

PARAQUAT (057)

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EXPLANATION

Paraquat, a non-selective contact herbicide, was first evaluated in 1970 for toxicology and residues. Subsequently, it was reviewed for toxicology in 1972, 1976, 1982, 1985 and 1986, and for residues in 1972, 1976, 1978 and 1981. The 2003 JMPR evaluated paraquat toxicologically under the Periodic Review Programme and recommended the current ADI of 00.005 mg paraquat cation/kg bw and ARfD of 0.006 mg paraquat ion/kg bw. The 2004 JMPR evaluated paraquat for residues under the Periodic Review Programme and concluded that the definition of residue for compliance with MRLs and for estimation of dietary intake was paraquat cation. That Meeting recommended 25 new and 7 revised maximum residue levels, maintained one maximum residue level, and withdrew 14 previous recommendations including those for rice and polished rice.

The existing Codex MRLs for rice and polished rice were recommended for withdrawal by the 2004 JMPR due to insufficient trial data. The current Meeting received information on previously submitted and additional residue trials on rice and the US label.

USE PATTERNS

Paraquat, available in soluble concentrate (SL) formulation, is registered in many countries as a non-selective herbicide to control weeds and permitted for use on a wide range of crops, pre-plant, pre-emergence or post-emergence.

Paraquat is recommended for use in the cultivation of rice either during pre-plant or pre-emergence treatment to the seed beds for weed control. The registered use of paraquat on rice as described on the US label is summarized in Table 1.

Table 1 Registered uses of paraquat on rice

Crops	Country	Formulation conc. g ai/L	Application			PHI days	Note
			Use/Method	Max rate kg ai/ha	No.		
Rice	USA	360	Pre-plant or pre-emergence broadcast	1.12	1	-	Do not flood/flush within 48 hours of application.

Note: PHI is not relevant due to the early application.

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

A series of trials were conducted between 1978 and 1993, three in Guatemala in 1983, two in Italy in 1993 and six in the USA in 1978 and 1982, where rice seed-beds were treated with paraquat SL formulations for weed control, prior to planting seedling rice plants or pre-emergence of rice plants from seed. Applications were made as broadcast treatments and rates of application were between 0.3 and 1.12 kg ai/ha.

In 2007, three additional trials, two in Arkansas and one in Louisiana, were conducted in which paraquat SL formulation was applied to rice seed beds as a pre-emergence broadcast application. In these and other US trials, paraquat was applied prior to flooding.

Rice grain and straw samples were collected at their maturity and analyzed. The time of storage before analysis was much shorter than the stable period of paraquat demonstrated in the storage stability study with maize samples.

The data from all these trials are presented in Table 2. Residue data are recorded as mg paraquat cation/kg and not corrected for recovery. Residue values from the trials conducted according to maximum GAP were used for the estimation of maximum residue levels. Where duplicate plots were used or duplicate samples were taken, the higher analytical result was used as previously agreed by the Meeting. These results are underlined.

Table 2 Paraquat residues in rice from supervised trials in Guatemala, Italy and USA

Country, year Rice (variety)	Application			PHI days	Paraquat ion mg/kg	Notes	Reference
	kg ai/ha	water, l/ha	no.				
Guatemala 1983 (Blue Belle)	0.60	400	1	0B*	< 0.05	Pre-emergence Dehusked seed	Kennedy 1984, M3739B
	1.00	400	1	108	< 0.05, < 0.05		
	0.60	400	1	108	< 0.05		
Italy, 1993				0B*	< 0.05	5 days pre-planting	Anderson <i>et al</i> 1995, RJ1728B IT10-93-H370
Lombardia (Loto)	0.92	400	1	119	<u>< 0.05</u>		
Piemonte (Koral)	0.92	400	1	151	<u>< 0.05</u>		
CA, USA, 1978 (Calrose)				0B*	< 0.01	Pre-emergence	Anon 1985, PP5F3188 M209-4642
	0.56	187	1	217	< 0.01		
	0.56	187	1	230	< 0.01		
CA, USA, 1982 (M-101)				0B*	< 0.01	Pre-emergence	Anon 1985 PP5F3188 M209-5649
	0.56	93.5	1	167	< 0.01		
	1.12	187	1	167	<u>< 0.01</u>		
(M-9)	0.56	93.5	1	163	< 0.01		M209-5650 M209-5651
	0.56	93.5	1	166	< 0.01		
	1.12	187	1	166	<u>< 0.01</u>		
(Labelle)	1.12	187	1	106	<u>< 0.01</u>		M209-5583
				0B*	< 0.01		
				126	<u>< 0.01, < 0.01</u>		
Procter, AR, USA, 2007 (Wells)				0B*	< 0.01	Pre-emergence	Moore <i>et al.</i> 2008, T011693-06 C24AR078271
	1.12	133	1	126	<u>< 0.01, < 0.01</u>		
New Port, AR, USA, 2007 (Wells)				0B*	< 0.01	Pre-emergence	Moore <i>et al.</i> 2008, T011693-06 C23AR078272
	1.12	185	1	138	<u>< 0.01, < 0.01</u>		
Tallulah, LO, USA, 2007 (Cocodrie)				0B*	0.04	Pre-emergence	Moore <i>et al.</i> 2008, T011693-06 E13LA078270
	1.12	197	1	124	0.03, 0.04 ^a		

* B=control

^a This trial was excluded from the current evaluation as the control sample was found to contain residues above the LOQ.

