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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 received by the Secretariat

The Secretariat has the honour to provide, in the annex to the present note, additional information received regarding the proposal 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 set out in the annex is presented as received, without formal editing by the Secretariat.

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

Annex

Chile

English translation of Resolution No. 909/2001 restricting the use and management of all agricultural pesticides formulations containing Paraquat as active ingredient (provided by Chile in Spanish in document UNEP/FAO/RC/CRC.7/Add.2.

Trinidad and Tobago

Information on the severely hazardous pesticide formulation, Gramoxone Super as per part 2 of Annex IV to the Rotterdam Convention: Submission by the Government of Trinidad and Tobago.

Ref:- SAG's Resolution N° 909/2001.Restricts the use and management of all agricultural pesticides formulations containing Paraquat as active ingredient.

Considering that:

- According to the information presented by the Ministry of Health, Paraquat does not have antidote and the different alternatives of medical treatment do not permit to reverse the damages caused by pulmonary fibrosis which is generally mortal.
- The risk Assessment for Paraquat, detected that the diverse condition of uses of this pesticide in Chile, causes intoxication or adverse effects to human beings and from this study derives that the main risk is for manipulators of Paraquat based products, mainly, applicators, mixers and carriers of this pesticides.
- The main exposition source to Paraquat is the splatter of the concentrated product onto the manipulator, when preparing the mix for application.
- Paraquat drift during application can be harmful to birds, mammals, and plants including aquatic plants for which the application was not intended.

The Resolution establishes:

- That aerial application of Paraquat based products is forbidden.
- That the application of Paraquat based products must be done in specific conditions that are detailed.
- That the label of the referred products shall include some minimal information dealing with protective measures to avoid the contact with the pesticide, like special clothes and additional measures that shall be taken after the application.
- That warning advices during the application shall be available indicating date and time of treatment among other information.

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Ref: SAG's Resolution N° 3191/2001. Modifies Resolution N° 909/2001 that restricts the use and management of pesticides containing Paraquat as active ingredient.

- Establishes the way terrestrial applications of Paraquat based products can be carried out.
- Establishes the obligation to produce, import, distribute and sell Paraquat based products only if they contain in their formulation a security agent like a color, unpleasant smell or an emetic agent.

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Information on the Severely Hazardous Pesticide formulation, Gramoxone Super as per Part 2 of Annex IV of the Rotterdam Convention

Submission by the Government of the Republic of Trinidad and Tobago

a) The physic-chemical, toxicological and ecotoxicological properties of the formulation

Information on the physico-chemical, toxicological ad ecotoxicological properties of the formulation were taken from the registration dossier for the Gramoxone Super as submitted for the registered product PR 119 (Trinidad and Tobago). See Appendix I and III, attached.

b) The existence of handling or applicator restrictions in other States

There are no handling or applicator restrictions in place for the purchase of Gramoxone Super by retail in Trinidad and Tobago. Shop owners are only required to maintain a register indicating the name of the purchase item, the quantity, and the area where the purchaser resides.

c) Information on incidents related to the formulation in other States

No incidents have been officially reported to the Pesticides and Toxic Chemicals Control Board of Trinidad and Tobago. Incidents reported in the media are related to suicides and attempted suicides utilizing the product in question.

d) Information submitted by other Parties, international organizations, non-governmental organizations or other relevant sources, whether national or international

European Union decision regarding Courts Directive to remove Paraquat as an active plant protection substance. (Please see Appendix II).

