of paraquat as the SL formulation is equivalent to 1100 g as/ha. The 120 hour oral and contact LD50s are 11 and 51 μg as/bee respectively. Using the above toxicity data and the maximum application rate the oral and contact hazard ratio (i.e. g paraquat/ha ÷ LD50 in μg as/bee) are 100 and 21 respectively. The acute contact hazard ratio is less than the Directive 91/414/EEC Annex VI trigger of 50 for acceptable effects and indicates that the risk to bees from this route of exposure is acceptable. However, the acute oral toxicity hazard ratio is greater than the Directive 91/414/EEC Annex VI trigger of 50 for acceptable effects and indicates a risk and according to Annex III further data (e.g. a cage or field trial) are required.

According to the Council of Europe/European and Mediterranean Plant Protection Organisation honeybee risk assessment scheme, when a hazard ratio of more than 50 is determined, then an assessment of the persistence of the active substance on

foliage should be made. No data are available to indicate whether paraquat is persistent on flowers.

Paraquat, when applied to flowering weeds may pose a risk to foraging honeybees. It is proposed that further information on the persistence of the active substance on flowers is determined. Once these data are available the risk to honeybees can be re-assessed.

Other arthropods

Annex II of Directive 91/414/EEC requires laboratory toxicity data to be submitted on the toxicity of the active substance (can be tested in formulation) to two standard species: the aphid parasitoid *Aphidius rhopalosiphi* and the predatory mite *Typhlodromus pyri*. According to Annex II of Directive 91/414/EEC results from tests using *Trichogramma cacoeciae* would be acceptable instead of data on *Aphidius rhopalosiphi*. Data on these or related species have not been submitted, therefore, in order to satisfy the requirements of Annex II and Annex III, data are required on the toxicity of paraquat to an aphid parasitoid, for example *Aphidius rhopalosiphi*, and a predatory mite, for example *Typhlodromus pyri*.

According to Annex II and III of Directive 91/414/EEC, data are also required on two additional species that are relevant to the use of the plant protection product. It is considered likely that due to the timing of most applications of products containing paraquat, for example autumn through to spring, ground dwelling predators will be the functional group of non-target arthropods that most likely to be exposed. Data have been submitted on two ground dwelling arthropods, these studies indicate that paraquat applied at 1000 g as/ha causes no significant effect on the survival of *Pterostichus melanarius*, whilst applications of 600 g a/ha cause an overall reduction in 20% of 'beneficial capacity' in *Aleochara bilineata*. As the effect on these two species is less than the trigger value of 30% stated in the appropriate EPPO guideline, the risk to non-target arthropods is considered to be acceptable.

2.9.4 Effects on earthworms and other macro-organisms

No data were submitted on the toxicity of the active substance to earthworms, however data were submitted on the toxicity of a 200 g/l SL formulation. This study indicated that the 14-day LC50 was in excess of 1000 mg as/kg soil, with a NOEC of less than 1000 mg paraquat/kg. Using the above predicted environmental concentration, the resulting TER will be 1369. This TER is greater than the trigger value of 100 as outlined in Annex VI of Directive 91/414/EEC and indicates that paraquat, as the SL formulation, is unlikely to cause unacceptable effects.

Paraquat is persistent, with a half-life measured in years (see Section B.7.1.4), therefore earthworms may be exposed to residues of paraquat present in the soil over a longer period. Data have been submitted that indicate that large single applications of paraquat, approximately equivalent to 180 and 654 times the maximum application rate, caused effects when incorporated to 120 mm. Effects were also seen at 109 times the maximum dose when the paraquat was

incorporated to 25 mm. After six years all treatments were comparable to the control, except the top dose, i.e. 654 times the maximum dose. These plots had a significantly lower number of earthworms than the control, although earthworm biomass was comparable. As paraquat is very persistent in soil (see Section B.7.1.4), it is feasible that one large application may simulate several years use. Therefore, it is considered that these data indicate that the use of paraquat should not pose a significant risk to earthworm populations.

2.9.5 Effects on soil micro-organisms

Annex III of Directive 91/414/EEC requires that the effect of paraquat products on other soil non-target macro-organisms must be investigated where exposure of such organisms is possible and where the field soil DT50 is greater than 100 days. Both these criteria apply for paraquat (see Section B.7.1). However, Annex III also states that where no risk to earthworms or soil microbial processes are identified, no further data are required. The company have submitted data on the effects of paraquat to soil microarthropods. These data indicate that the overall impact of paraquat applied at rates of up to 720 kg as/ha had no clear effect on the population of soil microarthropods.

