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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

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Chemical Review Committee
Seventh meeting
Rome, 28 March–1 April 2011
Item 4 (d) of the provisional agenda*

Technical work: review of the proposal for Gramoxone Super as a severely hazardous pesticide formulation

Gramoxone Super

Note by the Secretariat

Addendum

Additional information collected by the Secretariat

1. The Secretariat has the honour to provide, in the annex to the present note, documentation pertaining to the proposal by Burkina Faso to list Gramoxone Super as a severely hazardous pesticide formulation in Annex III to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. The documentation was collected by the Secretariat in accordance with part 2 of Annex IV to the Convention and includes basic information on the physical, chemical and toxicological properties of paraquat, which is the active ingredient contained in Gramoxone Super. The documentation set out in the annex is presented as collected, without formal editing by the Secretariat.

2. In addition, information on paraquat can also be found in the notifications of final regulatory action for the chemical and supporting documentation that were reviewed by the Chemical Review Committee at its previous meetings. Notifications provided by Sri Lanka, Sweden and Uruguay were circulated for consideration at the Committee's fifth meeting in document UNEP/FAO/RC/CRC.5/8. Supporting documentation provided by Sri Lanka was circulated in documents UNEP/FAO/RC/CRC.5/8/Add.3–5. Supporting documentation provided by Sweden was circulated in document UNEP/FAO/RC/CRC.5/8/Add.1/Rev.1 and additional supporting documentation was provided to the Committee at its sixth meeting in document UNEP/FAO/RC/CRC.6/9/Add.2. Supporting documentation provided by Uruguay was circulated in document UNEP/FAO/RC/CRC.5/8/Add.2.

* UNEP/FAO/RC/CRC.7/1.

Annex

1. **Pesticide Manual (electronic version 5.0.1, 2010, 15th edition)**

2. **Excerpt of the Joint Meeting on Pesticide Residues (JMPR) report on pesticide residues in food 2003**

3. **Excerpt of the JMPR report on pesticide residues in food 2004**

4. **Excerpt of the JMPR report on pesticide residues in food 2009**

E-Pesticide Manual

Version 5.0.1, 2010

15th edition

653 paraquat dichloride **Herbicide**

HRAC D **WSSA** 22 bipyridylium

Information about paraquat is available on the Internet at http://www.paraquat.com/

NOMENCLATURE

paraquat dichloride

IUPAC name 1,1′-dimethyl-4,4′-bipyridinediium dichloride; 1,1′-dimethyl-4,4′-bipyridinium dichloride; 1,1′-dimethyl-4,4′-bipyridylium dichloride

Chemical Abstracts name 1,1′-dimethyl-4,4′-bipyridinium dichloride **Other names** methyl viologen dichloride **CAS RN** *[1910–42–5]* **EC no** 217–615–7 **Development codes** PP148 (ICI) **Smiles code** [Cl-].[Cl-].C[n+]1ccc(cc1)c2cc[n+](C)cc2

paraquat dication

Common name paraquat (BSI, E-ISO, (*m*) F-ISO, ANSI, WSSA, JMAF); no name (Germany)

IUPAC name 1,1′-dimethyl-4,4′-bipyridinediium; 1,1′-dimethyl-4,4′-bipyridinium; 1,1′-dimethyl-4,4′-bipyridylium

Chemical Abstracts name 1,1′-dimethyl-4,4′-bipyridinium **Other names** methyl viologen **CAS RN** *[4685–14–7]* **EC no** 225–141–7 **Smiles code** C[n+]1ccc(cc1)c2cc[n+](C)cc2

PHYSICAL CHEMISTRY

paraquat dichloride

Composition Tech. paraquat dichloride is commercialised in aqueous solution (min. 500 g/l, 20 °C - FAO specification).

Mol. wt. 257.2 **M.f.** $C_{12}H_{14}Cl_2N_2$ **Form** Colourless, hygroscopic crystals. **M.p.** Decomposes at *c.* 340 °C **V.p.** <1 × 10^{-2} mPa (25 °C) **K_{ow}** logP = –4.5 (20 °C) **Henry** <4 × 10^{-9} Pa m^3 mol^{-1} (calc.) **S.g./density** *c.* 1.5 (25 °C) **Solubility** In water *c.* 620 g/l (pH *c.* 5–9, 20 °C). In methanol 143 g/l (20 °C); practically insoluble in most other organic solvents. **Stability** Decomposes at *c.* 340 °C. Hydrolytically stable in alkaline, neutral and acidic media. Photolytically stable in aqueous solution at pH 7.

paraquat dication

Mol. wt. 186.3 **M.f.** $C_{12}H_{14}N_2$

COMMERCIALISATION

History Herbicidal properties of the dichloride and bis(methyl sulfate) described by R. C. Brian (*Nature (London),* 1958, **181,** 446) and their properties reviewed by A. Calderbank (*Adv. Pest Control Res.,* 1968, **8,** 127). Both salts (though only the former is still sold) were introduced by ICI Plant Protection Division (now Syngenta AG). Herbicidal properties of paraquat dichloride discovered in 1955, and first marketed in 1962.

Patents GB 813531 **Manufacturers** Syngenta; AgroDragon; Anhui Huaxing; CAC; ChemChina Agrochemical; Crystal; Fengle; Hailir; Hubei Sanonda; Hui Kwang; Iprochem; KSA; Kuo Ching; Luba; Pilarquim; Rainbow; Red Sun; Sanex; Sanonda Zhengzhou; Shandong Qiaochang; Sinon; Sundat; United Phosphorus; Zhejiang Yongnong

APPLICATIONS

paraquat dichloride

Biochemistry During photosynthesis, superoxide is generated, which damages cell membranes and cytoplasm. **Mode of action** Non-selective contact herbicide, absorbed by the foliage, with some translocation in the xylem.

Uses Broad-spectrum control of broad-leaved weeds and grasses in fruit orchards (including citrus), plantation crops (bananas, coffee, cocoa palms, coconut palms, oil palms, rubber, etc.), vines, olives, tea, alfalfa, onions, leeks, sugar beet, asparagus, ornamental trees and shrubs, in forestry, etc. Also used for general weed control on non-crop land; as a defoliant for cotton and hops; for destruction of potato haulms; as a desiccant for pineapples, sugar cane, soya beans and sunflowers; for strawberry runner control; and in pasture renovation. For control of annual weeds, applied at 0.4–1.0 kg ion/ha.

Formulation types SG; SL. **Compatibility** Incompatible with alkaline materials, anionic surfactants, and clay-containing inert materials.

PRODUCTS

paraquat dichloride

Selected products 'Gramoxone' (Syngenta); 'Gramoquat Super' (Baocheng); 'Herbaxon' (Westrade); 'Herbikill' (Vapco); 'Paraqate' (Mobedco); 'Pilarxone' (Pilarquim); 'Sunox' (Sundat); 'Total' (Barclay); 'Weedless' (Hubei Sanonda); **mixtures** 'Gramocil' (+ diuron) (Syngenta); 'Preglone' (+ diquat dibromide) (Syngenta); 'Seccatutto' (+ diquat dibromide) (Syngenta). **Other products** 'Gramoxone Inteon' (Syngenta); 'Agroquat' (Plaaskem S.A.); 'Boa' (DuPont); 'Bren' (Efal); 'Destroyer' (Doğal); 'Dextrone' (Nomix Enviro); 'Dhanuxone' (Dhanuka); 'Dipaxone' (Papaeconomou); 'Dragocson' (Agricultura Nacional); 'Efoxon' (Efthymiadis); 'Everzone' (Zagro); 'Fernpath Graminite' (Agriguard); 'Firestorm' (Chemtura); 'Forwazone' (Zagro); 'Fuego' (Zagro); 'Goldquat' (Zagro); 'Herboxone' (Crystal, Premier.Shukuroglou); 'Kapiq' (Krishi Rasayan); 'Lucaquat' (Lucava); 'Nuquat' (Nufarm Ltd); 'Ojiva' (Ingeniería Industrial, Zagro); 'Parachute' (Devidayal); 'Paradox' (Sinon); 'Paragon' (Hui Kwang); 'Paragone' (Plaaskem S.A.); 'Paraxone' (Hekta351); 'Parazone' (Makhteshim-Agan); 'Priquat' (Efthymiadis); 'Scythe' (BASF); 'Sipquat' (Unichem); 'Uniquat' (United Phosphorus); 'Weedol' (Scotts UK); **mixtures** 'Doblete' (+ diquat dibromide) (Syngenta); 'Farmon' (+ diquat dibromide) (Syngenta); 'Gramoxone Plus' (+ diquat dibromide) (Syngenta); 'Gramuron' (+ diuron) (Syngenta); 'Preeglox L' (+ diquat dibromide) (Syngenta); 'Preglox' (+ diquat dibromide) (Syngenta); 'Spray.Seed' (+ diquat dibromide) (Syngenta); 'Alliance' (+ amitrole) (Nufarm Ltd); 'Fernpath Pronto' (+ diquat dibromide) (Agriguard); 'Myzet' (+ diquat dibromide) (Otsuka); 'Pardy' (+ diuron) (Agricultura Nacional); 'Pramato' (+ bentazone) (Iharabras); 'Revolver' (+ diquat dibromide) (Nufarm Ltd); 'Surefire' (+ diuron) (Loveland). **Discontinued products** 'Cyclone' * (Syngenta); 'R-Bix' * (Syngenta); 'Speedway' * (Zeneca); 'Starfire' * (Syngenta); 'Sweep' * (Zeneca); 'Cekuquat' * (Cequisa); 'Crisquat' * (Crystal); 'Osaquat' * (Productos OSA); 'Plusquat' * (Productos OSA); **mixtures** 'Gramonol' * (+ monolinuron) (Zeneca); 'Parable' * (+ diquat dibromide) (Zeneca);

'PDQ' * (+ diquat dibromide) (Syngenta); 'Prelude' * (+ linuron + metolachlor) (Syngenta); 'Antox' * (+ MSMA) (Ancom); 'Anuron' * (+ diuron) (Ancom); 'Azote' * (+ amitrole) (Productos OSA); 'Crisquat D' * (+ diuron) (Crystal); 'Dexuron' * (+ diuron) (Nomix-Chipman); 'Duplex' * (+ amitrole) (Productos OSA); 'Giror' * (+ amitrole) (with ammonium thiocyanate) (Sopra); 'Herboxone D' * (+ diuron) (Crystal); 'Priglox' * (+ diquat dibromide) (Nihon Nohyaku).

ANALYSIS

Product analysis by colorimetry (*AOAC Methods,* 18th Ed., 969.09; *CIPAC Handbook,* 1992, **E**, 166–168; 1995, **G**, 128); free 4,4′-bipyridyl, *ibid.,* 1998, **H**, 216; in mixture with diquat, by colorimetry (*CIPAC Handbook*, 1992, **E**, 73–78; 1995, **G**, 49); or by hplc/uv. **Residues** determined by colorimetry after reduction (A. Calderbank & S. H. Yuen, *Analyst (London),* 1965, **90,** 99; P. F. Lott *et al., J. Chromatogr. Sci.,* 1978, **16,** 390; J. B. Leary, *Anal. Methods Pestic. Plant Growth Regul.,* 1978, **10,** 321) or by hplc/uv (*Resid. Anal. Methods*); residues in potatoes by rplc with dual channel uv detection (*AOAC Methods*, 18th Ed., 992.17). See also *Pestic. Anal. Man.,* **I**, 602, 605; *ibid.*, **II**, 180.205; or by hplc/ms/ms. In **soil** by spectrophotometry (*Environ. Chem. Methods*), by hplc/uv or hplc/ms/ms. Details of methods available from Syngenta.

TOXICOLOGICAL & ENVIRONMENTAL REVIEWS

EHC 39 (1984). *JMPR Mtg.* 101 (2004); *JMPR Evaln.* 37 (1981); *JMPR Evaln. I* 102 (2004); *JMPR Evaln. II* 100 (2003). *HSG* 51 (1991). *PDS* 4 (1975). *ICSC* 0005 (2001). EPA RED (1997). **91/414/EC Annex I status** Not included; inclusion in Annex 1 (2003/112/EC) annulled by Judgement of the (EC) Court of First Instance, 11 July 2007.

MAMMALIAN TOXICOLOGY

paraquat dichloride

Oral Acute oral LD_{50} for rats 129–157, guinea pigs 22–80 mg/kg. **Skin and eye** Acute percutaneous LD_{50} for rats >911 mg/kg. Irritating to skin and eyes (rabbits). Absorption through intact human skin is minimal; exposures can cause irritation and a delay in the healing of cuts and wounds; can cause temporary damage to nails. Not a skin sensitiser (guinea pigs). **Inhalation** No vapour toxicity, due to very low vapour pressure. Extreme exposure to spray droplets may cause nose bleeding. **NOEL** (1 y) for dogs 0.65 mg/kg b.w. daily; (2 y) for rats 1.7 mg/kg b.w. daily. **ADI/RfD** (Values expressed as paraquat ion): (JMPR) 0.005 mg/kg b.w. [2003, 2004]; (EC) 0.004 mg/kg b.w. [2003]; (EPA) cRfD 0.0045 mg/kg b.w. [1991, 1997].
Toxicity Class WHO (a.i.) II; EPA (formulation) II (oral, a.i.); III (dermal, a.i.)
EC classification T+; R26| T; R24/25, R48/25| Xi; R36/37/38| N; R50, R53

ECOTOXICOLOGY

paraquat dichloride

Birds Acute oral LD_{50} for bobwhite quail 175, mallard ducks 75 mg/kg. LC_{50} (5 d) for bobwhite quail 981, Japanese quail 970, mallard ducks 4048, ring-necked pheasants 1468 mg/kg diet. **Fish** LC_{50} (96 h) for rainbow trout 26, mirror carp 135 mg/l. **Daphnia** EC_{50} (48 h) 6.1 mg/l. **Algae** E_bC_{50} (96 h) for green algae 0.10 mg/l; E_rC_{50} 0.28 mg/l. **Bees** LD_{50} (120 h) (oral) 15 µg/bee; (contact) 70 µg/bee. **Worms** LC_{50} (14 d) >1380 mg/kg soil.

ENVIRONMENTAL FATE

Animals In rats, following oral administration, 76–90% of the dose was excreted in the faeces, and 11–20% in the urine. Paraquat does not bioaccumulate, with >90% of the dose eliminated in 72 hours. **Plants** Photochemical degradation occurs. Degradation products which have been isolated include 1-methyl-4-carboxypyridinium chloride and methylamine hydrochloride.

Soil/Environment Paraquat is rapidly and strongly adsorbed to soil and sediment, resulting in complete deactivation. When desorbed, it is quickly degraded by soil micro-organisms (DT_{50} of unadsorbed paraquat <1 w). The potential risk to leach into groundwater is negligible.

The IESTI for spinach is 310% of the acute RfD for the children. The information provided to the Meeting precludes an estimate that the short-term dietary intake of spinach by children would be below the acute reference dose. The Meeting noted that a conservative acute RfD was established and that a refinement is possible.