Pesticides News Number 32 of 1996, pages 20 – 21 states the following information regarding Gramoxone super:

- Banned: Finland, Sweden and Austria
- Severely restricted: Hungary
- Restricted: USA
- Limited registration: Germany
- Voluntarily cancelled: Norway

e) Risk and/or hazard evaluations, where available

Risk evaluation information from the United Stated Environmental Protection Agency's (EPA) Re-registration Eligibility Decision (RED) for paraquat dichloride was utilized. See attached document.

f) Indications, if available, of the extent of use of the formulation, such as the number of registrations or production or sales quantity

i. Under the trade name Gramoxone Super two (2) registrations exist in Trinidad and Tobago
ii. The number of registered products containing paraquat dichloride as the active ingredient is sixteen (16).
iii. For the year January to December 2010, the amount of Gramoxone Super that was imported into the country was 50,976 litres. If similar formulations or generics are considered then an additional 92,186 litres were imported, making a total of 143,144 litres.

g) Other formulations of the pesticide in question, and incidents, if any, relating to these formulations

There were no incidents relating to other formulations.

h) Alternative pest-control practices

a) Chemical Alternatives: (i) Glyphosphate (ii) Glufosinate Ammonium
b) Mechanical Alternatives: (i) Manual weed removal (ii) Use of plastic ground cover

syngenta

Dark red-brown clear – technical active ingredient

No characteristic odor – pure active ingredient
Earthy – technical active ingredient

8.24 Other characteristics known to applicant

None.

SECTION IX – TOXICOLOGICAL DATA

9.1 Acute oral toxicity

Zeneca central toxicology laboratory. Paraquat dichloride technical concentrate: acute oral toxicity to the rat.1994.CTL/P/4424-1.

A sample of paraquat dichloride technical concentrate was assessed for its acute oral toxicity.

Groups of five male and five female rats received a single oral dose of either 100 mg, 250 mg or 400 mg/Kg and one group of five males received a single oral dose of 600 mg/Kg. The animals were assessed daily for any signs of systemic toxicity and their bodyweights were recorder at intervals throughout the study. Animal in extremis and those surviving to the end of the study were killed and , together with those found dead, were subjeted to a macroscopic post mortem examination.
Following a dose of 100 mg/Kg, there were no deaths and no signs of toxicity.

Following a dose of 250 mg/Kg, one male and two females were either found dead or were killed in extremis on days 4 or 7. Signs of transient, slight toxicity were observed in the surviving animals.

Following a dose of 400 mg/Kg, thee male and four females were either found dead or were killed in extremis on days 4 or 5. Signs of slight or moderate toxicity were observed in the surviving animals.

Following a dose of 600 mg/Kg to males only, all animals were either found dead or were killed in extremis on day 4.

Post mortem examination of some animals which were killed in extremis or were found dead revealed mottling and dark areas in the lungs. Such findings are consistent with the mode of toxic action of paraquat and are therefore considered to be related to treatment.

The acute oral median lethal dose of paraquat dichloride technical concentrate was 344 mg/Kg (95% confidence limits 246, 457) to male rats and 283 mg/Kg (95% confidence limits 182, 469) to female rats.

Product

Zeneca Central toxicology Laboratory. Paraquat: acute oral toxicity to the rat of a 200 g/L SL formulation. Report No CTL/P/3969

The acute oral median lethal dose of a 200 g/L SL formulation of paraquat was calculated to be 707 mg formulation /Kg (approximate 95% confidence limits: 500, 1000) to male rats and 612 mg formulation /Kg (95% confidence limits: 458, 817) to female rats.

9.2 Acute dermal toxicity

Zeneca central toxicology laboratory. Paraquat dichloride technical concentrate: acute dermal to the rat.1994.CTL/P/4424-1.

A sample of paraquat dichloride technical concentrate was assessed for its acute dermal toxicity.

Groups of five male and five female rats received a single dermal application of 2000 mg/Kg of the test sample. The animals were assessed daily for any signs of systemic toxicity and dermal irritation and their bodyweights were recorded at intervals throughout the study. At the end of the study the animals were killed and subjected to a macroscopic post mortem examination.

Following a dermal application of 2000 mg/Kg there where no deaths and no significant signs of toxicity. Signs of slight or moderate skin irritation were observed.