Rice straw and fodder, dry

Table 3 Paraquat residues in rice straw and fodder, dry, from supervised trials in Italy and USA.

Country, year Rice (variety)	Application			PHI days	Paraquat mg/kg	Notes	Reference
	kg ai/ha	water, l/ha	no.				
Italy, 1993				0B*	< 0.05	5 days Pre planting	Anderson et al 1995, RJ1728B IT10-93-H370 IT10-93-H371
Lombardia (Loto)	0.92	400	1	119	< 0.05		
Piemonte (Koral)	0.92	400	1	151	< 0.05		
CA, USA, 1978				0B*	< 0.06	Pre emergence	Anon 1985, PP5F3188 M209-4642 M209-4641
(Calrose)	0.56	187	1	217	< 0.06		
(Calrose)	0.56	187	1	230	< 0.06		
CA, USA, 1982				0B*	< 0.02 or < 0.03	Pre emergence	Anon 1985 PP5F3188 M209-5650 M209-5651 M209-5649 M209-5583
(M-9)	0.56	93.5	1	163	< 0.03		
(M-301)	0.56	93.5	1	166	< 0.02		
	1.12	187	1	166	< 0.02		
(M-101)	0.56	93.5	1	167	0.04, < 0.03		
	1.12	187	1	167	< 0.03		
(Labelle)	1.12	187	1	106	< 0.02		M209-5583
Procter, AR, USA, 2007 (Wells)				0B*	< 0.01	Pre-emergence	Moore et al. 2008, T011693-06 C24AR078271
	1.12	133	1	126	< 0.01, < 0.01		
New Port, AR, USA, 2007 (Wells)				0B*	< 0.01	Pre-emergence	Moore et al. 2008, T011693-06 C23AR078272
	1.12	185	1	138	< 0.01, < 0.01		
Tallulah, LO, USA, 2007 (Cocodrie)				0B*	0.01	Pre-emergence	Moore et al. 2008, T011693-06 E13LA078270
	1.12	197	1	124	< 0.01, < 0.01		

*B=control

APPRAISAL

Paraquat, a non-selective contact herbicide, was first evaluated in 1970 for toxicology and residues. The 2003 JMPR evaluated paraquat toxicologically under the Periodic Review Programme and recommended the current ADI of 0–0.005 mg paraquat cation/kg bw and ARfD of 0.006 mg paraquat cation/kg bw. The 2004 JMPR evaluated paraquat for residues under the Periodic Review Programme, concluded that the definition of residue for compliance with MRLs and for estimation of dietary intake was paraquat cation. It withdrew the previously recommended maximum residue levels for rice and polished rice due to insufficient data provided to the Meeting. The current Meeting received information on previously submitted and additional residue trials on rice and the US label.

Results of supervised trials on crops

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the

statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Rice

Paraquat is registered for weed control in rice production in the USA by pre-plant or pre-emergence broadcast application at a maximum rate of 1.12 kg ai/ha, with no PHI specified.

When used in a pre-plant or pre-emergence treatment, paraquat is not sprayed directly onto the crop, the time between the application and harvest is sufficiently long, and paraquat is strongly adsorbed to soil with negligible dissociation, with little paraquat cation expected to be found in rice grain or straw at harvest. As agreed by the 2004 JMPR, the Meeting evaluated data from trials of pre-plant and pre-emergence application against any GAP available to the Meeting, regardless of the country or region.

A total of 14 trials on rice conducted in Guatemala, Italy and the USA were provided to the current Meeting. Paraquat was applied prior to flooding in these trials. Rice grain and straw samples were collected at harvest.

Three trials were conducted in Guatemala in 1983 in which paraquat was applied as a pre-emergence treatment at rates of 0.60 and 1.0 kg ai/ha. The residues in de-husked rice in one trial conducted in accordance with US GAP were below the LOQ of 0.05 mg/kg. The residues in rice grain were not analysed.

Two trials were conducted in Italy in 1993, in which paraquat was applied at a rate of 0.92 kg ai/ha to the seed bed 5 days before rice was sown. Rice grain samples taken at harvest did not contain residues of paraquat at levels above the LOQ of 0.05 mg/kg (2).