Data indicated that a 100 g/l SL formulation applied at the rate equivalent to 600 and 3000 g as/ha and incorporated to a depth of 5 cm did not have any significant effect over a 4 week study period on nitrogen transformation and carbon mineralisation. Paraquat applied as a 240 g/l formulation (type not stated) did not have any overall effect on ammonification in the soils tested. Field data indicated that nitrogen transformation and carbon mineralisation was not affected by rates of paraquat equivalent to 654 kg as/ha, i.e. equivalent to 600 years usage. Data from a litter bag study indicated that paraquat did adversely effect the overall decomposition of leaf litter. However, the relevance of the application rate or method of application is not known.

The above data broadly meet the Annex VI of Directive 91/414/EEC 'acceptability' requirement of less than 25% effect after 100 days. Thus indicating that the risk to soil microbial processes from the use of paraquat is low. As an identical trigger for further testing is adopted in Annex III of Directive 91/414/EEC, no further data on the effects of paraquat on soil microbial processes are required.

2.9.6 Effects on biological sewage treatment

It is not considered likely that the normal use of paraquat will result in contamination of sewage treatment plants. Therefore, as the risk of exposure is considered to be low, no data are required.

2.10 Classification and labelling

Full details of classification including the proposals made by the notifier and the comments made by the rapporteur are given in Annex B to this report - Section B.9.

2.10.1 Active substance classification and labelling requirements proposed by the rapporteur

Classification of active substance on the basis of toxicological properties

acute oral	Harmful	R22
acute dermal	none	-
acute inhalation	none*	-
skin irritant	Irritant	R38
eye irritant	Irritant	R36
respiratory irritant	Irritant	R37
skin sensitiser	none	-
reproduction	none	-
mutagenicity	none	-
carcinogenicity	none	-
serious damage on long term exposure	Toxic	R48/25

*not a vapour, gas, aerosol or particulate

The overall classification proposed is therefore:

Hazard symbol	T, Xi
Indication of danger	Toxic, Irritant
Risk phrases	R 22 R 36/37/38 R48/25
Safety phrases	S 2 S 20/23/24/26/28 S 36/37/39 S45 S 46

R48/25 is considered appropriate due to the production of clearly defined ocular lesions in the chronic rat study at 75ppm (*ca* 3.6mg/kg bw/d) and lung lesions in dogs at 60ppm (*ca* 2mg/kg bw/d), paraquat in the diet. The NOAELs for these effects were below 5mg paraquat dichloride/kg bw/d.

R37 is considered appropriate based on reports of nose bleeds in pesticide users and production plant workers. This indicates that droplets/aerosols of paraquat may be generated and whilst inspiration is not anticipated, local effects on the nasal passages cannot be dismissed.

R38 is not warranted based on the rabbit irritancy study but experience of human exposures indicates that skin irritancy is a property of technical paraquat dichloride. The applicant has also proposed the use of R38.

Classification of active substance for environmental effects

As the 96 hour EC_b50 for *Raphidocellis subcapitata* of 0.16 mg as/l (ref Smyth *et al* 1990) it should be classified as **'Very toxic to aquatic organisms'** (R50). It should also be classified as **'May cause long-term adverse effects in the aquatic environment'** (R53) as it is not seen to be readily biodegraded in the aquatic environment.

The active substance should be classified as R50-R53 which is as follows:-

'Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.'

On the basis of allocated the R50-R53 classification above, the active substance paraquat should also be classified as:- 'dangerous for the environment' and should carry the 'N' symbol on the active substance label.

The classification proposed is therefore:

Hazard symbol	N
Indication of danger	dangerous for the environment
Risk phrases	R 50-53

On the basis of the above classification, the active substance must also be classified as S60-61, which is as follows:-

'This material and its container must be disposed of as hazardous waste.'

'Avoid release to the environment. Refer to special instructions/Safety data sheet'

2.10.2 Preparations: classification and labelling requirements proposed by the rapporteur

Consideration of the hazard classification of preparations with respect to environmental effects (aquatic life and honeybees) based current UK guidance (in the absence of EC guidance) is given in Annex B to this report - Section 9.2.3.