Apart from scabbing and thickening of the skin at the application site, there were no findings at the post mortem examination. The acute dermal median lethal dose of paraquat dichloride technical concentrate was estimated to be in excess of 2000 mg/Kg to male and female rats.

9.3 Acute toxicity by inhalation

Paraquat: 4 hour acute inhalation toxicity study in the rat CTL/P/1325

Groups of five male and five female rats were exposed nose-only for a single four-hour period to aerosols generated from a paraquat formulation (paraquat plus) at target paraquat ion concentrations of 0.2, 0.7 or 1.5 mg/m3. a concurrent control group was exposed only to air.

The animals were observed for abnormalities during exposure and were given a detailed clinical examination immediately afterwards and daily for a 14-day observation

period. Their bodyweights and food consumption were measured at intervals throughout the study.

On day 15 surviving animals were killed and subjected to a macroscopic post mortem examination. Lung, liver, kidneys and testers were weighed. Animals which died were similarly examined as soon after death as possible except that only the lungs were weighed.

Analysis of the trapped 'particulate showed the actual concentrations of paraquat to be 0.20, 0.60 and 1.4 mg/m3. The aerosols generated were highly respirable (over 90% of the particles had an aerodynamic equivalent diameter (AED) of less than 0.3 microns).

Thetre were no deaths at the 0.20 and 0.60 mg/m3 levels but all animals in the 1.4 mg/m3 group either died or were killed in extremis before day 7 of the observation period.

The abnormalities see were dose-related and indicative of irritation of the respiratory tract and general debility in the top dose animals.

Irritation of the respiratory tract persisted in a high proportion of the test animals in the 0.20 and 0.60 mg/ m3 groups during the first 7-10 days of the observation period but was no evident by day 15.

There was a considerable increase in the lung damage see at post mortem examination of these animals. No increase in lung weight was seen at the lower dose levels except for one animal in the 0.20 mg/m3 group which also showed signs of lung damage at post mortem examination.

The four hour LC50 of the paraquat formulation tested in this study as an aerosol with an AED <0.3 microns), was between 0.60 and 1.4 mg/m3. This is in general agreement with the value (0.5 to 1.0 mg/m3) found from an earlier study (Gage and Manley 1965, Hathaway 1966) with an inspirable (<15 microns) aerosol.

Product

TECAM – Tecnologia Ambiental Ltda. Zeneca Brasil. Acute inhalation toxicity test, 1998.

The acute inhalation toxicity of the product ZEH 031-99 to rats (Wistar), under the test conditions and based on nominal concentration of the product, was: LC50 > 5.01 mg/L.

9.4 Skin irritation

Paraquat dichloride technical concentrate: skin irritation to the Rabbit CTL/P/4411

A sample of paraquat dichloride technical concentrate was assessed for its skin irritation potential.

9.18 Biotransformation in mammals

9.18.1 Other studies in mammals (hematology, kidney, liver function tests, effect on enzymes)

See Subchronic toxicity and chronic toxicity .

9.19 Ecotoxicological data

9.19.1 Accumulation in soil

Paraquat is rapidly adsorbed and deactivated in soil.

9.19.2 Leaching and mobility

Robbins, A.J., M.C.G. Lane, and D. Riley. 1988. Paraquat: adsorption and desorption equilibrium in soils. Laboratory Project and Report No. RJ0662B.

Paraquat dichloride was immobile in silty clay loam, loam, loamy sand, and sand soils. It was not possible to determine Freundlich Kads values because no paraquat was detected in the adsorption solution at the lower application rates. At high application rates (50-1000 times the field application rate), Kads values ranged

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9.19.3 Adsorption to soil particles

Robbins, A.J., M.C.G. Lane, and D. Riley. 1988. Paraquat: adsorption and desorption equilibrium in soils. Laboratory Project and Report No. RJ0662B.

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9.19.4 Adsorption Adsorption to organic matter

Vickers, J.A., A.D. Hurt, and D.W. Bewick. 1989. Paraquat: degradation in aerobic soil. Laboratory Project No. 88JH386/Report No. RJ0788B.

