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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Paraquat Assessment, D323223

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I. Summary

BEAD conducted an assessment to determine whether the potential benefit (i.e., the avoidance of unintentional death and illness due to paraquat ingestion) of the new formulation of paraquat justifies the increased cost to growers. Since HED is unable to determine the number of deaths and illnesses that may be reduced by the use of the new formulation, the benefit estimate in this analysis represents a range from zero to the upper bound estimate on the assumption that the new formulation will have the improved safety features to avoid incidences of unintentional death and illness. BEAD also provided use and usage data and identified potential alternatives for certain crops.

The benefit of annual avoided cases as a result of using the new formulation was estimated to be between $0 and $15.4 million. The total additional cost of new formulation to growers was estimated at $1.8 million to $2.3 million.

II. Background

Paraquat is a toxic herbicide that has been widely used for broadleaf weed and grass control. Gramoxone manufactured by Syngenta is the most common trade name for paraquat and is used on more than 50 crops in the United States. Due to its toxicity, paraquat is available for use only by commercially licensed users in the United States. Syngenta has developed the new paraquat product, Gramoxone Inteon®. This product has an increased amount of emetic and the addition of a gelling agent, which Syngenta expects will result in a reduction of the number of unintentional deaths and illnesses when accidental ingestion occurs. Syngenta has requested the registration of this new product to replace their existing paraquat products, which may affect "Me Too" paraquat registrations. BEAD has evaluated whether the potential health benefit of the new formulation outweighs the expected increased cost of this product to growers.

III. Use, Usage, and Potential Alternatives

[redacted] BEAD recognizes that there are crops with a high percent crop treated but that do not constitute a majority of the paraquat used in the United States and so are not included in this analysis.

Table 1. Percent Crop Treated of Sites with the Majority of Paraquat Usage in the United States

Crops	% of Total Paraquat Use	% Crop Treated	Major Production States	States with Highest % Crop Treated
Corn	[redacted]	[redacted]	IA, IL, NE, MN, and IN	[redacted]
Cotton	[redacted]	[redacted]	TX, CA, MS, GA, and NC	[redacted]
Soybeans	[redacted]	[redacted]	IA, IL, MN, IN, and OH	[redacted]
Almonds	[redacted]	[redacted]	CA	[redacted]
Grapes, wine	[redacted]	[redacted]	CA, WA	[redacted]
Apples	[redacted]	[redacted]	WA, MI, NY, CA, and VA	[redacted]
Alfalfa	[redacted]	[redacted]	CA, MN, ID, IA, and SD	N/A
Total	[redacted]			

Source [redacted]; Agricultural Statistics 2004; USDA NASS; Crop Profile for Wine Grapes in WA, 2003.

In general, paraquat is used to burn down existing weeds. Paraquat is often used in no-tillage or reduced tillage cropping systems before planting. In some crops, such as corn and soybeans, paraquat may also be used to control weeds before harvest (Crop Profile for Field Corn in NC, 2005; York, 2004). For cotton, paraquat is often used as a harvest aid to desiccate crop foliage and weeds (Crop Profile for Cotton in California, 2002; Crop Profile for Cotton in TX, 1999). For orchard and grape crops, paraquat is used throughout the year to control emerged annual weeds and to suppress perennial weeds (California Pesticide Information Portal (CalPIP); Crop Profile for Almonds in CA, 1999; Crop Profile for Grapes (Wine) in CA, 2002; Crop Profile for Wine Grapes in WA, 2003).

Potential alternatives vary by crop and the manner in which paraquat is used. For pre-plant applications and preharvest weed control for corn and soybeans, another commonly used herbicide is glyphosate (Crop Profile for Corn in KY, 2002; York, 2004). Sodium chlorate is a harvest aid for cotton that is used similarly to paraquat (Jost and Brown, 2003; Crop Profile for Cotton in TX, 1999). There are a number of herbicides registered for use on orchard crops. For almonds, glyphosate is an herbicide that can provide post-emergence control of grass and broadleaf weeds (Crop Profile for Almonds in CA, 1999). For wine grapes, glyphosate and glufosinate-ammonium are a couple of the herbicides that may also be used to control weeds (Crop Profile for Grapes (Wine) in CA, 2002).