For all the other commodities considered, the percentage of the acute RfD varied from 0% to 100%. The Meeting concluded that short-term intake of residues of methoxyfenozide in these commodities, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

4.15 PARAQUAT

TOXICOLOGY

Paraquat is a bipyridilium herbicide that was evaluated by the JMPR in 1970, 1972, 1976, 1985 and 1986, in order to establish an ADI. A toxicological monograph was published after the 1970 JMPR and addenda to the monograph were published after the 1972, 1976 and 1982 Meetings. A toxicological monograph was published after the 1986 JMPR. At the 1970 JMPR, an ADI of 0–0.001 mg/kg bw, as paraquat dichloride, was established. The 1972 JMPR assigned an ADI of 0–0.002 mg/kg bw, while the 1982 JMPR reduced the ADI to 0–0.001 mg/kg bw. The 1986 JMPR established an ADI of 0–0.004 mg/kg bw as paraquat ion (equal to 0–0.006 mg/kg bw as the dichloride).

Paraquat was re-evaluated by the present Meeting within the periodic review programme of the Codex Committee on Pesticide Residues. A considerable amount of data has been generated since 1986 and was submitted for evaluation; these data include studies on the absorption, distribution, metabolism and excretion of paraquat and numerous studies of toxicity (acute, reproductive and developmental). Furthermore, a substantial number of papers in the open literature on, *inter alia*, the genotoxicity and neurotoxicity of paraquat have been reviewed. In all studies relevant to risk assessment, doses and intakes are expressed as paraquat ion.

The pharmacokinetics and metabolism of paraquat have been the subject of many studies. Paraquat is not well-absorbed when administered orally. After oral administration of radiolabelled paraquat to rats, more than half the dose (60–70%) appeared in the faeces and a small proportion (10–20%) in the urine. In studies involving single or repeated doses, excretion of the radiolabel was rapid; about 90% was excreted within 72 h. Residual radioactivity was primarily found in the lungs, liver and kidneys. Some studies have found small amounts in the brain, but only in structures outside the blood–brain barrier or in structures without a blood–brain barrier (the pineal gland and linings of the cerebral ventricles, the anterior portion of the olfactory bulb, hypothalamus and area postrema). Paraquat is taken up into the lungs by an active process, whose normal substrate is endogenous diamines, e.g. putrescine and polyamines such as spermine and spermidine. In rats, dogs and monkeys, there are indications that paraquat is actively secreted in the kidneys.

Paraquat is largely eliminated unchanged; in rats, approximately 90–95% of radiolabelled paraquat in urine was excreted as the parent compound. Some studies have failed to show the presence of any metabolites after oral administration of paraquat, while others have shown a small degree of metabolism probably occurring in the gut as a result of microbial metabolism. Paraquat was not found in the bile.

The acute LD_{50} after oral administration was 290–360 mg/kg bw in mice and 112–350 mg/kg bw in rats, while the guinea-pig was more sensitive (LD_{50} of 22–30 mg/kg bw). The LD_{50} in cynomolgus monkeys was 50–70 mg/kg bw. Paraquat was considered to be a mild skin irritant and a moderate eye irritant and was not a skin sensitizer in the Magnusson and Kligman test.

The predominant feature of exposure to repeated doses of paraquat was lung toxicity. Renal toxicity (proximal tubular damage) and toxicity to the liver (jaundice and elevations of enzyme activity) were also found. In some studies, lens opacities were seen. At higher doses, decreased body-weight gain, clinical signs (dyspnoea, increased respiratory sounds, swellings and sores in the genital area), haematological changes and effects on organ weight were reported, as well as increased mortality.

Lung abnormalities observed in mice, rats and dogs consisted of increased lung weight and gross pathological changes. Associated histopathological changes included cell necrosis, alveolar cell proliferation and hypertrophy, oedema, infiltration of macrophages and mononuclear cells and exudate. Dogs were most sensitive to paraquat-induced lung toxicity, followed by rats and mice; a NOAEL of 0.45 mg paraquat ion/kg bw per day was found in a 1-year study in dogs, on the basis of signs of respiratory dysfunction and histopathological changes at higher doses. This finding was supported by the NOAEL of 0.55 mg paraquat ion/kg bw per day from a 13-week study in dogs.

Ophthalmoscopy in-life and histopathological examination of eyes at necropsy revealed corneal opacity and cataracts in animals receiving doses of 3.75 mg and 7.5 mg paraquat ion/kg bw per day in a lifetime study in Fischer rats. Other ocular effects included lenticular degeneration, lens capsular fibrosis and/or lens ruptures, peripheral retinal degeneration, and proteinaceous vitreous humour. At time-points after 2 years (i.e. after the study would have ended according to current guidelines), rats receiving the lowest dose exhibited age-related peripheral morgagnian corpuscles and slight peripheral and moderate mid-zonal lenticular degeneration. Histopathological evidence of cataracts was also found at the highest dose (7.67 mg paraquat ion/kg bw per day) in a 2-year study in Fischer rats, but not at lower doses. In another 2-year study in Wistar rats, no intergroup differences in the prevalence of cataracts were seen. These differences between effects on the lens in the three long-term studies in rats may be indicative of a difference between Wistar and Fischer rats.

Paraquat elicited renal toxicity, which comprised changes in the proximal tubules of the kidneys (hydropic degeneration, eosinophilia and dilatation) in mice fed with 15.0 mg paraquat ion/kg bw per day in a lifetime study. Some very mild changes were also observed in males at 5.62 mg paraquat ion/kg bw per day, however, there was a clear NOAEL at 1.88 mg paraquat ion/kg bw per day. There were some histopathological effects on renal distal tubular cells at 1.75 mg and 3.52 mg paraquat ion/kg bw per day in a 13-week study in dogs, the NOAEL being 0.55 mg paraquat ion/kg bw per day.

The frequency of pulmonary adenoma was increased in females in a 2-year study in rats receiving a dose of 8.47 mg paraquat ion/kg bw per day; however, there was a clear NOAEL at 3.13 mg paraquat ion/kg bw per day. In males, adenocarcinoma was found in three animals (out of 80) receiving a dose of 10.6 mg paraquat ion/kg bw per day, one animal (out of 80) receiving 3.52 mg paraquat ion/kg bw per day and two animals (out of 80) receiving 1.34 mg paraquat ion/kg bw per day. The NOAEL for males in this study was 0.77 mg paraquat ion/kg bw per day, on the basis of histopathology of the lungs. In a second 2-year study in rats, no intergroup differences in tumour incidence were seen at any site. After review of the histopathological findings in the lifetime study in rats, it was concluded that the incidence of lung neoplasms in the test groups was comparable to that in the control groups. Thus tumours were seen in only one out of three long-term studies in rats. The Meeting concluded that the weight of evidence suggested that paraquat was not carcinogenic in the rat. Paraquat was not considered to be tumorigenic in two studies in mice.

Paraquat has been tested extensively in a broad range of in vitro and in vivo assays for genotoxicity, with mixed results. Studies more commonly gave positive results when DNA damage or clastogenicity were the end-points. Paraquat is known to produce active oxygen species and the available evidence indicates that it is probably this property that is responsible for its genotoxicity. Consequently, there is a threshold below which genotoxic activity will not be evident, provided that normally functioning antioxidant defence mechanisms have not been overwhelmed. The Meeting concluded that paraquat is unlikely to pose a genotoxic risk to humans.

Because of the nature of the genotoxicity observed and the lack of carcinogenicity in rats and

mice, the Meeting concluded that paraquat was unlikely to pose a carcinogenic risk to humans.

Three studies of reproductive toxicity in rats were reported. The overall NOAEL for parental toxicity was 1.67 mg paraquat ion/kg bw per day, and the NOAEL for pup toxicity was 5.0 mg paraquat ion/kg bw per day. Impaired fertility was not seen in these studies. Two studies of developmental toxicity in rats and two in mice were available for evaluation. The lowest NOAELs observed for both maternal and developmental toxicity in rats were 1 mg paraquat ion/kg bw per day, on the basis of clinical signs, and reduced body-weight gain in the dams and reduced mean fetal weights and retarded ossification in the fetuses. Higher NOAELs for maternal and developmental toxicity were seen in mice. Teratogenicity was not seen at any dose in any study in either rats or mice.

Paraquat is structurally similar to the known dopaminergic neurotoxicant 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MPTP). As a result, paraquat has been considered as a possible etiologic factor in Parkinson's disease. However, paraquat is a quaternary nitrogen compound and therefore crosses biological membranes poorly, unlike MPTP, the precursor of the neurotoxicant methylphenylpyridinium ion (MPP^+). Data made available to the Meeting suggested that paraquat was not taken up by the dopamine transporter. Studies on the effects of paraquat on the central nervous system have used a variety of routes, including subcutaneous or intraperitoneal injection and direct injection into the central nervous system, and end-points observed have been behavioural, morphological and neurochemical. Behavioural effects and loss of neurones in the substantia nigra were observed and, neurochemically, depletion of dopamine was reported in many, but not all of these studies. However, the design of these studies renders the relevance of these data questionable for the risk assessment of dietary exposure to paraquat residues.

Persistent hypoactivity was observed in mice given paraquat by mouth on post-natal days 10 and 11. Reduced striatal content of dopamine and its metabolites was seen, but concentrations of serotonin were not affected. In a similar study of which the Meeting was aware, these findings had not been reproduced.

The Meeting concluded that the available mechanistic and other animal studies did not support the hypothesis that paraquat residues in food are a risk factor for Parkinson's disease in humans.

Two studies carried out to assess the potential involvement of combined exposure to the herbicide paraquat and the manganese-containing ethylene*bis*dithiocarbamate fungicide maneb in the etiology of idiopathic Parkinson's disease were evaluated by the Meeting. Paraquat or maneb, or a combination of the two, was given intraperitoneally to mice. The study was not designed appropriately to investigate potentiation and the results could have reflected dose-additivity.

Intentional and accidental poisoning with paraquat has been a major cause of death in many countries. Most incidents are caused by ingestion of the concentrate intended for agricultural use. Local effects include damage to the skin, nails, mouth, eyes and nose. Sore throat, dysphagia and epigastric pain may occur. Systemic effects, which produce the fatal outcome seen in those who have ingested a sufficient quantity of paraquat, mainly involve the respiratory system. The changes in the lungs that underly the symptoms and clinical signs comprise a proliferative alveolitis similar to that seen in most experimental animals treated with paraquat. In most, but not all, patients who develop the characteristic lung changes, the condition progresses inevitably towards a fatal outcome, death being due to respiratory failure. Numerous therapies have been tested but none has been consistently successful.

A number of epidemiological (case–control) studies have been carried out in humans with Parkinson's disease. In some of these, associations with exposure to chemicals including pesticides (in some cases specifically paraquat) were sought. Some but not all studies have shown a relationship between working in situations which might involve contact with or use of pesticides and Parkinson's disease, but associations with exposure to specific pesticides have not been shown consistently.

The Meeting established an ADI of 0–0.005 mg paraquat ion/kg bw on the basis of a NOAEL

of 0.45 mg paraquat ion/kg bw per day in the 1-year study in dogs and using a safety factor of 100. Although a 1-year study in dogs is not considered to be a long-term study, the nature and time-course of the pathogenesis of the lung lesions were such that the application of an additional safety factor was not considered necessary.

The Meeting established an acute RfD of 0.006 mg paraquat ion/kg bw based on the NOAEL of 0.55 mg paraquat ion/kg bw per day in the 13-week study in dogs, with a safety factor of 100. Histopathological changes in the lungs were present at higher doses in both studies in dogs.

A toxicological monograph was prepared.

Toxicological evaluation

Levels relevant to risk assessment

Species	Study	Effect	NOAEL[a]	LOAEL[a]
Mouse	13-week study	Toxicity	100 ppm, equal to 8.33 mg ion/kg bw per day	300 ppm, equal to 25.9 mg ion/kg bw per day
	97–99-week study	Toxicity	12.5 ppm, equivalent to 1.88 mg ion/kg bw per day	37.5 ppm, equivalent to 5.62 mg ion/kg bw per day
		Carcinogenicity	100 ppm equivalent to 15.0 mg ion/kg bw per day[b]	—
	Study of developmental toxicity	Maternal toxicity	10 mg/kg bw per day[b]	—
		Embryo- and fetotoxicity	10 mg/kg bw per day[b]	—
Rat	13-week study	Toxicity	100 ppm, equal to 4.74 mg/kg bw per day	300 ppm, equal to 14.2 mg/kg bw per day
	104-week study	Toxicity	30 ppm, equal to 0.77 mg/kg bw per day	100 ppm, equal to 2.55 mg/kg bw per day
		Carcinogenicity	300 ppm, equal to 7.67 mg ion/kg bw per day[b]	—
	Multigeneration study of reproductive toxicity	Parental toxicity	25 ppm, equivalent to 1.67 mg/kg bw per day	75 ppm, equivalent to 5.0 mg/kg bw per day
		Pup toxicity	75 ppm, equivalent to 5.0 mg/kg bw per day	150 ppm, equivalent to 10.0 mg/kg bw per day
	Study of developmental toxicity	Maternal toxicity	1 mg/kg bw per day	5 mg/kg bw per day
		Embryo- and fetotoxicity	1 mg/kg bw per day	5 mg/kg bw per day
Dog	13-week study	Toxicity	20 ppm, equal to 0.55 mg/kg bw per day	60 ppm, equal to 1.75 mg/kg bw per day
	1-year	Toxicity	15 ppm, equal to 0.45 mg/kg bw per day	30 ppm, equal to 0.93 mg/kg bw per day

[a] Dietary concentrations are expressed as dichloride or ion as in the study report; intakes and doses are expressed as paraquat ion

[b] Highest dose tested

Estimate of acceptable daily intake for humans

0–0.005 mg paraquat ion/kg bw

Estimate of acute reference dose

0.006 mg paraquat ion/kg bw

Studies that would provide information useful for continued evaluation of the compound

Further observations in humans

Summary of critical end-points for paraquat

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Poor
Dermal absorption	Poor; 0.25–0.29% absorbed (humans)
Distribution	Highest concentrations found in the lungs, liver and kidneys
Potential for accumulation	No potential for passive accumulation; active uptake into type II pneumocytes
Rate and extent of excretion	Rapid, about 64% in 24 h; 10% in urine, the remainder in the faeces; none is found in bile
Metabolism	Some metabolism (< 5%) in gut (probably microbial); paraquat is largely excreted unchanged
Toxicologically significant compounds	Parent compound
(animals, plants and environment)	
Acute toxicity	
Rat, LD_{50}, oral	100–300 mg paraquat ion/kg bw
Rat, LD_{50}, dermal	80–> 660 mg paraquat ion/kg bw
Rat, LC_{50}, inhalation	0.0006–0.0014 mg paraquat ion/l (4-h exposure)
Rabbit, skin irritation	Mild
Rabbit, eye irritation	Moderate
Skin sensitization	Not sensitizing (Magnusson and Kligman test)
Short term toxicity	
Target organ/critical effect	Lung toxicity
Lowest relevant oral NOAEL	0.55 mg paraquat ion/kg bw per day (13-week study in dogs); 0.45 mg paraquat ion/kg bw per day (1-year study in dogs)
Lowest relevant dermal NOAEL	1.15 mg paraquat ion/kg bw per day (21-day study in rabbits)

	rabbits)
Lowest relevant inhalation NOAEC	0.00001 mg/l (21-day study in rats)
Genotoxicity	Paraquat was clastogenic at high concentrations Unlikely to pose a genotoxic risk to humans at dietary concentrations
Long term studies of toxicity and carcinogenicity	
Target organ/critical effect	Lung toxicity
Lowest relevant NOAEL	0.77 mg paraquat ion/kg bw per day (2-year study in rats)
Carcinogenicity	Not carcinogenic; unlikely to pose a carcinogenic risk to humans
Reproductive toxicity	
Reproduction target/critical effect	Lung toxicity in pups
Lowest relevant reproductive NOAEL	5 mg paraquat ion/kg bw per day (three- generation study in rats)
Developmental target/critical effect	Not teratogenic; reduced fetus weight and ossification at maternally toxic dose
Lowest relevant developmental NOAEL	1 mg paraquat ion/kg bw per day (rats)
Neurotoxicity/delayed neurotoxicity	
	Not neurotoxic by oral route
Other toxicological studies	Mechanistic studies on lung, liver and kidney toxicity
Medical data	Causes acute poisoning

Summary	**Value**	**Study**	**Safety factor**
ADI	0–0.005 mg/kg bw	Dog, 1-year study	100
Acute RfD	0.006 mg/kg bw	Dog, 13-week study	100

Pesticide residues in food – 2004

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estimated a highest residue level of 0 mg/kg for cattle fat, eggs, meat of cattle, pigs and sheep, pig fat, poultry fats, poultry meat and sheep fat.