Six residue trials were conducted in the USA in 1978 and 1982 in which paraquat was applied as a pre-emergence treatment at rates of 0.56 or 1.12 kg ai/ha. In trials conducted in compliance with the maximum US GAP, the residues were below the LOQ of 0.01 mg/kg (3).

Three new residue trials were conducted in the USA in 2007 in which paraquat was applied as a pre-emergence treatment at a rate of 1.12 kg ai/ha. The residues of paraquat in rice grain samples taken at harvest were < 0.01 mg/kg (2).

No trials were conducted at rates higher than the maximum allowed in US GAP for rice.

The residues in rice grain from trials in compliance with maximum US GAP in rank order were: < 0.01 (5), < 0.05 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.05(*) mg/kg and STMR of 0 mg/kg for rice grain, taking into consideration readily achievable LOQ of analytical methods used in enforcement of MRLs.

As the residues from all the trials matching GAP were below the LOQs, the NAFTA calculator was not used.

Rice straw

In two trials conducted in Italy in 1993, rice straw samples taken at harvest did not contain residues of paraquat at levels above the LOQ of 0.05 mg/kg (2).

In three residue trials conducted according to maximum US GAP in the USA in 1978 and 1982, the residues were < 0.02 mg/kg (2) and < 0.03 mg/kg. However, in one trial with the application rate of 0.56 kg ai/ha (one half of the maximum rate), the residues in duplicate straw samples were < 0.03 and 0.04 mg/kg. In comparison with the results of other trials, sample contamination was suspected but without any concrete evidence.

In three new residue trials in the USA in 2007, the residues of paraquat in rice straw samples taken at harvest were < 0.01 mg/kg (3).

The residues from trials in compliance with US GAP in rank order were: < 0.01 (3), < 0.02 (2), 0.04 and < 0.05 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg, STMR of 0.02 mg/kg and highest residue of 0.04 mg/kg for rice straw.

As the residues from seven out of eight trials matching GAP were below the LOQs, the NAFTA calculator was not used.

Residues in animal commodities

The addition of new maximum residue levels for rice grain and straw at 0.05 mg/kg would not affect the animal dietary burden calculated in 2004 in which much higher residue levels in cottonseed and maize forage were used in calculation. The Meeting concluded that there was no need to change the previous recommendations for animal commodities.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

Plant commodities and animal commodities

Definition of the residue for compliance with MRLs: *paraquat cation*

Definition of the residue for estimation of dietary intake: *paraquat cation*

Commodity		Recommended MRL, mg/kg		STMR mg/kg	HR mg/kg
CCN	Name	New	Previous		
GC 0649	Rice	0.05*	w	0	-
AS 0649	Rice straw and fodder, dry	0.05	-	0.02	0.04

DIETARY RISK ASSESSMENT

Long-term intake

Since the STMR for rice is estimated by the current Meeting to be 0 mg/kg, no new IEDI calculation was conducted. The Meeting confirmed the previous conclusion that the IEDIs were 2–5% of the maximum ADI of 0.005 mg/kg bw and that the intake of residues of paraquat resulting from uses considered by the 2004 and the current JMPR was unlikely to present a public health concern.

Short-term intake

Since the STMR for rice is estimated by the current Meeting to be 0 mg/kg, IESTI was not calculated for rice (IESTI of 0 µg/kg bw/day). The Meeting concluded that the short-term intake of residues of paraquat from uses on rice was unlikely to present a public health concern.

REFERENCES

Code	Author(s)	Year	Title, Report reference, GLP/Non-GLP, published/Unpublished
M3739B	Kennedy, S.H.	1984	DIURON/ PARAQUAT: Residues on rice from trials carried out during 1983 in Guatemala. ICI Protection Division Panamericana South America, Report No M3739B. Non-GLP, Not published, Syngenta File N° PP148/1049
RJ1728B	Anderson L, Lant M S, Bonfanti F	1995	PARAQUAT and DIQUAT: Residue levels in rice grain and straw from trials carried out in Italy during 1993. ZENECA Agrochemicals, Jealott's Hill Research Station, Bracknell Berkshire, UK, Report No RJ1728B, GLP, Not published, Syngenta File N° PP148/0463
PP5F3188	Anonymous	1985	Section D, Paraquat Residue Tolerance Petition Rice, Pesticide Petition 5F3188, EPA reg 239-2186/. Non-GLP, Not published, Syngenta File N° ASF378/0050
T011693-06	Moore M E, Mayer T J	2008	Paraquat – Magnitude of the Residues in or on Rice. Syngenta Crop Protection AG, Basel, Switzerland, Report No T0011693-06, GLP, Not published, Syngenta File N° PP148/3378