IV. Economic Assessment

In this section, BEAD quantitatively measured the additional cost to growers and benefit of the cases of unintentional death and illness that may be potentially avoided as a result of paraquat reformulation. The benefit estimate in this analysis was based on the assumption that the new formulation will have the improved safety features to reduce incidences of death and illness. However, there is no scientific evidence that shows the new formulation would indeed affect health outcomes. Therefore, the benefit measured in this analysis represents the upper bound estimate with the possibility that it could range from zero.

1. Costs of New Formulation to Growers

[redacted] BEAD does not have any evidence that indicates the new formulation will affect efficacy or yield. [redacted] Table 2 details the cost increase per acre to growers.

[redacted] while 3 pounds of paraquat cation are contained in a gallon of Gramoxone. This analysis was based on the assumption that all the paraquat used in the United States is sold as the product Gramoxone. However, there are other products available in the market, which make up an insignificant share of the market.

Because the new formulation would increase the chemical cost by 5%, the cost increase per acre to growers ranges from $0.20 for cotton to $0.50 for almonds, wine grapes, and apples. The increases in cost as a percentage of the total operating cost per acre are minor and those increases would not likely influence a grower's decision to purchase paraquat or another herbicide.

Table 2: The potential cost increase per acre with the use of new formulation

Crop	Average Gramoxone Cost per Acre (A)	Average Gramoxone Inteon[3] Cost per Acre (B)	Cost Increase per Acre (B – A)	Total Operating Cost per Acre[4]	Cost Increase as a % of the Total Operating Cost
Alfalfa	[redacted]	[redacted]	$0.35	$228	0.15%
Almonds			$0.50	$2,168	0.02%
Soybeans			$0.35	$210	0.17%
Cotton			$0.20	$437	0.05%
Grapes, Wine			$0.50	$2,732	0.02%
Apples	[redacted]		$0.50	$4,365	0.01%
Corn			$0.35	$300	0.12%

Source: [redacted]; Crop budget data from the National AG Budget Library

2. The Benefits of New Formulation

This section presents quantitative valuation of the cases of unintentional death and illness that may be potentially avoided as a result of paraquat reformulation[5]. These cases are first characterized into the following the Toxic Exposure Surveillance System (TESS) outcome categories for which 1) the average costs for outpatient physician visits, 2) inpatient hospitalizations, 3) lost productivity, and 4) premature mortality are estimated.

The five outcome categories are:

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[3] Paraquat reformulation with the Alginate Technology for the improved safety features

[4] Total operating cost per acre for each crop was obtained from the National AG Budget Library. In this analysis, total operating cost per acre for alfalfa is for Idaho; almonds for California; soybeans for Iowa; cotton for Texas; grapes, wine for California; apples for Washington; and corn for Illinois. There are variations in total operating costs across states for the same crop, but the variations are not significant enough to affect the results of this analysis.

[5] The health valuation approach employed in this analysis is extensively discussed in "Economic Analysis of the Bulk Pesticide Container Design and Residue Removal Standard" by the Biological and Economic Analysis Division (BEAD) in the Office of Pesticides Program (OPP), July 2005.

- **No effect:** A patient who reported an exposure but developed no signs of symptoms. These cases theoretically would not result in any medical cost, but the TESS data show that some of the no-effect case incurred medical costs for health facility visits. In addition, there are likely to be costs associated with lost productivity for the time and anxiety associated with a call to a poison control center.

- **Minor effect:** patient developed some signs or symptoms as a result of the exposure but they were minimally bothersome and generally resolved with no permanent disability or disfigurement.

- **Moderate effect:** patient exhibited signs or symptoms as a result of the exposure that were more pronounced, more prolonged, or more of a systemic nature than minor symptoms (usually some form of treatment is indicated).

- **Major effect:** patient exhibited signs or symptoms as a result of the exposure that were life-threatening or resulted in significant residual disability or disfigurement.

- **Death:** patient died as a result of the exposure or as a direct complication of the exposure.

Health effect data on unintentional ingestions of paraquat for the period 1993 to 2003 was reported to the Poison Control Centers (PCC) that covers an average of 91.1% of the U.S. population. However, this data usually account for only a quarter of the total cases that occur, especially those requiring inpatient or outpatient treatment[6]. This data was adjusted for the potential reporting of only one-quarter of all cases occurred and for an average coverage of 91.1% of the U.S. population. Table 3 presents the estimated number of cases for each outcome category per year. It was estimated that on average 2.4 unintentional deaths[7] are associated with paraquat per year.