Paraquat dichloride at 4.32 ppm did not degrade in sandy loam soil incubated under aerobic conditions at 20 + 2° C for 180 days. Paraquat dichloride comprised 93% of the applied radioactivity at 180 days post treatment. Most of the radioactivity was extracted with technical grade paraquat by isotopic exchange. There was no volatile radioactivity. No degradates were reported from TLC or HPLC analyses.

9.19.5 Toxicity to soil organisms

Edwards, P.J; Coulson, J.M. Paraquat: toxicity for the earthworm (eisenia foetida) for a formulation SL containing 200 g/L. ICI. Jealott"Hill. Report TMJ3067B, 1993.

LC50 eisenia foetida: > 1000 mg/Kg soil

9.20 Accumulation in water

9.20.1 Biotic degradation

ANAEROBIC AQUATIC

N/A. This studies are not required because paraquat dichloride is not registered for aquatic uses, is tightly bound to soil, is not likely to be transported to aquatic environments in significant quantities from runoff or drift and is only slightly toxic to fish species.

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9.20.2 Toxicity to aquatic organisms

Imperial Chemical Industries. Paraquat: Determination of the 21 day LC50 to Rainbow trout (Salmo gairdneri). 1990. BL3860/B

Time	LC50	95% Confidence interval
4 day	63	49-96
7 day	46	37-63
10 day	44	35-59
14 day	42	33-56
21 day	42	33-56

9.21 Toxicity to beneficial insects

ORGANISM	EFFECT
Carabo, Pterostichus melanarius	none
Pardosa spp	none
Aleochara bilineata	none

9.22 Toxicity to wild fauna

N/A. Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. The available mammalian data indicate that paraquat dichloride is moderately toxic to small mammals on an acute oral basis.

9.23 Toxicity to birds

Paraquat: Acute oral LD50 to the Mallard Duck". Zeneca Agrochemicals. Jealotts Hill Research Station. England. Research Laboratory: Huntingdon Life Sciences Ltd. ISN 399/963860. Confidential Report. March 1998.

Over the conditions of this study, the acute LD50 value of paraquat to the mallard duck was 166 mg paraquat dichloride technical concentrate /Kg body weight (equivalent to 54 mg paraquat /Kg), with 95% confidence limits of 129 to 219 mg/Kg.

The no observed effect level was considered to be 56 mg/Kg.

Acute Oral LD50 – Bobwhite quail. Paraquat dichloride technical salt. Final Report. Octobre 8, 1979. Chevron Chemical Company.

The acute oral LD50 of Paraquat Dichloride Technical Salt (sx-1142) in the bobwhite quail is 176 mg/Kg, confidence limits 144 to 213 mg/Kg.

Hill, E.; Heath, R.; Spann, J. (1975) U.S. Department of Interior, Fish and Wildlife: Lethal Dietary Toxicity of Environmental Pollutants to Birds. Patuextant Wildlife Research Center.