Further work or information

Desirable

Data on the stability of stored analytical samples of raw agricultural commodities containing quantifiable residues of oxydemeton methyl are highly desirable, as the information provided was not representative of the various crop groups, did not cover extended storage and suggested variable storage stability.

DIETARY RISK ASSESSMENT

Long-term intake

STMR or STMR-P values were estimated by the 1998 JMPR and by the present Meeting for 27 commodities. When data on consumption were available, these values were used in the estimates of dietary intake.

The dietary intake from the five GEMS/Food regional diets, on the basis of the STMR values, represented 3–30% of ADI (Annex 3). The Meeting concluded that the intake of residues of oxydemeton methyl resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The IESTI for oxydemeton methyl was calculated for the commodities for which maximum residue levels, STMR values and highest residue levels were established and for which data on consumption (of large portions and unit weight) were available. The results are shown in Annex 4.

The ARfD for oxydemeton methyl is 0.002 mg/kg bw. The IESTI represented 0–220% of the ARfD for children and 0–90% of that for the general population. For children, 100% of the ARfD was exceeded in apple (130%), cabbage (120%), grape (220%) and orange (120%).

The Meeting concluded that the short-term intake of residues of oxydemeton methyl from uses on commodities other than apples, cabbages, grapes and oranges that have been considered by the JMPR is unlikely to present a public health concern.

4.19 PARAQUAT (057)

RESIDUE AND ANALYTICAL ASPECTS

Paraquat, a non-selective contact herbicide, was first evaluated by the JMPR for toxicology and residues in 1970. Subsequently, it was reviewed for toxicology in 1972, 1976, 1982, 1985 and 1986 and for residues in 1972, 1976, 1978 and 1981. The Meeting reviewed paraquat toxicologically within the periodic review programme in 2003 and established an ADI of 0–0.005 mg/kg bw and an ARfD of 0.006 mg/kg bw as

paraquat cation. Currently, there are 22 Codex MRLs for plant commodities, their derived products and animal commodities.

The CCPR at its Thirty-second Session identified paraquat as a priority for periodic review by the 2002 JMPR, but residue evaluation was postponed to the present Meeting.

Paraquat is usually available in the form of paraquat dichloride or paraquat bis(methylsulfate). The Meeting received data on metabolism, environmental fate, analytical methods, storage stability, supervised field trials, processing and use patterns.

Metabolism

Animals

The WHO Expert Group of the 2003 JMPR reviewed studies on the the excretion balance of paraquat in *rats* given a single dose of 1 or 50 mg/kg bw [1,1´-^{14}C-dimethyl]paraquat dichloride or 14 daily doses of 1 mg/kg bw unlabelled paraquat dichloride followed by 1 mg/kg bw of the labelled compound. They also evaluated studies of the biotransformation of paraquat in rats given the same doses of radiolabelled paraquat and other studies of metabolism and toxicity in rats. They concluded that orally administered paraquat is not well absorbed. Excretion was rapid, with 60–70% in faeces and 10–20% in urine; 90% was excreted within 72 h. Paraquat was eliminated largely unchanged: 90–95% of radiolabelled paraquat in urine was identified as the parent compound.

When 23 mg/kg [1,1´-^{14}C-dimethyl]paraquat dichloride were administered through a rumen fistula to one *sheep*, all the administered radiolabel was excreted within 10 days in urine (4%) and faeces (96%), indicating that residues of orally administered paraquat would not remain or accumulate in sheep tissues. Most of the radiolabel in urine and faeces was attributed to unchanged paraquat and 2–3% to paraquat monopyridone. Less than 1% 4-carboxy-1-methylpyridinium ion, paraquat dipyridone and monoquat were found.

When 0.92 mg/kg [1,1´-^{14}C-dimethyl]paraquat dichloride was administered subcutaneously to a sheep, paraquat was again excreted rapidly. Over 80% of the administered radioactivity was excreted in urine, 69% 1 day after treatment. Unchanged paraquat accounted for most of the radiolabel. The monopyridone was present at 2–3% and monoquat as a trace metabolite. The excretion patterns in the two sheep were virtually identical, regardless of the route of administration.

A *pig* weighing about 40 kg was fed twice daily with a diet containing [1,1´-^{14}C-dimethyl]paraquat ion at a rate equivalent to 50 mg/kg for 7 days. At sacrifice, 69% of the administered radiolabel had been excreted in faeces and 3.4% in urine; 13% was present in the stomach contents and viscera. All the radiolabel found in tissues, except in liver, was attributed to paraquat. About 70% of the radiolabel in the liver was identified as paraquat, with 7% as monoquat ion and about 0.6% as monopyridone ion. This result indicates that there is no significant metabolism of paraquat in pigs.

In a similar study, a pig was fed a diet containing [2,2´,6,6´-^{14}C]paraquat ion at a rate equivalent to 50 mg/kg for 7 days. At sacrifice, 72.5% of the administered radiolabel had been excreted in faeces and 2.8% in urine. In the liver, about 70% of the radiolabel was identified as paraquat and 4% as monoquat ion.

A Fresian *cow* weighing 475 kg given a single dose of about 8 mg/kg [1,1´-^{14}C-dimethyl]paraquat dichloride from a balling gun excreted 95.6% of the administered radioactivity in faeces within 9 days; 89% was excreted within the first 3 days. Analysis indicated that 97–99% of the radioactivity in 1–4-day faeces and 100% of that in 5–6-day faeces co-chromatographed with paraquat. A total of 0.7% of the administered dose was excreted in urine, 80% of which was excreted within the first 2 days. Paraquat accounted for 90% of the radiolabel in urine on day 1, 70% on day 3 and 62% on day 5. The remaining activity was attributed to paraquat monopyridone and monoquat. Only 0.0032% of the administered radiolabel was recovered from milk within 9 days. The traces of radioactivity in milk (a maximum of 0.005 mg/l as paraquat ion equivalent

milk taken in the morning of day 2) were attributed mainly to paraquat and its monopyridone and to a naturally occurring compound which appeared to be lactose. The residue level of any one compound in milk was ≤ 0.002 mg/kg.

When a lactating *goat* was dosed with [2,2´,6,6´-^{14}C]paraquat dichloride twice daily at each milking for 7 days at a total daily rate equivalent to approximately 100 mg/kg in the diet, 50.3% of the administered radioactivity was excreted in faeces, 2.4% in urine and 33.2% in stomach contents by the time of sacrifice. The total radioactivity, expressed in paraquat ion equivalents, in milk increased during the experimental period, reaching a maximum of 0.0092 mg/kg (equivalent to 0.003% of the daily dose) 4 h before slaughter. Of this radioactivity, 75.7% was attributed to paraquat, and 15.8% did not show a cationic character. There appeared to be no significant metabolism of paraquat in any tissue, except liver and peritoneal fat, where about half the radiolabel was attributed to paraquat, < 5% as monopyridone ion and 5% as monoquat ion.

Warren laying *hens* given [2,2´,6,6´-^{14}C]paraquat ion in gelatin capsules at a rate equivalent to 30 mg/kg normal diet for 10 days had excreted 99% of the administered radiolabel in faeces at the time of sacrifice; 96.6% of the radiolabel was attributed to unchanged paraquat. The amount of radiolabel in egg albumen did not exceed 0.0014 mg/kg in paraquat ion equivalents throughout the experimental period, while that in the yolk was < 0.001 mg/kg on day 1 and increased gradually to 0.18 mg/kg (in one bird) on day 8. All the radiolabel in yolk was identified as paraquat.

The studies on the fate of orally administered paraquat show that most is excreted unchanged, mainly in faeces and to a much smaller extent in urine. Excretion of paraquat was rapid in all the species studied, hens showing the most efficient excretion. Little paraquat was absorbed from the gastrointestinal tract, and the small amount absorbed was not significantly metabolized. Less than 0.05 mg/kg of paraquat was found in muscle, milk and eggs, even at the high dose rates used in these studies. These findings indicate that no significant bioaccumulation of paraquat is expected to occur in these species.

The metabolism of paraquat in these species was similar. Four metabolites were identified: monoquat, paraquat monopyridone, 4-carboxy-1-methylpyridinium ion and paraquat dipyridone. In all tissues except liver of all the species tested and in goat peritoneal fat, 80–100% of the total radiolabel was attributable to the parent compound, paraquat. In liver and goat peritoneal fat, 50–80% of the radiolabel was associated with paraquat, and absorbed paraquat was metabolized to monoquat and paraquat monopyridone and to a much smaller extent to 4-carboxy-1-methylpyridinium ion. The metabolism of paraquat involves oxygenation of one pyridine ring to form paraquat monopyridone and desmethylation of one pyridine ring to form monoquat. Cleavage of the pyridine–pyridine linkage produces 4-carboxy-1-methylpyridinium ion. The other *N*-methylpyridine moiety would produce carbon dioxide and methylamine.

Plants

When paraquat is used as a directed spray before sowing, before planting, before emergence and after emergence, it is present in soil as residues, but no direct contact occurs with crops. Sandy loam soil in pots in which *lettuce* and *carrots* were sown was sprayed with [U-^{14}C-bipyridyl]paraquat ion immediately after sowing at rates equivalent to 14.3 kg ai/ha for lettuce and 14.7 kg ai/ha for carrots, which are 13 times the highest current application rates for those crops, and maintained in a greenhouse. The radiolabel in mature lettuce and carrots harvested 65 and 96 days after treatment represented 0.0034 and 0.0048 mg/kg in paraquat ion equivalents, respectively. This result confirms the lack of significant translocation of residues of paraquat from treated soil to lettuce leaves or carrot roots.

Paraquat is also used as a crop desiccant and harvest aid, when it is in direct contact with crops. The foliage of *potatoes* and *soya beans* growing in pots in a greenhouse was treated with ^{14}C-paraquat at rates equivalent to 8.7 or 8.8 kg ai/ha (potato) and 8.2 kg ai/ha (soya beans), 14–16 times the highest current use for desiccation on potato and soya beans. The average TRR, expressed in paraquat ion equivalents, in soya and potato plants harvested 4 days after treatment were 638 mg/kg in soya foliage, 0.747 mg/kg in soya beans and 0.082 mg/kg in potato tuber. In all the samples, 89–94% of the TRR was identified as paraquat. The rest of the radioactive residue consisted of two or three fractions, none of which exceeded 10% of the respective

TRR. In soya foliage extracts, small amounts of 4-carboxy-1-methylpyridinium ion (0.3% TRR) and monoquat (0.3 % TRR) were found. The latter is a known photodegradation product of paraquat.

As paraquat is strongly adsorbed by soil (see above), its uptake by plants after pre-emergence or post-emergence directed use is insignificant, even at exaggerated application rates. When paraquat was applied as a desiccant to potato and soya bean at a rate > 10 times the highest recommended application rate, with a 4-day PHI, the main component in potato tuber, soya beans and soya foliage was paraquat. In soya foliage, monoquat and 4-carboxy-1-methylpyridinium ion were also found. Although the latter is a known photodegradation product and was not found in soya beans or potato tuber, biotransformation cannot be excluded because the TRR was too low for reliable identification. As the fate of paraquat in soya foliage appears to involve photodegradation, its fate is considered to be common among plants.

The metabolism of paraquat involves desmethylation of one pyridine ring to form monoquat. 4-Carboxy-1-methylpyridinium ion appears to be produced by photolysis of monoquat, with breakdown of the pyridine–pyridine linkage, but involvement of biotransformation cannot be excluded. Paraquat monopyridone and dipyridone, which are found in animals, were not found in plants even at much higher than normal application rates. The transformation of paraquat in plants is similar to its metabolism in animals.

Environmental fate

Soil

Paraquat was applied to slurries of loam, loamy sand, silty clay loam or coarse sand in 0.01 mol/l aqueous calcium chloride at rates higher than normal, to give 0.01 mg/l in the equilibrium solution after a 16-h equilibration. The calculated adsorption coefficients ranged from 480 in the coarse sand to 50 000 in the loam. At normal application rates, the concentration of paraquat in the equilibrium solution could not be determined (< 0.0075 mg/l). No significant desorption was observed.

A field survey of 242 agricultural soils in Denmark, Germany, Greece, Italy, The Netherlands and the United Kingdom showed that paraquat was strongly adsorbed to all the soil types studied. The adsorption coefficients calculated at application rates much higher than normal ranged from 980 to 400 000, and those adjusted for the organic carbon content of soil were 8400–40 000 000. Adsorption coefficients could not be calculated at normal application rates because the concentration in equilibrium solution was below the limit of determination (0.01 mg/l). On the McCall scale, paraquat was classified as ‘immobile’ in all these soils, without leaching.

[2,6-^{14}C]Paraquat was applied to sandy loam soil in pots at a nominal rate of 1.05 kg/ha and incubated in the dark at 20 ± 2 °C under aerobic conditions in order to study the aerobic degradation of paraquat. After 180 days of incubation, paraquat accounted for > 93% of the applied radiocarbon, with no detected degradation products. Less than 0.1% of the applied radioactivity evolved as $^{14}CO_2$ over the 180-day incubation period. The half-life of paraquat in soil under aerobic conditions could not be estimated, although a long half-life in soil was implied by the results of the study.

In long-term field dissipation studies conducted on cropped plots in Australia, Malaysia, The Netherlands, Thailand, the United Kingdom and the USA, the location had no major effect on the field dissipation rate. Generally, paraquat residue levels had declined to about 50% 10–20 years after the start of the studies. This implies a DT_{50} of 10–20 years after application of single, large doses of paraquat to soil. The DT_{90} could not be estimated in these studies, however, as the experimental periods were too short.

Conventional laboratory studies could not provide useful information on the route or rate of degradation of paraquat in soil because of its strong adsorption to soil minerals and organic matter. In order to obtain information, microbiological degradation studies were conducted with microorganisms isolated from soil. The most effective soil organism for decomposing paraquat was a yeast species, *Lipomyces starkeyi*. When incubated with radiolabelled paraquat, the yeast culture or cultures originating from two sandy loam soils decomposed most of the paraquat, released CO_2 and formed oxalic acid at 24–25 °C.

An unidentified bacterium isolated from soil metabolized [1,1´-^{14}C]paraquat to monoquat and 4-carboxy-1-methylpyridinium ion. Extracts of *Achromobacter* D were found to produce CO_2, methylamine, succinate and formate as metabolites of 4-carboxy-1-methylpyridinium ion. The results showed that the CO_2 originated from a carboxyl group, methylamine from the *N*-methyl group and the carbon skeletons of formate and succinate from the C-2 and C-3–C-6 atoms of the pyridine ring, respectively. These results indicate that the pyridine ring is split between C-2 and C-3.