Table 3: The estimated number of cases for each outcome category per year

Outcome Category	Estimated Number of Cases per Year
Death	2.4
Major Effect	2.4
Moderate Effect	12.0
Minor Effect	21.6
No Effect	21.6
Total	60.0

[6] Chafee-Bahamon et al. (1983) found that only 24% of 19,544 inpatient or outpatient cases in Massachusetts in 1979 were referred to the State's PCC. Harchelroad et al. (1990) also found that 26% of identified 470 toxic exposures in Pennsylvania were referred to the local PCC in 1988.

[7] Six deaths were reported for 11-year period from 1993 to 2003. The estimated 2.4 unintentional deaths due to paraquat per year was calculated by dividing 26 deaths [(6/.911) × 4] by 11 years. Please see the Appendix A for a detailed calculation of the estimated annual number of cases for each outcome category.

The health benefit associated with reduced morbidity is measured as the sum of the cost savings for outpatient visits, inpatient hospitalization stays, and lost productivity[8]. The health benefits associated with reduced premature mortality was based on the "value of a statistical life" (VSL) approach. The value of reduced morbidity is estimated using the TESS data on the likelihood of morbidity cases of varying severity levels seeking medical care. These data are then used to generate unit costs associated with physician visits, hospital stays, and lost productivity for each level of clinical severity. Subsequently, the total value of reduced morbidity is estimated by applying these costs to the number of avoided cases by level of severity and summing across severity levels. The premature mortality valuation is performed by first generating a VSL estimate in year 2005 dollars and then applying the number of premature deaths.

Outpatient Physician Unit Cost

The outpatient physician unit costs per case by level of clinical severity are estimated based on health care facility utilization data from TESS. Table 4 presents the adjusted unit costs for cases with no clinical effect, minor effect, moderate effect, and major effect. Unit costs represent the cost per case and are calculated by multiplying the benchmark cost[9] of $39.35 by the percentage of cases visiting health care facilities. The adjusted unit costs range from $8.89 for "no effect" to $34.11 for "major effect."

Table 4: Outpatient Physician Unit Costs by Medical Outcome

Medical Outcome/Severity	Unit Cost
No Effect	$8.89
Minor Effect	$11.93
Moderate Effect	$27.80
Major Effect	$34.11

Inpatient Hospitalization Unit Costs

The inpatient physician unit costs per case by level of clinical severity are estimated based on health care facility utilization data from TESS. Unit cost for "major

[8] Unit costs for an outpatient visit, inpatient hospitalization, and lost productivity day were directly extracted from "Economic Analysis of the Bulk Pesticide Container Design and Residue Removal Standard" by the Biological and Economic Analysis Division (BEAD) in the Office of Pesticides Program (OPP), July 2005.

[9] The benchmark cost of $39.35 does not represent the full outpatient physician charge. It is the price that the patient pays the provider directly in the form of deductible, co-pay, or full-pay after services are provided and before leaving the facility. It does not include some cost components such as diagnostic and medicinal costs.

effect" is the average cost across all "major effect" cases. Unit costs represent the cost per case and are calculated by multiplying the benchmark cost of $6,856 by the percentage of cases visiting health care facilities. Table 5 presents inpatient hospitalization unit cost with an assumption that only cases with major effects will have inpatient hospital stays.

Table 5: Inpatient Hospitalization Unit Costs

Medical Outcome/Severity	Unit Cost
No Effect	$0
Mild Effect	$0
Moderate Effect	$0
Major Effect	$5,942

Lost Productivity

The value of a day of full productivity was estimated at $194.80 and the TESS data on the duration of illness by medical outcome/severity were used. For each severity level, an average duration of clinical illness was generated and the proportion of a day spent with the illness was calculated. This proportion was applied to the value of a day of full productivity to estimate the indirect cost of illness. Therefore, the loss in productivity is directly proportional to the time spent with the illness. Table 6 presents the average clinical effect duration (low-end estimate by the TESS) and unit cost for lost productivity day.