2.10.2.1 Weedol

EEC Classification	:	Not classified
Hazard symbol:		Not applicable
Risk phrases:		Not applicable
Safety phrases:		Not applicable
PRECAUTIONS:		KEEP OFF SKIN WASH OFF SPLASHES IMMEDIATELY WASH HANDS AFTER USE KEEP AWAY FROM CHILDREN AND PETS KEEP PETS OFF TREATED AREAS UNTIL DRY KEEP IN ORIGINAL CONTAINER, tightly closed in a safe place EMPTY SACHET COMPLETELY and dispose of safely

2.10.2.2 Gramoxone

EEC Classification	:	HARMFUL
Hazard symbol		T, Xi
Indication of danger		Toxic, Irritant
Risk phrases		R 21/22 R 36/37/38 R48/25
Safety phrases		S 2 S 20/23/24/26/28 S 36/37/39 S 45 S 46

LEVEL 3

Paraquat

PROPOSAL FOR THE DECISION

3.1 Background to the proposed decision.

Paraquat is the ISO common name for 1,1'-dimethyl-4,4'-bipyridinium, a bipyridinium herbicide derived from pyridine. The active substance is presented in the form of the dichloride salt. It may be formulated as a soluble concentrate or water dispersible granules.

Paraquat acts with great rapidity in the green parts of plants to produce disruption of the plant cells, leading to death and desiccation of the foliage. It is not translocated through plants, and its destructive action is restricted to the site of application. Paraquat is quickly deactivated in the soil, and is not taken up by the roots of existing plants, or by subsequently planted crops.

Paraquat is usually applied either when the crop is not present, in early post emergence or in a manner such that the crop is not treated, (e.g. by the use of guards or around the base of trees).

An ADI of 0-0.004 mg paraquat ion/kg bw; a short term systemic AOEL of 0.0005 mg paraquat ion/kg bw/day and a long term systemic AOEL of 0.0004 mg paraquat ion/kg bw/day can be proposed.

It is expected that residues of paraquat, consequent on application consistent with good plant protection practice, will not have harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment. Such residues can be measured by methods using conventional analytical equipment.

It is also expected that the use of paraquat, consistent with good plant protection practice, will not have any harmful effects on human or animal health or any unacceptable effects on the environment. However some further data are required to confirm this assessment.

3.2 Proposed decision

That a decision on the inclusion of paraquat in Annex I of Council Directive 91/414/EEC is postponed pending receipt and evaluation of further data listed in Section 4.1.

If, in the future, the inclusion of paraquat in Annex I is agreed the following conditions should be attached to its inclusion:

i) all liquid formulations of paraquat should contain suitable alerting agents (dye and stench) to reduce the risk of accidental oral ingestion of the product.

ii) all solid formulations of paraquat should contain a suitable dye to reduce the risk of accidental oral ingestion of the product.

iii) all formulations of paraquat should contain an appropriate level of emetic, to increase the likelihood of emesis in case of significant accidental or deliberate oral ingestion.

In addition to the above Member States should be advised that:

i) consideration should be given to whether a resistance management strategy for the use of paraquat in perennial crops needs to be developed. This is in order to prevent resistance to paraquat developing in certain weeds following long-term, repeated use. The addition of suitable label warning statements may be necessary.

ii) wherever practical and reasonable, the availability and use of high-strength liquid formulations should be limited to *bona fide* agriculturalists, horticulturalists and professional users.

3.3 Rationale for the proposed decision

The data provided indicate no specific concern with the use of paraquat in plant protection products. However, additional data are required to make a complete assessment of whether the conditions contained in Article 5(1) of Council Directive 91/414/EEC are satisfied, in particular, further ecotoxicology data.

The imposition of various restrictions following any future decision to include paraquat in Annex I of Council Directive 91/414/EEC are proposed. The restrictions concern measures to minimise the risk, and consequences, of accidental ingestion.

LEVEL 4

Paraquat

DEMAND FOR FURTHER INFORMATION

4.1 Demand for further information - Data required before inclusion in Annex I can be considered

Deadline for receipt of a commitment to provide additional data - 6 months

Data submission deadline - 4 years

Identity

The information supplied on identity is sufficient to recommend Annex I listing for paraquat.

Physical and chemical properties

The information supplied with regard to physical and chemical properties of the active substance and plant protection products is sufficient to allow paraquat to be listed in Annex I.