Appendix II

ПЪРВОИНСТАНЦИОНЕН СЪД НА ЕВРОПЕЙСКИТЕ ОБЩНОСТИ
TRIBUNAL DE PRIMERA INSTANCIA DE LAS COMUNIDADES EUROPEAS
SOUD PRVNÍHO STUPNĚ EVROPSKÝCH SPOLEČENSTVÍ
DE EUROPÆISKE FÆLLESSKABERS RET I FØRSTE INSTANS
GERICHT ERSTER INSTANZ DER EUROPÄISCHEN GEMEINSCHAFTEN
EUROOPA ÜHENDUSTE ESIMESE ASTME KOHUS
ΠΡΩΤΟΔΙΚΕΙΟ ΤΩΝ ΕΥΡΩΠΑΪΚΩΝ ΚΟΙΝΟΤΗΤΩΝ
COURT OF FIRST INSTANCE OF THE EUROPEAN COMMUNITIES
TRIBUNAL DE PREMIÈRE INSTANCE DES COMMUNAUTÉS EUROPÉENNES
CÚIRT CHÉADCHÉIME NA GCÓMHPHOBAL EORPACH
TRIBUNALE DI PRIMO GRADO DELLE COMUNITÀ EUROPEE
EIROPAS KOPIENU PIRMĀS INSTANCES TIESA
EUROPOS BENDRIJŲ PIRMOSIOS INSTANCIJOS TEISMAS
AZ EURÓPAI KÖZÖSSÉGEK ELSŐFOKÚ BÍRÓSÁGA
IL-QORTI TAL-PRIMISTANZA TAL-KOMUNITAJIET EWROPEJ
GERECHT VAN EERSTE AANLEG VAN DE EUROPESE GEMEENSCHAPPEN
SĄD PIERWSZEJ INSTANCJI WSPÓLNOT EUROPEJSKICH
TRIBUNAL DE PRIMEIRA INSTÂNCIA DAS COMUNIDADES EUROPEIAS
TRIBUNALUL DE PRIMĂ INSTANȚĂ AL COMUNITĂȚILOR EUROPENE
SÚD PRVÉHO STUPŇA EURÓPSKYCH SPOLOČENSTIEV
SODIŠČE PRVE STOPNJE EVROPSKIH SKUPNOSTI
EUROOPAN YHTEISÖJEN ENSIMMÄISEN OIKEUSASTEEN TUOMIOISTUIN
EUROPEISKA GEMENSKAPERNAS FÖRSTAINSTANSRÄTT

LUXEMBOURG

Press and Information

PRESS RELEASE No° 45/07

11 July 2007

Judgment of the Court of First Instance in Case T-229/04

Kingdom of Sweden v Commission of the European Communities

THE COURT OF FIRST INSTANCE ANNULS THE DIRECTIVE AUTHORISING PARAQUAT AS AN ACTIVE PLANT PROTECTION SUBSTANCE

The Commission's handling of the file does not satisfy the applicable procedural requirements and the directive fails to satisfy the requirement of protection of human and animal health

Paraquat is an active substance which is a component of one of the three most widely-used weed-killers in the world. It acts as a non-selective, broad-spectrum herbicide particularly active against weeds. It destroys the green tissue of the plant by drying the leaves. It does not attack the radicular system. The abortive and destructive action is localised at the place of application of the product. It has been used on more than 50 varieties of crops in more than 120 countries and marketed in the form of a herbicide for some 60 years.

This active substance has been banned in 13 countries, including Sweden, Denmark, Austria and Finland.

The Community provisions governing authorisations for plant protection products must ensure a high level of protection, which must avoid in particular situations where risks to health, ground water and the environment have not been properly researched. Annex I to the directive in question[1] contains the list of authorised active substances.

In 1993, a number of paraquat producers, including Zeneca as the notifier, notified the Commission of their wish to have paraquat included in Annex I to Directive 94/414. After issuing an assessment report on paraquat, on 1 December 2003 the Commission adopted Directive 2003/112 [2] including paraquat in Annex I as an authorised substance, subject to certain conditions.

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[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1).

[2] Commission Directive 2003/112/EC of 1 December 2003 amending Directive 91/414 (OJ 2003 L 321 p. 32).

Sweden, supported by Denmark, Austria and Finland, brought an action for annulment of Directive 2003/112 before the Court of First Instance. Sweden put forward a number of pleas, some of which relate to procedure, whilst others allege failure to protect the environment and human and animal health.

Handling of the file

The Court notes that **although there are studies on the link between paraquat and Parkinson's disease, that issue was never referred to** by the notifier. Moreover, the Commission's reports did not contain any assessment of the literature relating to possible links between paraquat and Parkinson's disease.

The statement contained in the Commission's assessment report to the effect that there are no indications of neurotoxicity associated with paraquat therefore follows from a **handling of the file which does not satisfy the procedural requirements** laid down by the Community rules.