Table 6: Average Clinical Effect Duration and Unit Cost for Lost Productivity Day

Medical Outcome/Severity	Average Duration of Clinical Effect (Days)	Unit Cost for Lost Productivity Day
No Effect	0.01	$1.83
Minor Effect	0.9	$179.82
Moderate Effect	3.7	$717.35
Major Effect	16.4	$3,192.25

Premature Mortality

A "value of a statistical life" (VSL) was used to estimate a value of the potential reduction in fatalities from pesticide-related illnesses. EPA's Office of Air and Radiation's (OAR) work on the value of a statistical life has been widely cited throughout the Agency[10]. In this analysis, the estimated VSL was calculated to be $6.42 million in 2005 dollars.

3. Result

The total value of annual avoided cases as a result of using new formulation with improved safety features was estimated at a range from $0 to $15.4 million. The value of avoided mortality cases of 2.4 comprises about 99 percent of the total value estimated in this analysis. This is because the high unit value of $6.42 million for VSL. Table 7 presents the potential upper-bound benefit of annual avoided cases when new formulation is used

Table 7: Potential Benefit of Annual Avoided Cases with New Formulation (2005 dollars)

	Estimated Number of Outcomes per Year	Outpatient cost (A)	Inpatient cost (B)	Lost Productivity Day (C)	VSL (D)	Total Value (A+B+C+D)
Death	2.4	$0	$0	$0	$6,420,000	$15,408,000
Major Effect	2.4	$34	$5,942	$3,192	$0	$22,003
Moderate Effect	12.0	$28	$0	$717	$0	$8,938
Minor Effect	21.6	$12	$0	$180	$0	$4,146
No Effect	21.6	$9	$0	$2	$0	$235
					Total Benefit	$15,443,322

[10] For more information on VSL, please see "An Empirical Bayes Approach to Combining Estimates of the Values of a Statistical Life for Environmental Policy Analysis." by Ikuho Kochi, Bryan Hubbell, and Randall Kramer.

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APPENDIX A

Table A-1 presents the number of unintentional ingestions of paraquat reported to the Poison Control Centers (PCC) from 1993 to 2003.

Table A-1. The number of unintentional ingestions of paraquat reported to the PCC from 1993 to 2003

Total unintentional ingestions reported : 150	
Total cases with outcome determined : 92	**Total cases with unknown outcome : 58**
Fatal outcomes: 6	
Life-threatening outcomes: 6	Potentially toxic: 16
Moderate outcomes: 14	
Minor outcomes: 28	Possible minor effect: 26
No symptoms: 38	No effect expected: 16

Source: American Association for the Poison Control Centers; Health Effect Division (HED), Office of Pesticide Program, US EPA.

The unintentional ingestion data reported to the PCC was reconciled to each outcome category by the Toxic Exposure Surveillance System (TESS). Six fatal outcomes are categorized into the outcome category of "death" under the TESS. Six life-threatening outcomes are categorized into "major effect." Fourteen moderate outcomes and 16 potentially toxic outcomes are classified into "moderate effect." The cases with potentially toxic outcomes could range from moderate to major outcomes. For this analysis, BEAD assumed the potentially toxic outcomes are likely moderate outcomes. Twenty-eight minor outcomes and 26 possible minor effects are classified into "minor effect." Thirty-eight no symptoms and 16 no effect expected were categorized into the outcome category of "no effect" under the TESS. Table A-2 presents the number of the cases reported to the PCC by the each outcome category from 1993 to 2003.

Table A-2. The estimated number of cases for each outcome category by the TESS.

Outcome Category	Number of Cases Reported to the PCC from 1993 to 2003	Estimated Number of Cases Occurred per Year
Death	6	2.4
Major Effect	6	2.4
Moderate Effect	30	12
Minor Effect	54	21.6
No Effect	54	21.6
Total	150	60

In order to estimate the expected annual number of cases for each outcome category, data from the PCC was adjusted for the potential reporting of only one-quarter of all cases occurred and for an average coverage of 91.1% of the U.S. population. The number of death of six was multiplied by 4 due to the fact that only 25 percent of all cases occurred is reported to the PCC. Twenty-four (4 times of 6 deaths) was then divided by the factor of 0.919 because the PCC covers only 91.1% of the U.S. population. As a result, the total of 26 deaths was estimated for 11 years from 1993 to 2003. Finally, the estimated 2.4 death per year was calculated by dividing 26 deaths by 11 years. Table A-2 also presents the estimated number of the cases occurred per year.