Details of uses and further information

The information supplied is sufficient to recommend Annex I listing for paraquat.

Methods of analysis

The information supplied with regard to methods of analysis is sufficient to allow paraquat to be included in Annex I.

Impact on human and animal health

Toxicology and metabolism

The information supplied with regard to toxicology and metabolism is sufficient to allow paraquat to be included in Annex I.

Residues

The information supplied with regard to residues is sufficient to allow paraquat to be included in Annex I.

Fate and behaviour in the environment

The information supplied with regard to fate and behaviour in the environment is sufficient to allow paraquat to be included in Annex I.

Effects on non-target species

The information supplied with regard to effects on non-target species is not sufficient to allow paraquat to be included in Annex I. The following data are required:

i) data on the effects of the active substance on bird reproduction (Annex III 10.1.2)

ii) data on the toxicity of the active substance to *Lemna* spp (Annex II 8.2.8)

iii) further information on the toxicity of the active substance to hares (these data should address the risk to hares from the use of paraquat and include data on, for example the residues of paraquat on treated vegetation, the risk from grooming as well as data on the toxicity of paraquat to hares) (Annex III 10.3)

iv) data on the toxicity of the active substance to an aphid parasitoid, for example *Aphidius rhopalosiphi*, and a predatory mite, for example *Typhlodromus pyri*. These data may be generated using either the active substance or a suitable plant protection product. (Annex II 8.3.2)

v) a laboratory study using appropriate sediment concentrations (i.e. to simulate the range of application rates) investigating the chronic risk to sediment dwelling invertebrates (e.g. *Chironomid* sp.).

vii) further information on the persistence of the active substance on flowers to allow the risk to honeybees to be assessed

4.2 Demand for further information - Data which should be required and evaluated at Member State level for the plant protection products

The following additional data should be required and evaluated at Member State level for plant protection products:

i) Validation data for the method of analysis submitted for the determination of impurities in technical material.

ii) The following confirmatory residues trials data should be requested and evaluated at Member State level to support applications for use on the specified crops:

   a) One seasons confirmatory residues trials data on strawberries.

   b) One seasons confirmatory residues trials data on a range of brassica, leafy, legume and stem vegetables.

   c) One seasons confirmatory residues trials data on maize, analysing immature maize cobs and mature grain and silage.

   d) One seasons confirmatory residues trials data on alfalfa.

iii) If re-registration applications are made for the use of paraquat after the end of flowering to fruit trees and direct application to olives then additional residues trials data will be required to support such uses. The trials data submitted to address these uses, and considered in this review, indicated that positive residues would be present in the fruit and thus the established EU MRLs may be exceeded. Therefore, the following additional trials data are required:

a) One seasons residues trials data on olives, to support the commercial practice of treating olives on nets and on the ground to aid harvesting of olives used for processing into oil, analysing the treated olives and the oil from the treated olives.

b) One seasons residues trials data on various fruits, to address the possibility of fruit falling on to treated ground and picking up residues of paraquat.

If trials data are not supplied to support the above uses then Member States should consider appropriate restrictions such as amending the latest time of application of paraquat products to fruit trees to 'before the end of flowering' and not permitting the direct application of paraquat products to olives to aid harvesting.

iv) Required to support the near water use of paraquat (ditchbanks, canal banks)

A mesocosm study investigating the acute risk to aquatic life using appropriate application rates when used near water i.e. ditchbanks/canal banks. Protocol to be discussed with the appropriate registration authority.

For Gramoxone 100

i) Shelf life (of both the product and container) to include a shelf life specification conducted in accordance with the guidelines described in GIFAP Monograph 17.

ii) Data to support the effectiveness of cleaning procedures for application equipment.

iii) Data on the toxicity of the 'Gramoxone' formulation to *Lemna* spp. (NB: these data are only required if the study using the active substance shows that it is more sensitive than algae)

For Weedol

i) Shelf life (of both the product and container) to include a shelf life specification conducted in accordance with the guidelines described in GIFAP Monograph 17.

ii) Flowability of water soluble granules before and after storage under ambient conditions - to include an explanation of caking observed when the product was examined using CIPAC MT 172.

iii) Data to support the effectiveness of cleaning procedures for application equipment.

4.3 Data required to remove restrictions recommended for inclusion in Annex I

None specified.