The Court further finds that a French study on paraquat operators' level of exposure, which was of some importance in the assessment of the substance, was not put through an assessment procedure and that that omission constitutes **a disregard of the applicable procedural provisions**.

Protection of human health

The Court notes that in a Guatemalan study one of the participating operators underwent exposure to paraquat equivalent to 118% of the acceptable operator exposure level fixed for that substance, despite use under the proposed conditions. Accordingly, the Community requirements, which prohibit any exposure higher than the acceptable operator exposure level, have not been satisfied. Consequently, Directive 2003/112 **fails to satisfy the requirement of protection of human health**.

Moreover, given that the abovementioned French study had played an important role in the Commission's decision to include paraquat in Annex I to Directive 91/414, that study's conclusion advising against uses requiring the use of treatment with a knapsack crop duster is **a serious indication which reasonably supports doubts as to the innocuousness of paraquat** during such use.

Protection of animal health

The Court notes that the Commission alleges that it based its assessment that paraquat did not have harmful effects on animal health on the assessment of 14 types of use envisaged by the notifier. However, **in order to assess the effects of paraquat on the health of hares and bird embryos, only two areas of use were assessed**, namely the use of paraquat in stubble fields in respect of hares and the use of paraquat in alfalfa fields in the autumn and winter in respect of birds. The Commission did not state any reason why it was not necessary to assess the 12 other types of use. The Court accordingly finds that the Commission did not conduct a sufficient assessment of the file on this point.

The Court also finds that the Commission relied on a file which did **not make it possible to establish to the requisite legal standard that the measures identified by it as likely to reduce the risks for hares were effective or appropriate** for reducing those risks.

The Court dismisses the other pleas in law put forward in the case.

The Court accepts in part in the applicants' pleas and **annuls Directive 2003/112**.

REMINDER: An appeal, limited to points of law only, may be brought before the Court of Justice of the European Communities against a decision of the Court of First Instance, within two months of its notification.

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Appendix III

United States Environmental Protection Agency

Prevention, Pesticides And Toxic Substances (7508W)

EPA 738-F-96-018
August 1997

EPA

Reregistration Eligibility Decision (RED)

Paraquat Dichloride

3. Risk Assessment

a. Dietary

Residues

Tolerances for paraquat residues in/on raw agricultural and animal commodities are published in 40 CFR §180.205(a) and (b), in processed food in 185.4700, and in feed at 186.4700. The available data support the established tolerances on all but sorghum forage, ruminant kidney, oats, rye, soybeans and hops. Thus, for the purposes of this analysis, the tolerances for sorghum forage was reassessed from 0.05ppm to the higher value of 0.1 ppm, while kidney was reassessed

from 0.3 ppm to 0.5 ppm, soybeans from 0.05 ppm to 0.25 ppm, and hops from 0.2 ppm to 0.5 ppm.

Chronic Dietary Exposure

A DRES (Dietary Risk Evaluation System) chronic exposure analysis was performed using tolerance level residues and percent crop treated to estimate the Anticipated Residue Concentration (ARC) for the general population and 22 population subgroups. Even with rye, oats, and poultry commodities included, the Reference Dose (RfD) was not exceeded for any of the 22 population subgroups analyzed.

As there are presently no registered uses of paraquat on rye, it is recommended that tolerances for this commodity be revoked. It is also recommended to revoke the tolerance on oats, as the registrant has indicated that they do not wish to support this use. Additionally, it is recommended that tolerances for poultry (except for eggs) be revoked. Further, a tolerance for popcorn (0.05 ppm) was included in this analysis and should be proposed (See Section IV, Tolerance Reassessment Summary and Table).

Chronic Dietary Exposure Using Tolerances

Existing tolerances result in a Theoretical Maximum Residue Contribution (TMRC) which represents 10% of the RfD for the U.S. general population. The highest subgroup, non-nursing infants (<1 year old) occupies 31% of the RfD.