The degradation rate of paraquat in soil was determined by cultivating 10 mg/kg [U-^{14}C-dipyridyl]paraquat with *Lipomyces* and mixed cultures derived from two soils. The degradation of paraquat was rapid, with a DT_{50} between 0.02 and 1.3 days after a lag phase of about 2 days, accompanied by rapid mineralization to CO_2 and the formation of several unidentified minor polar metabolites.

The photolysis of [2,2´,6,6´-^{14}C]-paraquat was studied by applying it to the surface of a highly sandy soil which was exposed to natural sunlight. The proportion of paraquat in samples declined during 85 weeks, at which time paraquat represented 86.6–89.5% of the total radiolabel found in unmixed and mixed soil samples. Thin-layer chromatographic analysis of the 6 mol/l HCl extracts of mixed and unmixed soils contained monoquat ion, paraquat monopyridone ion and an uncharacterized compound, which accounted for 1.4–2.4%, 1.2–1.3% and 1.8–2.4%, respectively, of the total radioactivity after 85 weeks. Photodegradation on the soil surface is not considered to be a major environmental degradation process for paraquat.

Water–sediment systems

Aqueous photolysis of paraquat was examined by maintaining ring-labelled paraquat in sterilized 0.01 mol/l phosphate buffer solution (28 mg/l) at 25 °C under light. After 36 days of irradiation simulating summer sunlight in Florida (USA), most of the recovered radioactivity was attributed to paraquat, with 0.13% as CO_2 and no photodegradation products. When solutions of radiolabelled paraquat were exposed to unfiltered ultraviolet light, no paraquat remained after 3 days, with formation of CO_2, methylamine and 4-carboxy-1-methylpyridinium ion; the last metabolite further degraded to CO_2 and methylamine. These results indicate that, while paraquat appears to be stable to photolysis at pH 7, it readily degrades into CO_2 and methylamine when exposed to unfiltered ultraviolet light.

[U-^{14}C-dipyridyl]Paraquat in deionized water was applied to the water surface of two continuously aerated sediment–water systems at a rate equivalent to 1.1 kg ai/ha. Paraquat was strongly adsorbed to the sediment in both systems, even immediately after treatment. After 100 days of incubation, 0.1–0.2% of the applied radioactivity was found in the aqueous phase, 92.9–94.9% in extracts from sediment fractions and 4.2–4.5% in unextracted sediment fractions. Most of the radiolabel recovered from the aqueous phase and sediment extract was attributed to paraquat, while no degradation products were detected. The DT_{50} or the DT_{90} could not be estimated as no significant degradation of paraquat was observed during the experimental period.

Residues in succeeding crops

Seeds of wheat, lettuce and carrot were sown into individual pots containing a sandy loam soil 0, 30, 120 and 360 days after treatment of the soil with [2,2´,6,6´-^{14}C]paraquat at an application rate equivalent to 1.05 kg ai/ha, and were maintained in a glasshouse until maturity. Over the course of the study, the TRR in soil represented an average of 99.2% of the applied radioactivity. ^{14}C-Paraquat accounted for 72.7–99.3% of the TRR in soil extracts and no other radioactive compounds were detected in any soil sample. Radioactive residues, expressed in paraquat ion equivalents per kilogram, were below the LOQ in most crop samples sown 0, 30 and 120 days after treatment. The highest radioactive residue level, 0.009 mg/kg in paraquat ion equivalents, was found in wheat straw sown 30 days after treatment.

Seeds of lettuce and carrot were sown in pots containing sandy loam soil, and the soil was treated immediately afterwards with [U-^{14}C-dipyridyl]paraquat at exaggerated rates of 14.3 and 14.7 kg/ha respectively, corresponding to approximately 13 times the highest current application rate. The lettuce was harvested 65 days after treatment and the carrots 96 days after treatment. The levels of radioactive residues in

lettuce leaf and carrot root at harvest were 0.0034 and 0.0048 mg/kg in paraquat ion equivalents, respectively. There is therefore no significant uptake of paraquat into rotational crops, even when the soil is treated at exaggerated rates.

Methods of analysis

With the long history of registration of paraquat in many countries, many analytical methods have been developed and used for measuring residues in plant and animal commodities. All the methods provided to the Meeting were for analysis of paraquat only. Some analytical methods allow separate determination of paraquat and diquat in a sample.

Samples of plant origin

Six analytical methods for the determination of paraquat in plant commodities and oil and oil cake were submitted.

Three of the methods involve extraction of paraquat by refluxing homogenized or comminuted samples in 0.5 mol/l sulfuric acid for 5 h; filtration, cation-exchange chromatography from which paraquat is eluted with saturated ammonium chloride, conversion of paraquat to its coloured free radical with 0.2% (w/v) sodium dithionite in 0.3 mol/l NaOH and spectrophotometric measurement. The methods differ only in the spectrophotometric measures used: absorption of the free radical in the range 360–430 nm measured against a control solution or absorption in the range of 380–430 nm measured in second derivative mode against a paraquat standard.

In the most recent method, the eluate from cation-exchange chromatography is further cleaned up on a C18 SepPak solid phase extraction cartridge, and the second 5-ml eluate is analysed by reverse-phase ion-pair HPLC with ultraviolet detection at 258 nm.

Two other methods developed for the determination of paraquat in liquid samples, such as oil, also involve second derivative spectrophotometry (360–430 nm), but they do not involve extraction with sulfuric acid. Reverse-phase ion-pair HPLC is also used as the confirmatory method.

All these methods were validated in one or several laboratories for vegetables and fruits, cereal grains and seed, grass and straw, sugar-cane juice, oil seeds, oil and oil cake. The LOQ of these methods ranged from 0.01 to 0.05 mg/kg, except for oil cake, for which the LOQ was 0.5 mg/kg. The mean procedural recoveries were 61–107% at fortification rates reflecting both the LOQ and the actual levels of incurred residues. In general, lower recoveries were made from oil and oil cake. The mean recovery from rape-seed oil cake and olive oil was 67% and that from coffee beans was 61%; those from other commodities were > 70%. The relative standard deviation of recoveries ranged from 2% to 19%.

Samples of animal origin

Three analytical methods for the determination of paraquat in animal products were submitted.

Two methods, including the most recent, for determining paraquat in milk, eggs and animal tissues involve extraction of paraquat by homogenizing samples in 10% trichloroacetic acid, centrifugation, dilution with water, application to a cation-exchange column, sequential washing, elution of paraquat with saturated ammonium chloride, determination by reverse-phase ion-pair HPLC with ultraviolet detection at 258 nm. Fat in milk, skin with subcutaneous fat and fat samples must be removed by hexane extraction before cation exchange.

A method for analysing liquid samples, including milk, does not involve acid extraction or defatting, and milk is mixed directly with cation exchange resin before packing. Otherwise, this method is the same as those described above.

The LOQs were reported to be 0.005 mg/kg for milk, eggs and bovine, ovine and chicken tissues. The mean procedural recoveries were 75–105%, with a relative standard deviation of 2–13%.

The currently used methods for plant and animal samples were found to be suitable for quantification of paraquat in plant and animal commodities for enforcement purposes. The methods are fully validated and include confirmatory techniques. The earlier methods for quantification of paraquat in plant and animal samples were also found to be suitable in validation; however, a mean recovery < 70% was seen for rape-seed cake, olive oil and coffee beans analysed by one of the methods.

Stability of residues in stored analytical samples

Investigations were reported of the stability of residues in ground samples of prunes, banana, cabbage, potato, carrot, tomato, maize (grain, forage, fodder and silage), wheat grain, coffee beans, birdsfoot trefoil (forage and hay), meat, milk and eggs stored in a deep freezer at a temperature < –15 °C for 1–4 years.

No decrease in residue levels of paraquat, whether fortified or incurred, was observed in any of the crop matrices during the test period, the longest being 46 months. The exception was a slight decrease in birdsfoot trefoil forage that had been treated at a rate equivalent to 0.54 kg ai/ha and contained incurred residues at 57 mg/kg.

No decrease in the levels of residues of paraquat in animal commodity matrices over time was observed under storage for up to 28 months. The test matrices represented a diverse selection of animal tissues, and the studies demonstrate the stability of paraquat under various storage conditions.

Definition of the residue

Paraquat is usually available as the dichloride salt or the bis(methylsulfate) salt but is determined as paraquat ion in analysis. Paraquat is known to adsorb strongly to soil, and most of the small amount incorporated into plant remains as paraquat (90%). Its metabolites were not found when paraquat was applied at normal rates. When it was applied post-emergence, most of the applied compound remained, with minimal amounts of photodegradation products, indicating the involvement of photolysis in the transformation of paraquat. The residue of concern in plants is paraquat ion.

In studies of metabolism in rats, cattle, goats, pigs and hens, the metabolic pathway was similar, producing minor levels of oxidized metabolites. The metabolic pathways in animals and plants are similar. In animals, the residue of concern is also paraquat ion.

The definition of the residue in all countries that provided national MRLs to the Meeting was paraquat ion.

All the identified metabolites have been covered by toxicological evaluations, owing either to their occurrence in rats or in independent studies. The ADI recommended by the JMPR is for paraquat cation.

The Meeting therefore agreed that the definition of residues for plant and animal commodities should be: Paraquat cation (for both compliance with MRLs and estimation of dietary intake).

Results of supervised trials on crops

When used for weed control, paraquat is not sprayed directly onto crops and is strongly adsorbed to soil. Therefore, little paraquat is expected to be found in harvested crops. After pre-emergence application, no residues were expected to be detected in the harvested crops, although some samples contained residues. After use as a harvest aid desiccant, however, paraquat is in direct contact with crops, and the residue levels tend to be much higher than when it is used for weed control.

The Meeting agreed that data from trials of pre-plant and pre-emergence application should be evaluated against any GAP available to the Meeting, regardless of the country or region; while data on trials of post-emergence application and harvest aid desiccation should be evaluated against GAP of the country in which the trials were conducted or of a neighbouring country.

As degradation of paraquat on the surface of crops appears to involve photolysis, residue levels are expected to be similar in all crops, justifying estimation of group MRLs for paraquat.

For estimating STMR from the results of two or more sets of trials with different LOQs in which no residues exceeding the LOQs are reported, the lowest LOQ should be used, as stated in the 2002 *FAO Manual*, unless the residue level can be assumed to be essentially zero. The size of the trial database supporting the lowest LOQ was taken into account in making decisions in these cases.

Since maximum residue levels were estimated for a number of vegetable groups in which the levels were below the LOQ, the Meeting decided to withdraw the previous recommendation for vegetables (except as otherwise listed) of 0.05 * mg/kg.

In Germany, information is required on the possible contamination of fruits that have fallen onto ground treated with pesticides. Therefore, tests were carried out on apples, stone fruits, grapes and olives to simulate the residue situation in fruit used for juice and other processed products. Nevertheless, direct consumption of fruit picked up from the ground is regarded as inappropriate.

Citrus fruit

Numerous supervised residue trials have been carried out over several seasons and in several locations on orange in Italy and in California and Florida, USA, and on lime, lemon and grapefruit in Florida.

Paraquat is registered for the control of weeds around the base of citrus fruit trees at a maximum rate of 1 kg ai/ha as an inter-row spray, with no PHI, in Italy and at a maximum rate of 1.14 kg ai/ha as a directed spray, with no PHI, in the USA. The residue levels of paraquat in whole mature *oranges* in trials in Italy and the USA were below the LOQs of 0.01, 0.02 or 0.05 mg/kg, even when paraquat was applied at twice or 30 times the maximum application rate, except in two trials. In one trial with an application rate of 2.44 kg ai/ha, mature fruit from one plot contained paraquat residues at a level of 0.01 mg/kg. In a trial with an application rate of 1.12 kg ai/ha, residue levels of 0.06 and 0.08 mg/kg were found in whole fruit. In this trial, however, the lower fruit-bearing branches were deliberately sprayed, the fruit fell onto sprayed weeds, and they were picked up from the ground within 3 days of spraying for analysis. Even though this represents the worst-case scenario, it does not reflect GAP in any country and is therefore inappropriate for use in estimating a maximum residue level. The residue levels in whole mature oranges in valid trials were, in ranked order: < 0.01 (15), 0.01, < 0.02 (two) and < 0.05 mg/kg (one).

In one trial in the USA, both juice and pulp were analysed for paraquat residues. Although the levels were below the LOQ of 0.01 mg/kg, the procedural recovery was too low for the results to be regarded as reliable.

In trials in the USA on *grapefruit*, *lemon* and *lime* in 1970 and 1972, with application rates reflecting GAP in the USA, the paraquat residue levels were < 0.01 (one) and < 0.05 mg/kg (three).

As the residue situation in oranges and other citrus fruits is similar and GAP is recommended for citrus fruits as a group in Italy and the USA, the Meeting considered it appropriate to establish a group maximum residue level for citrus fruits. The combined residue levels, in ranked order, were: < 0.01 (16), 0.01, < 0.02 (two) and < 0.05 (four) mg/kg. The Meeting estimated a maximum residue level of 0.02 mg/kg, an STMR of 0.01 mg/kg and a highest residue level of 0.02 mg/kg for paraquat in citrus fruits. The value of 0.02 mg/kg covers only the finite residue level found at 0.01 mg/kg.

Pome fruit

Trials were carried out on apples in Canada, Germany and the United Kingdom and on pears in Canada and Germany.

Paraquat is registered for use to control weeds around the base of pome fruit trees at a maximum rate of 0.66 kg ai/ha with one application and no PHI in the United Kingdom and at a maximum rate of 1.14 kg ai/ha with no PHI in the USA. No information on GAP was available for Canada or Germany, but the results

of trials conducted in those countries were reviewed against the GAP of the USA and United Kingdom, respectively.

Trials on *apple* were conducted at rates of 1.12–4.48 kg ai/ha, and in one trial in the United Kingdom at a highly exaggerated rate of 12.3 kg ai/ha, about 20 times the maximum rate permitted in that country. In the latter trial, paraquat was applied directly to the bark of the trees to simulate worst-case conditions. In some cases, two applications were made, in the same or subsequent years. Apples were harvested 0–780 days after the last application. In trials on *pear*, paraquat was applied at rates of 1.0–4.48 kg ai/ha once or twice, and pears were harvested 0–77 days after the last application. Paraquat residue levels were below the LOQ of 0.01 mg/kg in all apples and pears taken from trees, even after treatment at rates as high as 20 times the maximum GAP rate.

In the trials in Germany, apples and pears taken from the trees were placed on the ground 6–7 days after application and collected about 7 days later for analysis. Residue levels of paraquat of 0.02–0.19 mg/kg were found in the apples, which could be attributed to the transfer of paraquat from the sprayed weed. The Meeting concluded that these data are not appropriate for use in estimating a maximum residue level.

As the residue situations in apples and pears are similar, and GAP is recommended for pome fruits or orchard fruits as a whole in all the countries that provided information on GAP, the Meeting considered it appropriate to establish a group maximum residue level for pome fruits. As the paraquat residue levels in all the valid trials were below the LOQ, even after application at exaggerated rates, the Meeting estimated a maximum residue level for pome fruits of 0.01* mg/kg, an STMR of 0 mg/kg and a highest residue level of 0 mg/kg.

Stone fruit

Trials were carried out on peaches, plums, apricots and cherries in Canada, Germany, the United Kingdom and the USA.

Paraquat is registered for use to control weeds around the base of stone fruit trees at a maximum rate of 0.66 kg ai/ha, with one application and no PHI for stone fruits in the United Kingdom and at a maximum rate of 1.14 kg ai/ha, with three applications and a 28-day PHI for stone fruits other than peaches in the USA; the PHI for use on peach trees in the USA is 14 days. No information on GAP was available from Canada or Germany, and the results of trials conducted in those countries were reviewed against the GAP of the USA and the United Kingdom, respectively.

The application rates in the supervised trials ranged from 0.22 to 4.48 kg ai/ha, applied to the base of the fruit trees up to three times in a season; the fruit was harvested from the trees 0–103 days after the last application. No residues of paraquat above the LOQ of 0.01 or 0.05 mg/kg were found in fruit harvested directly from the trees in any trial, even after spraying three times at a rate four times the maximum permitted rate. In most of the US trials, paraquat was applied one or two times instead of the maximum of three, but because of the higher application rates, the total amount applied was higher than the maximum allowed by GAP.

In trials on plums in the United Kingdom, paraquat was applied directly to suckers at rates of 0.22–1.34 kg ai/ha. No residues were found above the LOQ of 0.01 mg/kg in fruit harvested 21 or 55 days later.

In the trials in Germany, fruit were placed on sprayed weeds and collected for analysis about 1 week later. Small amounts of paraquat residues were found (0.02 and 0.04 mg/kg on peach, < 0.01 mg/kg on plum and 0.07 mg/kg on cherry) in the fruit samples, due to transfer from the sprayed weeds. As stone fruit intended for juice production is usually grown in orchards in which herbicides are rarely used, these data were not used for estimating a maximum residue level.

As the residue situations in stone fruits are similar and GAP is recommended for stone fruits or similar GAPs are established for peach and stone fruits excluding peach, the Meeting considered it appropriate to establish a group maximum residue level for stone fruits. As the paraquat residue levels were

below the LOQ, even when applied at exaggerated rates and the methods of analysis in most of the trials had a LOQ of 0.01 mg/kg, the Meeting estimated a maximum residue level for stone fruits of 0.01* mg/kg and STMR and highest residue values of 0 mg/kg.

Berries and small fruit

Grape

Trials on residues in grapes have been conducted in Canada, Japan, Switzerland and the USA at rates of 0.3–4.4 kg ai/ha applied one to five times. Grapes were harvested from the vines at maturity 0–196 days after the last application. Four trials were conducted in Germany in which paraquat was applied between the rows of established vines at a rate of 1.0 kg ai/ha and grapes were sampled from the vines 0–14 days after application.

Paraquat is registered for weed control around grape vines at a maximum rate of 0.72 kg ai/ha, with five applications and a 30-day PHI in Japan and a maximum rate of 1.14 kg ai/ha, with the number of applications and the PHI unspecified in the USA. No information on GAP was available from Canada, Germany or Switzerland, but the results of trials in Canada were reviewed against US GAP.

In all trials in Canada, Japan and the USA reviewed against respective GAP, grapes obtained directly from the vine did not contain paraquat residues at levels above the LOQ of 0.01 or 0.02 mg/kg, even when applied at five times the recommended rate or with a shorter PHI.

In the German trials, bunches of grapes were also placed on the sprayed weed a few days after application and collected 7 days later for analysis. Small amounts of paraquat residues (0.04, 0.07, 0.09, 0.10, 0.13 and 0.17 mg/kg) were found in the grapes due to transfer from the sprayed weeds. When the fruits were sampled directly from the vine, the levels of residues were always below the LOQ of 0.01 mg/kg (six trials), which supports the results of the trials conducted in Canada, Japan and the USA.

The residue levels of paraquat in grapes in the trials that met the respective GAP or were conducted at higher rates were: < 0.01 (16), < 0.02 (three) and < 0.05 (two) mg/kg.

Cane fruit

Trials on residues were conducted in Canada on red and blackcurrants, blueberries, loganberries, gooseberries and raspberries at rates of application of paraquat of 0.56–2.24 kg ai/ha. Paraquat was applied once and the fruit was harvested 20–111 days after application.

GAP for cane fruit in the USA is a maximum rate of 1.14 kg ai/ha, with the number of applications and PHI unspecified.

Even at double the application rate, cane fruit did not contain paraquat residues at levels above the LOQ of 0.01 mg/kg. The residue levels in 25 trials following GAP or conducted at higher rates were < 0.01 mg/kg.

Strawberry

Supervised trials were conducted in France, Germany and the United Kingdom in which paraquat was used to control runners of strawberry plants at rates of 0.42–1.32 kg ai/ha once or twice. Berries were harvested 47–226 days after the last application. Three trials in Germany were conducted in plastic greenhouses.

GAP in the United Kingdom for strawberries is a maximum rate of 0.66 kg ai/ha, with one application and PHI unspecified.

The residue levels of paraquat in strawberries in trials following GAP or conducted at higher application rates were < 0.01 (six) and < 0.05 mg/kg.

As the samples analysed in all the trials except that in which grapes were kept and taken from the ground did not contain paraquat residues at levels above the LOQs and the application rate in the respective GAP is similar, the Meeting decided to propose a group maximum residue level for small fruits and berries. The residue levels in these fruits, in ranked order, were: $\underline{\leq 0.01}$ (47), < 0.02 (three) and < 0.05 mg/kg (three). The Meeting, considering that use of modern analytical methods would enable lower LOQs, agreed to disregard residue levels of < 0.05 mg/kg and < 0.02 mg/kg and estimated a maximum residue level of 0.01* mg/kg and STMR and highest residue values of 0 mg/kg.

Olive

Trials on residues in olives have been carried out in Greece, Italy, Spain and the USA (California).

Paraquat is registered for controlling weeds around the base of olive trees at a maximum rate of 1 kg ai/ha, with the number of applications unspecified and a 40-day PHI in Italy and at a maximum rate of 1.14 kg ai/ha, with four applications and a 13-day PHI in the USA. The results of trials conducted in Greece and Spain were reviewed against GAP in Italy.

In trials in Italy, paraquat was applied at rates of 0.54–1.8 kg ai/ha to the base of trees, and olives were harvested from the ground or trees 7–21 days after application. Although the delay was shorter than the recommended PHI of 40 days, the residue levels in the olives were < 0.05 and < 0.1 (two) mg/kg, indicating that at a PHI of 40 days the levels are likely to be < 0.1 mg/kg. No residues (< 0.05 mg/kg) of paraquat were detected in the oil from these fruits.

In one trial in the USA, paraquat was applied four times at an exaggerated rate (5.6 kg ai/ha; 22.4 kg/ha total) and the fruit was harvested from the trees 13 days later for analysis. The residue levels of paraquat were below the LOQ of 0.05 mg/kg, as were the levels in oil and cake prepared from the olives.

In six trials in Spain, olives were harvested from the ground 0, 1 and 7 days after application of paraquat at 0.60 kg ai/ha, simulating the worse-case scenario of collecting olives intended for oil production. In these trials, the application rate was 60% of the maximum allowed in Italy, but the olive fruit were harvested much earlier than the PHI of 40 days. The residue levels in whole fruit were 0.64–10 mg/kg, indicating that there had been transfer of paraquat from the sprayed weeds to the olives. In all the oil produced from these samples, however, the maximum residue levels of paraquat were 0.06 mg/kg, indicating that paraquat is not extracted into oil, as might be expected from its chemical nature.

In other trials in Spain, mature olives were sprayed directly on the ground with paraquat at rates of 0.36–1.3 kg/ha, and the fruit was analysed 3–17 days after application. The residue levels of paraquat in the olives were 0.08–4.4 mg/kg. Residues of paraquat did not transfer to extracted oil, and washing appeared to reduce the levels on the fruit.

In one trial in Greece, mature olives were sprayed directly with paraquat at a rate of 1.0 kg ai/ha to simulate direct spraying on fallen fruit in collection nets during weed control. No residues were found at levels above the LOQ (0.05 mg/kg) in oil extracted from treated fruit harvested 5 days after application.

Olives for oil production are often harvested from the ground and paraquat used for weed control may occasionally be applied directly to the fallen fruit on the ground. The whole fruit will contain some paraquat residue, either through transfer from treated vegetation or through direct spraying. Although the olives may contain relatively high levels of paraquat, no transfer of paraquat to oil occurs. This practice is not in compliance with GAP for olives.

The residue levels in olives taken directly from trees were: < 0.05 and < 0.10 mg/kg (two). In another trial, the level was < 0.05 mg/kg in olives taken from ground that had not been directly sprayed. The residue levels in one US trial conducted at five times the usual rate were below the LOQ of 0.05 mg/kg, indicating that when paraquat is applied in accordance with GAP no residues are expected to occur in olive fruit. The Meeting estimated a maximum residue level of 0.1 mg/kg to replace the previous recommendation

for olive at 1 mg/kg. The Meeting also estimated an STMR of 0.05 mg/kg and a highest residue level of 0.1 mg/kg.

Assorted tropical fruits minus inedible peel

Trials on residues were carried out on *passion fruit* in Hawaii, USA, at an application rate of 1.12–4.48 kg ai/ha, to control weeds. Fruit was harvested 1–28 days after application. GAP in the USA for use on passion fruit is a maximum rate of 1.05 kg ai/ha, with an unspecified number of applications and PHI. The residue level in whole fruit in a trial complying with the maximum GAP was 0.13 mg/kg. After application at a rate higher than the maximum GAP, residue levels of up to 0.19 mg/kg were found in whole fruit. The levels in the edible pulp of all passion fruits analysed in the trials, regardless of PHI, ranged from < 0.01 to 0.02 mg/kg at 1.12 kg ai/ha and from < 0.01 to 0.06 mg/kg at higher rates. Higher levels were found in peel than in the edible portion.

Trials on residues were carried out on *kiwifruit* in California, USA, at an application rate of 0.56–2.24 kg ai/ha, three times, to control weeds. Fruit was harvested 7–14 days after the last application. The US GAP for kiwifruit is a maximum rate of 1.14 kg ai/ha, with the number of applications unspecified and a 14-day PHI. The residue level in kiwifruit in one trial conducted in accordance with the maximum US GAP was < 0.01 mg/kg. Even at a higher application rate or a shorter PHI, the levels were below the LOQ of 0.01 mg/kg.

Trials on *guava* were carried out in two locations in Hawaii, USA, with three different application rates of 1.12–4.48 kg ai/ha at each location. Fruit was harvested 1–28 days after application. The US GAP for guava is identical to that for passion fruit. The residue levels of paraquat in all edible pulp and peel analysed were below the LOQ of 0.01 mg/kg at the maximum GAP rate and at rates up to four times the maximum GAP. No residue was found at levels above the LOQ of 0.01 or 0.02 mg/kg in juice, discarded skin or seed obtained from guava treated at 1.12 or 4.48 kg/ha with a 6-day PHI. Although no information was available on residues in whole fruit, levels above the LOQ were not expected in whole fruit in view of the residue situation in pulp, peel and other fractions.

Trials were carried out on *banana* in Honduras, with three applications of paraquat at 1.4 kg ai/ha or a single application at double this rate, to control weeds in established plantations. Fruit was harvested 0–90 days after the last application. As no information was available on GAP in Honduras, the data were reviewed against GAP of the USA (maximum rate of 1.14 kg ai/ha). The residue levels of paraquat in flesh (0- and 3-day PHI) and whole fruit (≥ 7-day PHI) were below the LOQ (0.01 mg/kg) in three trials, except in skin from fruit harvested immediately after application.

Except in the trials on passion fruit, the residue levels in tropical fruits in 10 trials conducted according to the respective GAP were all below the LOQ (< 0.01 mg/kg). The Meeting estimated a maximum residue level for paraquat in assorted tropical fruits with inedible peel, excluding passion fruit, of 0.01* mg/kg. The Meeting decided to withdraw the previous recommendation for passion fruit.

The residue levels in edible portions of these fruit were below the LOQ: <u>< 0.01</u> (11) mg/kg. The Meeting estimated STMR and highest residue values for paraquat in assorted tropical fruits minus inedible peel, excluding passion fruit, of 0.01mg/kg.

Bulb vegetables

Trials on residues were conducted on *onion* in Canada, Germany and the United Kingdom in the 1960s. Paraquat is registered in the USA for pre-plant or pre-emergence application to onion in a limited number of states at a maximum rate of 1.14 kg ai/ha, with one application and a 60-day PHI (200 days in California). Uses on bulb vegetables are not included in the label in the United Kingdom.

In one Canadian trial at twice the GAP rate and with a shorter PHI (36 days), the residue levels were below the LOQ of 0.01 mg/kg. In another Canadian trial at an application rate of 1.12 mg/kg, the levels were also < 0.01 mg/kg, but the PHI was 143 days.

Trials were conducted in Germany for post-emergence directed application and for harvest aid uses, but there was no related GAP.

In one trial conducted in the United Kingdom of pre-emergence application on spring onion, the residue level was 0.02 mg/kg, but the application rate was > 30% higher than the maximum rate allowed in the USA. A further trial on spring onion involved directed post-emergence application, for which no information on GAP was available.

The Meeting concluded that there were insufficient data to recommend a maximum residue level for paraquat in onion bulb or bulb vegetables.

Brassica vegetables

Residue trials were carried out on *broccoli* in Canada; *Brussels sprouts* in The Netherlands (harvest aid); *cabbage* in Canada, Japan, Spain and the USA; and *cauliflower* in Canada. Paraquat was applied once or twice at 0.67–2.2 kg ai/ha for inter-row weed control, and the crop was harvested 5–52 days after the last application.

Paraquat is registered for use in the cultivation of *Brassica* vegetables during seed-bed preparation as a pre-plant or pre-emergence treatment, or applied as a post-emergence directed or guarded spray for inter-row weed control. GAP in Japan is a maximum rate of 0.36 kg ai/ha, with three applications and a 30-day PHI, for broccoli, cabbage, cauliflower and Chinese cabbage as pre-plant inter-row applications. GAP in the USA is a maximum rate of 1.14 kg ai/ha, with the number of applications and PHI unspecified, for *Brassica* vegetables as pre-plant, pre-emergence treatment.

In trials conducted on broccoli, cabbage and cauliflower in Canada, the residue levels were below the LOQ of 0.01 mg/kg, even when applied at double the rate. The exception was one trial in Canada in which cabbage harvested 51 days after treatment at twice the rate contained a residue level of 0.06 mg/kg. The residue levels were < 0.01 (two) and 0.06 mg/kg.

In two trials conducted on cabbage in Japan, the residue levels were below the LOQ of 0.03 mg/kg even after application at a higher rate of 0.96 kg ai/ha and a shorter PHI of 5 days. At a highly exaggerated rate of 19.2 kg ai/ha but with only one application and a longer PHI of 52 days, the residue levels were also < 0.03 mg/kg.

No information was available on GAP that would allow evaluation of trials conducted in Spain.

Trials on Chinese cabbage were conducted in the USA in which paraquat was applied once as pre-emergence treatment at 1.05 kg ai/ha, followed by three post-emergence directed applications at 0.56 kg ai/ha. The residue levels were < 0.05 and 0.07 mg/kg. The US label allows only pre-plant and pre-emergence applications.

Trials on Brussels sprouts in The Netherlands involved a direct harvest aid application to the vegetable. In these trials, the unwashed vegetable contained a residue level of 7.3 mg/kg after 31 days, while washed vegetable had a reduced level of 1.6 after 31 days. Harvest aid desiccation was not, however, included in the labels provided to the Meeting.