Dietary Risk to Paraquat

Subgroup	Exposure (mg/kg/day)	%RfD
U.S. Population	0.000442	10
Non-Nursing Infants (<1 year old)	0.001398	31
Children (1-6 years old)	0.001070	24

b. Occupational and Residential

Risk From Handler Exposures

Based on biological monitoring data, the margins of exposure (MOEs) are acceptable (greater than 100) for: (1) mixing/loading to support ground applications; (2) mixing/loading to support aerial

applications; (3) applying using ground boom equipment; and (4) applying using aerial equipment (ground boom data were used as a surrogate for aerial). Surrogate exposure data from PHED indicate that: (1) mixing/loading liquid formulations to support several applicators using backpack sprayers; (2) flagging; (3) mixing/loading/applying for spot treatments using low-pressure sprayers or backpack sprayers are acceptable; and (4) with the addition of gloves mixing/loading/applying for resin soaking uses using low-pressure sprayers (MOEs greater than 100).

Based on exposure data from PHED, the MOE for backpack applicators (non-spot treatment) is unacceptable (MOE less than 100) when applicators are wearing long pants and long sleeved-shirt, and chemical-resistant gloves. The Agency is concerned about the practicality of adding another layer of PPE (woven material), due primarily to heat stress considerations and the "wicking" affect of multiple layers. As a risk mitigation measure, all paraquat labels could be modified to specify that backpack applications for spot treaments be made at application rates no higher than 0.0195 lb cation/gal (or 0.23% cation wt/wt spray solutions).

Risk From Post-Application Exposures

Based on the postapplication biological monitoring study The Agency has determined that a 12-hour restricted-entry interval is adequate for the uses of paraquat for preemergent or early-season weed control. In these use-situations, the paraquat is directed at the soil and weeds (if present) that are generally less than six inches tall and the workers' degree and duration of contact with treated surfaces is likely to be similar to or less than that for the scouts in the biological monitoring study.

Based on the postapplication biological monitoring study, The Agency also has determined that a 12-hour restricted-entry interval is adequate for the uses of paraquat for weed control in orchard and vegetable crops where the spray is directed solely at the weeds (not broadcast over the entire crop area). In these directed-spray use-situations where the paraquat is directed at the weeds, entering workers' degree and duration of contact with treated surfaces are likely to be similar to or less than that for the scouts in the biological monitoring study.

For desiccation and harvest aid applications of paraquat, The Agency is establishing a 24-hour restricted-entry interval (REI). The Agency believes that such uses may result in exposures to workers of greater degree and duration than that for the scouts in the biological monitoring study, particularly when the workers are performing harvesting-related tasks, such as removal or compacting (i.e. trampling) of desiccated foliage and stems on crops such as cotton, dry beans, potatoes, sunflowers, and sugar cane. It is well documented that paraquat is rendered biologically inactive upon contact with the soil. However less is known about its residues on leaves. After 21 days, 66% of paraquat is lost from plant surfaces. The Agency does not have any foliar dissipation curves for paraquat to better quantify post-applicator exposure. Personal protective equipment is required for workers who enter the treated area before the REI has expired.

The 12 and 24-hour post-application entry restrictions for paraquat dichloride do not apply to uses outside the scope of the Worker Protection Standard (WPS) for Agricultural Chemicals. The predicted frequency, duration, and degree of exposure by such uses do not warrant the same risk mitigation measures required for users covered by the WPS who are engaged in agriculture for commercial or research purposes. However, the Agency is concerned about exposures immediately following applications while the sprays are still wet.

Additional Occupational/Residential Exposure Studies Handler Studies

None are necessary.

Post-Application Studies

If the registrant believes that a restricted-entry interval of less than 24 hours is appropriate for the desiccation/harvest-aid uses of paraquat, an additional study is required. Requirements for post-application exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines. The required data include: Guideline