The residue levels in these crops in trials that followed GAP and in trials that showed residue levels below the LOQ were, in ranked order: < 0.01 (two), $\underline{< 0.03}$ (two) and 0.06 mg/kg. The Meeting concluded that there were insufficient data for estimating a maximum residue level for *Brassica* vegetables.

Fruiting vegetables

Numerous residue trials were carried out on tomatoes in Canada and the USA, on cucumbers, melons and summer squash in the USA and on peppers in Canada and the USA.

Paraquat is registered in the USA for use on tomatoes for pre-plant or pre-emergence application at a maximum rate of 1.14 kg ai/ha, with an unspecified number of applications and a 30-day PHI; on tomatoes

for post-emergence directed spray at a maximum rate of 0.55 kg ai/ha, with an unspecified number of applications and a 30-day PHI; on peppers by directed spray application at a maximum rate of 0.55 kg ai/ha, with three applications and no PHI; and on other fruiting vegetables for pre-plant or pre-emergence application at a maximum rate of 1.14 kg ai/ha, with unspecified number of applications and PHI.

The trials in Canada on *tomatoes* were for pre-emergence or pre-planting weed control, in which paraquat was used at a low rate of 0.11 kg ai/ha. Trials on tomatoes in the USA involved post-emergence directed application at 0.56–2.24 kg/ha and an exaggerated single high pre-emergence application at a rate of 11.2 kg ai/ha or pre-emergence application of 1.12 kg ai/ha followed by three inter-row directed applications at 2.8 kg ai/ha. Although samples were harvested 21 days after treatment, 30% shorter than the PHI in US GAP of 30 days, the residue levels in tomatoes were below the LOQ of 0.01 mg/kg after application at 0.56 kg ai/ha for post-emergence directed application, except in one trial in which levels up to 0.04 mg/kg were found. After application at exaggerated rates, the residue levels were still below the LOQ of 0.005 or 0.01 mg/kg or at a maximum of 0.02 mg/kg.

The residue levels in trials following GAP or conducted at higher application rates were, in ranked order: < 0.005 (two), $\underline{< 0.01}$ (seven) and 0.04 mg/kg.

The trials on *sweet peppers* were for use of paraquat in inter-row weed control at 0.56–2.2 kg ai/ha. The residue levels in trials at maximum GAP were < 0.01 and 0.01 mg/kg. The levels after exaggerated application rates were either below the LOQ of 0.01 mg/kg, 0.03 mg/kg (once at 1.12 kg ai/ha pre- emergence and four times at 1.12 or 2.24 kg ai/ha post-emergence applications) or 0.02 mg/kg (one trial).

The Meeting considered it appropriate to evaluate residues in tomato and peppers together for estimating the maximum residue level for fruiting vegetables, other than cucurbits. The combined levels were: < 0.005 (two), $\underline{< 0.01}$ (eight), 0.01 and 0.04 mg/kg. The Meeting estimated a maximum residue level for fruiting vegetables, other than cucurbits, of 0.05 mg/kg, an STMR of 0.01 mg/kg and a highest residue level of 0.04 mg/kg.

In trials on *cucumbers*, *melons* and *summer squash* in California (USA), paraquat was applied at 1.12 kg ai/ha pre-emergence, followed by three inter-row applications at 0.56 kg ai/ha. While US GAP allows pre-emergence application at a maximum of 1.12 kg ai/ha, the residue levels of paraquat in all 12 trials were below the LOQ of 0.025 mg/kg. The Meeting estimated a maximum residue level for cucurbits of 0.02 mg/kg and STMR and highest residue values of 0 mg/kg.

Leafy vegetables

Trials for residues were conducted on lettuce in Canada, Germany, Spain, the United Kingdom and the USA, on kale in France, Italy and the United Kingdom and on turnip greens in the USA.

Paraquat is registered for pre-emergence application on collard and lettuce in the USA at a maximum rate of 1.14 kg ai/ha, with the number of applications and PHI unspecified. Uses on leafy vegetables are not included on labels in Italy or the United Kingdom.

Trials on residues on *lettuce* were conducted in Canada, Germany, Spain, the United Kingdom and the USA at application rates of 0.42–2.24 kg/ha; lettuce was sampled 0–147 days after application. In trials conducted in Canada and the USA following US GAP, the residue levels in untrimmed head or bunch were 0.01, 0.04 and 0.05 mg/kg.

The results of trials in the United Kingdom were evaluated against US GAP, as the uses were similar in trials in the two countries. The residue levels in unwashed lettuce head in trials following US GAP were < 0.01, 0.01 and 0.02 mg/kg.

Residue levels up to 1.4 mg/kg were found in German trials on lettuce harvested immediately after one or two applications of paraquat for post-emergence inter-row weed control. The residues were believed to have derived from spray drift onto the outer leaves. In most of these trials, the whole lettuce head was analysed without removal of outer wrapper leaves that were yellow and withered. The residue levels had

declined to close to the LOQ (< 0.01 mg/kg) by 21 days after harvest. The results of trials in Germany and Spain could not be evaluated as no information on GAP in Europe was available.

Residue trials on *kale* were carried out in France, Italy and the United Kingdom at rates of 1.0–2.24 kg/ha, and kale was sampled 0–147 days after application. As no information was available on GAP in Europe, these data were not evaluated.

Six trials on *turnip greens* were carried out in the USA at a rate of 1.12 kg/ha, with sampling 55–128 days after application. The levels of paraquat residue were < 0.025 (three), 0.03, 0.04 and 0.05 mg/kg.

As the US GAPs for collard and lettuce are identical and the residue situations for these crops were similar, the Meeting considered it appropriate to combine the results for estimating a maximum residue level for leafy vegetables. The combined residue results, in ranked order were: < 0.01, 0.01 (two), 0.02, < 0.025 (three), 0.03, 0.04 (two) and 0.05 (two) mg/kg. The Meeting estimated a maximum residue level for paraquat in leafy vegetables of 0.07 mg/kg, an STMR of 0.025 mg/kg and a highest residue level of 0.05 mg/kg.

Legume vegetables and pulses

Residue trials were conducted on beans (with pod and dry) in Canada, Germany, Italy, The Netherlands and Spain, on broad beans in Spain, on peas in Australia, Canada and the USA, and on soya beans in Brazil and the USA.

Paraquat is registered for weed control and harvest aid on legume vegetables and pulses in Australia, Brazil and the USA as follows:

Country	Maximum rate (kg ai/ha)	No. of applications	PHI (days)	Crop	Type of application
Australia	0.2		14	Chickpea	Over-the-top spray
	0.2		14	Field pea	Over-the-top spray
	0.43			Soya bean	Pre-plant
Brazil	0.6	1	7	Soya bean	Pre-plant
	0.5	1	7	Soya bean	Desiccation
USA	1.14		–	Beans (lima, snap)	Pre-plant, pre-emergence
	1.14		–	Pea	Pre-plant, pre-emergence
	0.55	2	7	Pulses	Harvest aid
	1.14		–	Soya bean	Pre-plant or pre-emergence
					Should not exceed 1.9 l per season
	0.14	2	–	Soya bean	Post-emgence directed spray
					Second and final application 7–14 days later if needed
	0.28		15	Soya bean	Harvest aid

Uses on legumes and pulses were not included in the European labels provided to the current Meeting.

Residue trials were carried out on *dry beans* (genus *Phaseolus*) in Germany, Italy, The Netherlands and Spain, in which paraquat was used for pre-emergence weed control at single application of 0.56 or 2.24 kg ai/ha or post-emergence directed inter-row weeding at rates of 0.28–1.12 kg ai/ha. In trials in Europe, young pods were harvested 0–7 days after treatment and analysed. The residue levels in beans in pods were < 0.05–0.10 mg/kg (five trials). As no related GAP was available, these results were not used in estimating a

maximum residue level. The Meeting concluded that there were insufficient data to estimate a maximum residue level for legume vegetables.

The residue levels of paraquat in dry beans in Canadian trials after pre-emergence application following GAP were < 0.01 (two), < 0.05 and 0.07 mg/kg.

Residue trials were conducted on *broad beans* in Spain after post-emergence directed spray. The residue levels in seeds harvested on the day of application were < 0.05 mg/kg (two); however, no information was available on related GAP.

Residue trials were carried out on *peas* in Canada and the United Kingdom with paraquat used for pre-emergence weed control at single applications or post-emergence directed inter-row weeding at rates of 0.14–1.68 kg ai/ha and harvesting 55–152 days after application. The residue levels of paraquat in seeds were below the LOQ of 0.01 or 0.05 mg/kg in trials with post-emergence application; however, no GAP was available for post-emergence application on peas.

Paraquat was applied at 0.20 or 1.12 kg ai/ha to field peas and chick peas as a harvest aid desiccant in Australia and the USA, with samples taken 1–38 days after application. The resulting residues of paraquat in seed in trials following GAP were found at levels of: 0.05, 0.15, 0.23, 0.25, 0.31 and 0.41 mg/kg.

A number of trials were conducted on *soya beans* in Brazil between 1981 and 1983 with a harvest aid desiccation application of paraquat at 0.25–0.80 kg/ha and sampling 2–21 days after application. The residue levels of paraquat in seed in trials following GAP in Brazil were: < 0.02, 0.03 (two), < 0.05 (two), 0.07, 0.08, 0.09, 0.10, 0.11 (two), 0.13, 0.16 (two) and 0.28 (three) mg/kg.

In trials conducted in the USA with pre-emergence application with or without a post-emergence directed application at 0.14–1.4 kg/ha, the residue levels of paraquat in soya beans harvested 3–147 days after the last application in trials following GAP were < 0.025 (nine) and 0.03 mg/kg.

Other trials were conduced in the USA on harvest aid desiccation application at 0.28 or 0.56 kg/ha and sampling 6–36 days after application. The residue levels of paraquat in seeds in trials following GAP were: < 0.01, 0.02 (four), 0.03 (two), 0.04 (two), 0.05, 0.06, 0.07, 0.08 (two), 0.09, 0.12 and 0.13 mg/kg. The hulls of treated soya beans contained higher residues than seeds.

The results of these trials clearly indicate that the levels of residues arising from harvest desiccant uses are higher than those from pre-emergence or post-emergence application.

The Meeting considered it appropriate to combine the results of trials on field peas and chick peas in Australia and on soya beans in Brazil and the USA in which paraquat was used as a harvest aid desiccant to estimate a group maximum residue level for pulses. The combined residue levels in seeds were, in ranked order: < 0.01 (two), < 0.02, 0.02 (four), 0.03 (four), 0.04 (two), < 0.05 (two), 0.05 (two), 0.06, 0.07 (two), 0.08 (three), 0.09 (two), 0.10, 0.11 (two), 0.12, 0.13 (two), 0.15, 0.16 (two), 0.23, 0.25, 0.28 (three), 0.31 and 0.41 mg/kg. The Meeting estimated a maximum residue level of 0.5 mg/kg to replace the previous recommendation for soya bean and an STMR of 0.08 mg/kg and a highest residue level for pulses of 0.41 mg/kg.

Root and tuber vegetables

Paraquat is registered for use at a maximum rate of 0.36 kg ai/ha with three applications and a 30-day PHI in Japan for pre-plant, inter-row application on carrot and in the USA at a maximum rate of 1.14 kg ai/ha for pre-emergence treatment of root and tuber vegetables excluding potatoes.

Two residue trials carried out on *beetroot* in Canada and the United Kingdom for pre-emergence application in compliance with US GAP resulted in residue levels of < 0.01 and 0.03 mg/kg.

Residue trials were conducted in the United Kingdom on beetroot and *sugar-beet* in which paraquat was used pre-sowing or pre-emergence at 1.68 kg ai/ha, followed by two directed inter-row applications at

2.24 kg ai/ha after crop emergence. No information was available, however, on GAP for post-emergence application from Europe.

In trials conducted in four states of the USA with pre-emergence application at 1.12 kg ai/ha, the residue levels in sugar-beet roots harvested 136–178 days after application were < 0.05 mg/kg (six) after a single pre-emergence application at 1.12 kg ai/ha. After application at an exaggerated rate of 5.6 kg ai/ha, the residue levels in unwashed root were < 0.05 mg/kg.

Residue trials on *carrots* with use of paraquat for pre-emergence or inter-row weed control have been carried out in Canada, Japan, Germany and the United Kingdom. The residue levels of paraquat in carrot in the Japanese trials after both pre-emergence and inter-row applications were all below the LOQ of 0.03 mg/kg, despite a shorter PHI or use of a highly exaggerated rate of 19.2 kg ai/ha. The residue levels in carrot in four trials following GAP or conducted at higher rates or shorter PHI were < 0.03 mg/kg. In Canadian trials, the residue levels were below the LOQ of 0.01 mg/kg, even in one trial in which the rate was doubled and the PHI shorter.

As no information was available on GAP in Europe, the data from German trials with post-emergence application were not considered in estimating the maximum residue level.

Residue trials were carried out on *parsnips* and *swedes* in the United Kingdom and on *turnips* in Canada and United Kingdom with use of paraquat for pre-emergence weed control (Canada) or pre-emergence followed by inter-row weed control (United Kingdom). The rates of application were 0.56–2.24 kg ai/ha. Turnip, swede and parsnip roots were harvested 49–122 days after application. The residue levels of paraquat in turnips in two Canadian trials that followed US GAP were < 0.01 mg/kg. No information on GAP was available for post-emergence application in Europe.

One trial was conducted in France on *black salsify*, in which paraquat was applied as an inter-row treatment at 0.5 and 0.8 kg ai/ha. There were no residues (< 0.02 mg/kg) in salsify roots harvested 8 and 80 days after treatment; however, no information on GAP was available.

The combined residue levels in beetroot, sugar-beet, carrots and turnips were, in ranked order: < 0.01 (four), < 0.03 (four), 0.03 (two) and < 0.05 (six) mg/kg.

Potato

Trials were carried out on potatoes in Canada, Germany, the United Kingdom and the USA for pre-emergence, post-emergence and harvest aid applications of paraquat.

Paraquat is registered in the United Kingdom for pre-emergence use at a maximum rate of 0.66 kg ai/ha with one application. It is registered in the USA for pre-plant and pre-emergence broadcast application at a maximum rate of 0.55 kg ai/ha and for broadcast application for pre-harvest vine killing and weed dessication at a maximum rate of 0.42 kg ai/ha with a 3-day PHI. The latter application is restricted to fresh market produce, with a restriction of 2.3 l/ha per season; split applications must be applied a minimum of 5 days apart.

Trials were carried out in Germany with post-emergence directed application. The residue levels were below the LOQ of 0.01 mg/kg.

Several residue trials were carried out in Canada and the USA in which paraquat was applied for weed control by pre-emergence or post-crop emergence application at a rate of 0.20–1.12 kg ai/ha. The residue levels in the tubers in trials following US GAP were < 0.01 (eight) and 0.02 mg/kg. At double the application rate, the residue levels were below the LOQ of 0.01 mg/kg.

Trials were also carried out on harvest aid desiccant use in Canada, the United Kingdom and the USA. The US label allows use of paraquat for vine killing and weed desiccation at a maximum of 0.42 kg ai/ha, with a PHI of 3 days, but in these trials rates equivalent to or higher than twice the maximum rate or a much longer PHI were used. Harvest aid use is not included in the United Kingdom label.

The residue levels in trials of pre- and post-emergence application were < 0.01 (eight) and 0.02 mg/kg. The levels in trials with double the application rate in the USA and in trials conducted in Germany were all below the LOQ.

The Meeting decided to combine the results from trials on beetroot, sugar-beet, carrot, turnip and potato. The combined residue levels, in ranked order, were: < 0.01 (12), 0.02, < 0.03 (four), 0.03 (two) and < 0.05 (six) mg/kg. The Meeting estimated a maximum residue level of 0.05 mg/kg, an STMR of 0.02 mg/kg and a highest residue level of 0.05 mg/kg for root and tuber vegetables. The maximum residue level replaces the previous recommendation for potato.

Stem vegetables

Residue trials have been carried out on asparagus, celery and globe artichokes in Canada and the USA with use of paraquat for post-emergence directed inter-row weeding at rates of 1.12–3.25 kg ai/ha in a single application. Three applications of 1.12 or 1.35 kg/ha on artichokes were also tested.

Paraquat is registered in the USA for *asparagus* at a maximum rate of 1.14 kg ai/ha for pre-plant and pre-emergence broadcast or banded over-row application and at the same maximum rate with a 6-day PHI for asparagus more than 2 years old by broadcast or banded over-row application. The residue levels were < 0.02 (two) and < 0.05 mg/kg.

Although trials were conducted on *celery* in Canada and on *artichoke* in the USA, no information on GAP for these crops was available. The Meeting concluded that the data were insufficient for estimating a maximum residue level for asparagus.

Cereal grains

Maize

Residue trials were conducted on maize in Canada, Italy, the United Kingdom and the USA with pre- and post-emergence applications and harvest aid uses.

Paraquat is registered for use in the USA at a maximum rate of 1.14 kg ai/ha for pre-plant or pre-emergence broadcast of banded over-row applications and at a maximum rate of 0.55 kg ai/ha for post-emergence directed spray. Residue trials were conducted with use of paraquat for pre-emergence weed control or for post-emergence directed spray in Canada and the USA at rates of 0.28–1.12 kg ai/ha.

In a series of trials in the USA in 1987, one pre-emergence application at 1.12 kg ai/ha and two post-emergence applications at 0.31 kg ai/ha were made. Although the post-emergence application rate was not as high as the maximum rate, the pre-emergence application rate was the maximum allowed for pre-emergence application. The Meeting considered that these trials were conducted in accordance with US GAP. The residue levels in trials in Canada and the USA conducted in accordance with US GAP were: < 0.01 (eight) and < 0.025 mg/kg (16). In trials with higher application rates (up to four times), the residue levels were below the LOQ. The levels in maize cobs were also below the LOQ of 0.01 mg/kg (two trials).

In two residue trials in Italy, paraquat was applied pre-emergence at 0.92 kg ai/ha. The residue levels in cob were < 0.05 mg/kg; however, no analysis of kernels or grain was reported.

Trials were conducted in South Africa and the United Kingdom with post-emergence application; however, owing to the lack of relevant GAP for South Africa and the fact that post-emergence application is not included on the label in the United Kingdom, the results of these trials could not be evaluated by the Meeting.

Several trials were conducted in the USA on use of paraquat as a harvest aid desiccator at rates of 0.56–1.12 kg/ha. This use is not included in US GAP, although it is allowed in Argentina, Brazil and Uruguay.

On the basis of the residue levels in maize grain in trials with paraquat applied pre- or post-emergence in Canada and the USA, < 0.01 (eight) and < 0.025 mg/kg (16), the Meeting estimated a maximum residue level of 0.03 mg/kg to replace the previous recommendation for maize and STMR and highest residue values of 0.025 mg/kg.

Sorghum

A number of residue trials were conducted in the USA, where paraquat is registered for use on sorghum at a maximum rate of 1.14 kg ai/ha, with a PHI of 48 days for grain and 20 days for forage, for pre-plant or pre-emergence broadcast application, and at a maximum rate of 0.55 kg ai/ha in two applications with the same PHIs for post-emergence directed spray. In the latter application, the applications must not exceed 2.5 l per season.

Several residue trials were carried out in the USA in several years and locations, in which paraquat was applied for weed control, either pre-emergence, post-crop emergence directed or as a harvest aid, at rates of 0.21–7.8 kg ai/ha. Samples were taken 20–131 days after pre-emergence or post-emergence directed application. The residue levels in grain in 12 trials conducted in accordance with maximum GAP for pre-emergence or post-emergence applications were all ≤ 0.025 mg/kg. When both pre- and post-emergence applications were made, if the post-application rate was in compliance with GAP, the residue results were taken into consideration in estimating the maximum residue level. In one trial with one pre-emergence application at 0.56 kg ai/ha followed by a post-emergence application at 0.56 kg ai/ha, a residue level of 0.01 mg/kg was found.

In harvest aid desiccation applications, paraquat was applied at a rate of 0.21–2.8 kg/ha, and sorghum was sampled 7–49 days after application. Harvest aid desiccant use is not included on the US label.

The Meeting estimated a maximum residue level of 0.03 mg/kg to replace the previous recommendation and STMR and highest residue values of 0.025 mg/kg for sorghum.

Rice

Trials on residues of paraquat on rice were conducted in Guatemala, Italy and the USA. Paraquat is registered for use on rice in the USA by pre-plant or pre-emergence broadcast at a maximum rate of 1.14 kg ai/ha, with no PHI specified.

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 and straw samples taken at harvest did not contain residues of paraquat at levels above the LOQ of 0.05 mg/kg.

Three residue trials were conducted in Guatemala in 1983 in which paraquat was applied as a pre-emergence treatment at rates of 0.30 and 1.0 kg ai/ha to rice. Rice grain and straw samples were taken at harvest. The residues in de-husked rice in one trial conducted in compliance with the maximum rate in US GAP were < 0.05 mg/kg, but residues in rice grain were not analysed.

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 and 1.12 kg ai/ha to rice. In trials conducted at the maximum GAP, the residue levels in rice grain were below the LOQ of 0.01 (two) or 0.02 mg/kg. No trials were conducted at rates higher than the maximum allowed in US GAP for rice.

The Meeting concluded that there were insufficient data to estimate a maximum residue level and withdrew the previous recommendation for rice and rice, polished.

Tree nuts

It is common practice to harvest nuts from the ground, and this may result in residues of paraquat in the nuts.

Supervised residue trials were carried out over a number of years in Italy on *hazelnuts* and in the USA on *almonds* (California), *macadamia nuts* (Hawaii), *pecans* (Alabama and Texas), *pistachio nuts* (California) and *walnuts* (California).

Paraquat is registered for use on hazelnuts in Italy at a maximum rate of 1 kg ai/ha with a 40-day PHI and on walnuts at the same maximum rate but with no PHI specified. In the USA, paraquat is registered for use on pistachio nuts at a maximum rate of 1.14 kg ai/ha with a 7-day PHI, with the proviso that no more than two applications should be made after the nuts have split. It is registered for use in the USA on other tree nuts at the same maximum rate with no specification of the number of applications or PHI.

Two trials were conducted in Italy in which hazelnuts were harvested from the ground 1–10 days after treatment around the base of the trees at rates of 0.54–1.8 kg ai/ha. Although the PHI was shorter than 40 days, the residue levels in shelled nuts were below the LOQ of 0.05 mg/kg in one trial. At almost twice the maximum application rate and with a shorter PHI of 10 days, the levels were still below the LOQ.

In a trial in the USA, paraquat was applied at rates of 0.56–4.5 kg ai/ha one to eight times, to control weeds under mature nut trees. In some cases, applications were made over 2 years. Nuts were harvested, in some cases immature, 1–171 days after the last application. The residue levels in shelled nuts in trials following GAP were: < 0.01 (seven), 0.01, 0.02 and < 0.05 (three) mg/kg.

The combined results of all the trials, in ranked order, were: <u>< 0.01</u> (seven), 0.01, 0.02 and < 0.05 (four) mg/kg. The Meeting estimated a maximum residue level for paraquat in tree nuts of 0.05 mg/kg, an STMR of 0.01 mg/kg and a highest residue level of 0.05 mg/kg.

Oil seeds

Cotton-seed

Paraquat is registered for use on cotton in the USA at a maximum rate of 1.14 kg ai/ha, with no specification of the number of applications of PHI, for pre-plant or pre-emergence treatment, and at a maximum rate of 0.55 kg ai/ha, with repeated application if necessary and a 3-day PHI as a harvest aid, with the proviso that a total of 1.5 l should not be exceeded in this use.

Residue trials were conducted in the USA over several years and locations, involving pre-emergence applications at 1.12 kg/ha and harvesting 4–176 days after application. The residue levels in fuzzy seed in trials at the maximum GAP were < 0.01 (four) and 0.04 mg/kg.

In numerous trials with pre-emergence application followed by harvest aid desiccation application or a single application as harvest aid desiccant, the residue levels of paraquat in fuzzy seed in trials following maximum GAP were: 0.07, 0.09, 0.15, 0.16 (two), 0.18, 0.21, 0.23, 0.30, <u>0.34</u>, 0.35, 0.38, 0.44, 0.46, 0.49, 0.50, 0.58 and 2.0 mg/kg. On the basis of residue levels arising from harvest aid uses, the Meeting estimated a maximum residue level for cotton-seed of 2 mg/kg, to replace the previous recommendation, an STMR of 0.34 mg/kg and a highest residue level of 2 mg/kg.

Sunflower seed

In the USA, paraquat is registered for use on sunflower at a maximum rate of 1.14 kg ai/ha with no PHI specified for pre-plant or pre-emergence broadcast or banded over-row application and at a maximum rate of 0.55 kg ai/ha with a 7-day PHI for dessication use.

Trials were conducted with pre-emergence application to sunflowers at 1.12 or 5.6 kg/ha and sampling 41–131 days after application. The residue levels in seeds in four trials conducted in compliance with maximum GAP were < 0.05 mg/kg. When paraquat was applied at five times the maximum recommended rate, the levels were still below the LOQ of 0.05 mg/kg.

In further trials, paraquat was applied as a harvest aid desiccator at 0.28–1.12 kg/ha, and sunflower seeds were harvested 7–21 days after application. The residue levels of paraquat in seeds in trials conducted at maximum GAP were: 0.09, 0.14, 0.15, 0.16 (three), 0.19, <u>0.22</u>, 0.24, 0.32, 0.35, 0.51, 0.60, 0.74, 0.81

(two) and 0.93 mg/kg. The Meeting used the residue levels arising from harvest aid uses to estimate a maximum residue level for sunflower seed of 2 mg/kg, an STMR of 0.22 mg/kg and a highest residue level of 0.81 mg/kg.

Hops

Residue trials were conducted in Canada and the USA. Paraquat was registered in the USA for use as a directed spray or for suckering and stripping on hops at a maximum rate of 0.55 kg ai/ha in three applications with a 14-day PHI; no more than two applications or applications at no more than 1.5 l/ha were recommended.

In a trial in Canada, a single post-emergence directed application of 1.12 kg ai/ha, which is double the maximum recommended dose, resulted in residue levels of < 0.01 mg/kg in green hops harvested 53 days after application.

In the USA, trials were conducted in the states of Idaho, Oregon and Washington with three post-emergence directed applications of paraquat at 2.8 kg ai/ha. The residue levels of paraquat in dried hops prepared from hops harvested 14 days after the last of three directed application at the maximum GAP rate were 0.05 mg/kg in two trials. At double this rate, the levels in dried hops prepared from green hops harvested 13 or 14 days after the last treatment were below the LOQ of 0.1 mg/kg (0.01 and 0.07 mg/kg). Two applications at higher rates than that of maximum GAP resulted in 0.02 and 0.03 mg/kg in dried hops.

The residue levels in dried hops were 0.05 mg/kg (two). In view of the low levels of residues in the other trials, the Meeting estimated a maximum residue level of 0.1 mg/kg, to replace the previous recommendation, and STMR and highest residue values of 0.05 mg/kg for hops, dry.

Tea, green, black

Residue trials on tea were conducted in India, where paraquat is registered for use for pre-emergence or post-emergence directed application between rows at a maximum rate of 0.75 kg ai/ha in one application, with no PHI specified.

Six trials were conducted at a total application rate of 0.57–2.0 kg ai/ha over 5–6 months. Green tea leaves were harvested 7 or 21 days after blanket application (after the first or last spot application) and processed into black tea, which was analysed. The residue levels of paraquat in black tea from tea plants treated in accordance with GAP in India or at higher rates were almost always below the LOQ of 0.05 mg/kg. In trials conducted in accordance with GAP, the levels in black tea were: $\underline{\leq 0.05}$ (three), $\underline{0.07}$, 0.09 and 0.12 mg/kg.

In other trials in India, with application rates of 0.05–0.06 kg ai/ha, black tea samples from green tea leaves harvested 5 or 7 days after application contained 0.05 mg/kg (one) or < 0.05 mg/kg. As the application rate was much lower than the maximum, these results were not considered in estimating the maximum residue level.

The Meeting estimated a maximum residue level for teas, green, black of 0.2 mg/kg and an STMR of 0.06 mg/kg.

Animal feedstuffs

Soya forage and hay or fodder

Paraquat is registered for use in Australia, Brazil and the USA for weed control andas a harvest aid on soya beans. In the USA, it is registered for use at a maximum rate of 1.14 kg ai/ha for pre-plant or pre-emergence treatment, not to exceed 1.9 l per season, at a maximum rate of 0.14 kg ai/ha as a post-emergence directed spray with a second and final application 7–14 days later; it can also be used at a maximum rate of 0.28 kg ai/ha with a 15-day PHI as a harvest aid.

The residue levels in forage in trials conducted in the USA in accordance with US GAP were: < 0.025 (12), < 0.05 (13), 0.05, 0.06 (four), 0.07, 0.08, 0.15, 0.28 and 1.8 mg/kg, expressed on a dry weight basis.

The Meeting estimated a maximum residue level for soya bean forage (green) of 2 mg/kg, an STMR of 0.05 mg/kg and a highest residue level of 1.8 mg/kg.

The residue levels in hay or fodder in trials conducted in accordance with US GAP were: < 0.025 (five), 0.04, < 0.05 (four), 0.05, 0.1, 0.2 and 0.3 mg/kg, on a dry weight basis. The Meeting estimated a maximum residue level for soya bean fodder of 0.5 mg/kg, an STMR of 0.05 mg/kg and a highest residue level of 0.3 mg/kg.

Sugar-beet tops

Trials were conducted on beet and sugar-beet in the United Kingdom and the USA. The residue levels in sugar-beet tops in six trials conducted in accordance with US GAP were < 0.025 mg/kg, on a fresh weight basis. The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.11 mg/kg. On the basis of 23% dry matter and a highest residue level on a fresh weight basis of 0.025 mg/kg, the Meeting calculated the highest residue level on a dry weight basis to be 0.11 mg/kg. As there is no code for sugar-beet tops, the maximum residue level was recommended for fodder beet leaves and tops.

Maize forage and fodder

Trials were conducted in Italy and the USA. The residue levels in maize forage in trials in the USA conducted in accordance with US GAP were < 0.025 (eight), 0.09, 0.6, 2 (two) and 3 (two) mg/kg on a dry weight basis. The Meeting estimated a maximum residue level for maize forage of 5 mg/kg, an STMR of 0.025 mg/kg and a highest residue level of 3 mg/kg.

The levels of residues in silage were mostly below the LOQ of 0.025 or 0.05 mg/kg, except in one trial in which levels up to 0.04 mg/kg were found.

The residue levels in maize fodder in trials in the USA conducted in accordance with US GAP were: < 0.025 (eight), 0.03, 0.05, 0.06, 0.2, 1, 2 and 6 mg/kg on a dry weight basis. The Meeting estimated a maximum residue level for maize fodder of 10 mg/kg, an STMR of 0.025 mg/kg and a highest residue level of 6 mg/kg.

Sorghum forage (green) and straw and fodder, dry

In trials conducted in the USA in accordance with GAP, the residue levels in sorghum forage were: < 0.025 (six), 0.025 (three), 0.04, 0.06 and 0.2 mg/kg. The Meeting estimated a maximum residue level for sorghum forage (green) of 0.3 mg/kg, an STMR of 0.025 mg/kg and a highest residue level of 0.2 mg/kg.

The residue levels in sorghum fodder or hay (whichever gave higher levels) in trials conducted in accordance with GAP were: < 0.025 (four), 0.03, 0.04, 0.05, 0.06 (two), 0.09, 0.1 and 0.2 mg/kg. The Meeting estimated a maximum residue level for sorghum straw and fodder, dry, of 0.3 mg/kg, an STMR of 0.035 mg/kg and a highest residue level of 0.2 mg/kg.

Rice straw and fodder, dry

The Meeting concluded that there were insufficient data for estimating a maximum residue level for rice straw and fodder, dry.

Almond hulls

In three trials conducted in the USA in accordance with GAP, the residue levels in almond hulls were < 0.01 mg/kg. The Meeting estimated maximum residue, STMR and highest residue values of 0.01 mg/kg.

Cotton fodder

The Meeting concluded that there were insufficient data for estimating a maximum residue level for cotton fodder.

Fate of residues during processing

Numerous studies of residue levels after processing conducted in conjunction with supervised trials were submitted. Residue levels found after processing of raw agricultural commodities into animal feedstuffs are described in the section above. Some processed commodities for which maximum residue levels and STMR-Ps were estimated are also described in that section.

In this section, processing factors from raw commodities to processed food products and by-products are discussed. Information on processing was provided for orange, plum, grape, olive, tomato, sugar-beet, maize, sorghum, cotton-seed, sunflower seed and hop. Processing factors could not be reliably calculated for the processing of orange, plum, grape, tomato and sugar-beet because the paraquat residue levels in both raw commodities and processed products were all below the respective LOQs.

Processing factors were calculated for olive (oil), potato (crisps and granules), maize (milling fractions and oil), sorghum (milling fractions), cotton-seed (trash, gin products and oil), sunflower seed (oil) and hop (dried hop and beer) and are shown below.

Commodity	Processing factor	STMR-P (mg/kg)
Olive		0.05
Unwashed olives before processing	0.57	
Washed olives before processing	< 0.43	
Virgin oil	< 0.35	0.018
Refined oil	< 0.35	0.018
Potato		0.02
Wet peel	> 1.9	0.04
Dry peel	> 11	0.22
Peeled potato	0.27[a]	0.01
Crisps	> 0.95	0.02
Granules	> 2.7	0.05
Maize		0.025
Wet milling		
Coarse starch	< 0.25[a]	0.006
Starch	< 0.25[a]	0.006
Crude oil	< 0.25[a]	0.006
Refined oil	< 0.25[a]	0.006
Dry milling		
Germ	0.3[a]	0.0075
Grits	0.25–0.5[a]	0.0006–0.013
Coarse meal	1[a]	0.025
Meal	0.5[a]	0.013
Flour	1.5[a]	0.038
Crude oil	< 0.25[a]	0.006
Refined oil	< 0.05[a]	0.001
Sorghum		0.025

Commodity	Processing factor	STMR-P (mg/kg)
Hulled grain	0.07[a]	0.002
Dry milled bran	3.9	0.097
Coarse grits	0.17	0.004
Flour	0.14	0.004
Wet milled bran	2.3	0.058
Starch	0.07	0.002
Shorts	2.6	0.065
Germ	0.52[a]	0.013
Cotton (from cotton including trash and bolls)		
Fuzzy seed	0.08	0.34
Crude oil	< 0.006	0.01[b]
Meal	< 0.009	0.04
Sunflower seed		0.3
Hulls	2.8[a]	0.64
Meal	0.05[a]	0.01
Oil	< 0.05[a]	0[b]
Hop		
Dry cones	1.2	0.05[b]
Beer	< 0.28	0.0001[c]

[a] Based on only one trial.
[b] Estimated from supervised trials
[c] Calculated from a factor of 0.0001

The STMR values for processed products from raw commodities with no residues or for which the results of many supervised trials were available were estimated on the basis of supervised trials.

In four trials in the USA, orange fruit was processed into juice, and the paraquat residues were measured; in all cases, the levels were below the LOQ of 0.01 mg/kg. The residue levels in *orange juice*, including those in trials conducted at rates higher than the maximum application rate, were all below the LOQ of 0.01 mg/kg. The Meeting estimated an STMR-P for orange juice of 0 mg/kg.

No residues of paraquat were found at levels above the LOQ of 0.05 mg/kg in *dried prunes* prepared from plums in two trials. The STMR-P for dried prunes was estimated to be 0 mg/kg.

In a number of trials, olives were processed into oil for analysis of residues. *Olive oil* prepared from olive fruits harvested directly from trees did not contain levels above the LOQ of 0.05 mg/kg. Most samples of olive oil prepared from olive fruits picked up from ground or sprayed directly did not contain paraquat residues at levels above the LOQ; however, in some samples, paraquat residues were found at levels up to 0.06 mg/kg, and fruit harvested at the same time contained 6.8 mg/kg of paraquat residues. As paraquat is unlikely to be transferred into oil owing to its chemical and physical characteristics, its STMR-P is calculated from the processing factor to be 0.018 mg/kg.

Tomato juice and *ketchup* prepared from tomato in trials conducted at an exaggerated rate did not contain paraquat residues at levels above the respective LOQ (0.005 mg/kg for juice and 0.025 mg/kg for ketchup). The STMR values for these products were estimated to be 0 mg/kg.

The residue levels in oil prepared from soya bean treated with paraquat as a harvest aid desiccant in accordance with GAP were below the LOQ of 0.01 mg/kg in five trials. The Meeting estimated an STMR-P for *soya bean oil* of 0.01 mg/kg.

The residue levels in cotton-seed oil, crude, were below the LOQ of 0.01 mg/kg in two trials. The Meeting estimated an STMR-P for *cotton-seed oil* of 0.01 mg/kg and decided to withdraw the previous recommendation for cotton-seed oil, edible.

The residue levels in *sunflower seed oil* obtained from sunflower seed in eight trials conducted at the maximum GAP were < 0.01 mg/kg. Oil obtained from sunflower seed in a trial at double the rate did not contain residues at levels above the LOQ of 0.01 mg/kg. The Meeting estimated an STMR-P for sunflower seed oil of 0 mg/kg and decided to withdraw the previous recommendation for sunflower seed oil, crude and edible.

The residue levels of paraquat in *cotton gin by-product* in trials for harvest aid uses were (including results for cotton harvested 13–17 days after treatment): 5.2, 5.3, 5.9, 6.2, 7.3, 8.0, 9.4, 11, 12 (two), 18, 23, 32, 34 and 69 mg/kg. The Meeting estimated an STMR-P of 10.2 mg/kg for cotton gin by-products.

As *maize flour* contained a higher concentration of paraquat residues than maize grain in one trial, the Meeting estimated a maximum residue level of 0.05 mg/kg.

Residues in animal commodities

Dietary burden of farm animals

The Meeting estimated the dietary burden of paraquat residues for farm animals on the basis of the diets described in Appendix IX to the *FAO Manual* (FAO, 2002), by summing the contribution of each feed to the residue.

Estimated maximum dietary burden of farm animals

Crop	Residue (mg/kg)	Basis	Group	Dry matter (%)	Residue/ Dry matter (mg/kg)	Dietary content (mg/kg)			Residue contribution (mg/kg)		
						Beef cattle	Dairy cows	Poultry	Beef cattle	Dairy cows	Poultry
Sugar-beet tops	0.025	HR	AV	23	0.11						
Cotton-seed	2	HR	SO	88	2.27	25	25		0.57	0.57	
Cotton gin by-product	10.2	STMR-P		90	11.3	20	20		2.27	2.27	
Maize grain	0.025	HR	GC	88	0.03			80			0.023
Maize forage	3	HR	AF		3	40	50		1.2	1.5	–
Potato, wet peel	0.04	STMR-P	VR	15	0.27						
Sorghum grain	0.025	HR	GC	86	0.03				–		–
Sorgum forage	0.2	HR	AF	–	0.20				–		–
Soya bean	0.41	HR	VD	89	0.46			20			0.092
Soya bean, forage	1.8	HR	AL	–	1.8	15	5		0.27	0.09	–
Soya bean, hay	0.3	HR	AL	–	0.3				–		–
Sunflower meal	0.011	STMR-P	AL	92	0.01	–	–	–	–	–	–
Turnip tops	0.05	HR	VL	30	0.17						
Total									4.30	4.43	0.11

Estimated maximum dietary burden of farm animals

Crop	Residue (mg/kg)	Basis	Group	Dry matter (%)	Residue/ Dry matter (mg/kg)	Dietary content (mg/kg)			Residue contribution (mg/kg)		
						Beef cattle	Dairy cows	Poultry	Beef cattle	Dairy cows	Poultry
Sugar-beet tops	0.025	STMR	AV	23	0.11						–
Cotton-seed	0.34	STMR	SO	88	0.39	25	25		0.098	0.098	
Cotton gin by-product	10.2	STMR-P		90	11.3	20	20		2.27	2.27	
Maize grain	0.025	STMR	GC	88	0.028			80			0.02
Maize forage	0.025	STMR	AF		0.03	40	50		0.010	0.013	–
Potato wet peel	0.55	STMR-P	VR	15	0.27						
Sorghum grain	0.025	STMR	GC	86	0.03				–		–
Sorgum forage	0.025	STMR	AF		0.03				–		–
Soya bean	0.08	STMR	VD	89	0.09			20			0.02
Soya bean, forage	0.05	STMR	AL		0.05	15	5		0.008	0.003	–
Soya bean, hay	0.05	STMR	AL		0.05				–		–
Sunflower meal	0.011	STMR-P	AL	92	0.01	–	–	–	–		–
Turnip tops	0.025	STMR	VL	30	0.08						
Total									2.39	2.38	0.04

The dietary burdens of paraquat for estimation of MRL and STMR values for animal commodities are: beef cattle, 4.30 and 2.39 ppm; dairy cattle, 4.43 and 2.38 ppm; and poultry, 0.11 and 0.04 ppm.

Feeding studies

In a study of metabolism in goats (see above), one goat was dosed at a rate equivalent to 100 mg/kg of total diet. This is considerably higher than the estimated maximum dietary burden for cattle of 4.30 or 4.43 mg/kg. At 100 mg/kg of diet, the maximum TRRs, expressed in paraquat ion equivalents, found in milk and edible goat tissues were 0.009 mg/kg in milk, 0.12 mg/kg in meat, 0.03 mg/kg in fat, 0.56 mg/kg in liver and 0.74 mg/kg in kidney. In milk, 75.9% of the radiolabel was identified with paraquat.

At the estimated maximum animal burden of 4.30 or 4.43 mg/kg, the levels of paraquat residues were calculated to be < 0.005 mg/kg in milk, 0.005 mg/kg in meat, 0.025 mg/kg in liver and 0.033 mg/kg in kidney. The Meeting estimated maximum residue levels of 0.005* mg/kg for milks, 0.005 mg/kg for mammalian meat and 0.05 mg/kg for edible mammalian offal. These levels replace the previous recommendations for related animal commodities. The STMR values were estimated to be 0.00002 mg/kg for milk, 0.0003 mg/kg for meat and 0.0018 mg/kg for edible offal; and the highest residue level values were estimated to be 0.005 mg/kg for meat and 0.033 mg/kg for edible offal.

In the study of metabolism in hens (see above), birds were dosed at a rate equivalent to 30 mg/kg of total diet, which is considerably higher than the estimated maximum dietary burden for poultry of 0.11 mg/kg. At 30 mg/kg diet, the maximum TRRs, expressed in paraquat ion equivalents, found in eggs and edible chicken tissues were 0.18 mg/kg in egg yolk, 0.001 mg/kg in egg albumen, 0.05 mg/kg in meat, 0.05 mg/kg in fat and 0.09 mg/kg in liver.

At the estimated maximum animal burden of 0.11 mg/kg, the maximum residue levels were calculated to be far below the LOQ of 0.005 mg/kg in eggs and other tissues. The Meeting estimated the maximum residue levels to be 0.005* mg/kg for eggs, poultry meat and edible poultry offal. The STMR and highest residue level values were estimated to be 0 for these commodities.

DIETARY RISK ASSESSMENT

Long-term intake

The IEDIs were calculated for the five GEMS/Food regional diets from the STMR values for fruit, vegetables, maize, sorghum, cotton-seed, sunflower, hops, tea and animal commodities and the STMR-P values for their processed products, as estimated by the current Meeting (Annex 3). The ADI is 0–0.005 mg/kg bw, and the calculated IEDIs were 2–5% of the ADI. The Meeting concluded that the intake of residues of paraquat resulting from uses considered by the current JMPR was unlikely to present a public health concern.

Short-term intake

The IESTIs of paraquat by the general population and by children were calculated for commodities for which STMR or STMR-P values had been estimated by the current Meeting when information on consumption was available (Annex 4). The ARfD is 0.006 mg/kg; the calculated IESTIs for children up to 6 years range from 0 to 50% and those for the general population from 0 to 20% of the ARfD. The Meeting concluded that the short-term intake of residues of paraquat from uses considered by the current Meeting was unlikely to present a public health concern.

4.20 PHORATE (112)

TOXICOLOGY

Phorate is the ISO approved name for phosphorothioic acid, *O*-diethyl *S*-(ethyl thio)methyl ester, which is an organophosphate insecticide that inhibits acetylcholinesterase activity and is a systemic and contact insecticide and acaricide. Phorate was first evaluated by the JMPR in 1977. In 1985, an ADI of 0–0.0002 mg/kg bw was established. Phorate was re-evaluated in 1994 when an ADI of 0–0.0005 mg/kg bw was established. In 1994, because it was reported in a limited study of metabolism in rats that < 40% of the administered dose was excreted, the Meeting requested adequate studies on absorption, for review in 1996. Such studies were received and the ADI established previously was confirmed.

Since the 1994 JMPR, a study of acute neurotoxicity and a 13-week study of neurotoxicity in rats have been submitted. The present Meeting re-evaluated phorate within the periodic review programme of the CCPR, using new data that had not been reviewed previously and relevant data from previous evaluations.

After oral administration of radiolabelled phorate to rats, 77% of the administered dose was recovered in the urine within 24 h after dosing. Faecal excretion accounted for approximately 12% of the administered dose. Over the total duration of the study (192 h), essentially the entire administered dose was eliminated by excretion.

Phorate was highly toxic when administered orally, dermally or by inhalation. The oral LD_{50} values for rats were 3.7 mg/kg bw in males and 1.4 mg/kg bw in females. The dermal LD_{50} values for rats were 9.3 mg/kg bw in males and 3.9 mg/kg bw in females. The LC_{50}s for rats after exposure for 1 h were 0.06 and 0.011 mg/l of air in males and females respectively. Studies of dermal and eye irritation and of dermal sensitization were not performed owing to the high acute toxicity of phorate by skin contact.

5.18 PARAQUAT (057)

RESIDUE AND ANALYTICAL ASPECTS

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 cotton seed and maize forage were used in calculation. The Meeting concluded that there was no need to change the previous recommendations for animal commodities.

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.