UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAR 13 2000

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DECISION MEMORANDUM

SUBJECT: Denial of Registration of Chlorfenapyr for Use on Cotton

----- **DECISION MEMORANDUM** -----

FROM: Jim Jones, Director
Registration Division (7505C)

THRU: Susan Hazen, Acting Deputy Director
Office of Pesticide Programs (7501C)

TO: Susan H. Wayland, Acting Assistant Administrator
Office of Prevention, Pesticides and Toxic Substances

Background. On December 12, 1994, American Cyanamid submitted an application to register chlorfenapyr for use to control a number of cotton pests, including beet armyworm, and a tolerance petition (PP 5F4456). EPA has provided the public many opportunities to comment on this use pattern as follows: the EPA published the Federal Register notices required by the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") and the Federal Food, Drug and Cosmetic Act ("FFDCA"); and in January 1999, EPA made available for public comment both EPA's and American Cyanamid's risk assessments. In addition, EPA submitted both EPA's and the American Cyanamid's risk assessments to peer review by the Scientific Advisory Panel (SAP) and the Fish and Wildlife Service (FWS). Thus, in addition to the data submitted by American Cyanamid, the EPA has considered all substantive public and peer review comments in its review of this chemical.

OPP findings are presented below. A more detailed presentation, with supporting materials, tables, and references is included in the appendices and attachments to this decision memorandum.

Environmental Fate and Effects Findings. Since 1994, OPP has conducted several increasingly refined assessments of the risks to terrestrial and aquatic organisms resulting from chlorfenapyr use

on cotton. For further details see Appendix 1. OPP has concluded, based on the extensive supporting data, the following:

- **Chlorfenapyr causes a wide variety of significant reproductive effects in birds:** Laboratory testing of mallard ducks and bobwhite quail show reduced eggs laid, reduced viable embryos, reduced embryo survival, reduced normal hatchlings and reduced hatchling survival -- all associated with exposure to chlorfenapyr. These effects occurred at very low concentrations of chlorfenapyr in the diet.

- **Chlorfenapyr residues in food items are well in excess of levels that could produce adverse effects on bird reproduction:** A comparison of the effect's threshold for reproductive effects in birds with residues in avian food items shows that for all cotton application scenarios proposed by product labels, initial dietary exposure would exceed levels required for reproduction impairment. Furthermore, the pattern of decline of chlorfenapyr residues in food items suggested that dietary exposures would exceed levels causing reproduction impairment following a single application. Multiple applications, as allowed on the label, would extend the period over which residues would be above reproduction effects thresholds proportionately.

- **Chlorfenapyr residues have been measured in avian food items:** The applicant has provided data regarding the concentrations of chlorfenapyr in avian food items including adult and larval insects, weed seeds, weed seed heads, and forage from treated areas. These data show that chlorfenapyr is detectable in avian food items on the day of application. Further, residues persist at concentrations that are expected to cause reproductive effects.

- **Birds are associated with cotton fields and surrounding habitats:** The applicant has provided avian census data for cotton fields and surrounding habitat. These data show many bird species occur within cotton fields or in an area within 50 meters of the field edge. Birds use cotton fields and have been observed to feed in these fields during and after the proposed application periods.

- **Even assumption of minimal field use by birds does not eliminate concerns for reproductive effects:** A large variety of avian species use cotton fields with appreciable frequency and the observed instances of bird use of cotton fields include a substantial number of foraging behavior observations. However, even when it is assumed that a small proportion of the avian diet (10%) comes from treated cotton fields, risks are still above levels of concern following the application of chlorfenapyr.

- **Routes of exposure in addition to diet and chlorfenapyr metabolites may contribute to risk:** Because of considerations of dietary exposures only, the actual exposure of a given bird in a treated cotton field could be higher than estimated in the Agency's risk assessment. If evaluated, we believe the combined burdens associated with dermal, inhalation, and drinking water exposures would have increased the potential risk for birds in and around cotton fields treated with chlorfenapyr. Furthermore, the available residue data in wildlife food items do not include measurements of chlorfenapyr metabolites of known toxicity to

non-target organisms. It has been suggested that exposure to chlorfenapyr metabolites may also increase the risks to birds in and around treated cotton fields.

- **Chlorfenapyr application periods coincide with avian reproduction periods**: The applicant provided information on the reproduction periods of all avian species reported to occur in cotton fields. Many of these reproduction periods are likely to overlap with periods of chlorfenapyr application to cotton fields.

- **Chlorfenapyr applications to cotton present risks to water dwelling animals in cotton-growing regions.** OPP has found acute risks to freshwater fish and invertebrates, acute and chronic risks for estuarine and marine organisms and acute risks for sediment dwelling organisms. These concerns are increased by the persistence of the chemical in aquatic environments and the potential for accumulation in invertebrates.

- **Chlorfenapyr is persistent, and residues will build up quickly in the environment:** The half-life of chlorfenapyr in soil is more than one year. OPP has concerns for pesticides with such persistence, particularly when combined with the toxicity and the many routes of exposure. In addition, it is hard to predict accurately the full extent of on-site accumulation and off-site transport. Environmental levels of chlorfenapyr in soil can be expected to reach levels approximately two and ½ times the annual application rate after only a few years of continued use.

OPP's findings have been externally reviewed by the Scientific Advisory Panel (SAP) and the U.S. Fish and Wildlife Service (FWS). Their findings generally add support to OPP's conclusions, articulate additional concerns, and caution that OPP may have underestimated risks. Among other concerns, FWS expressed concern about risks to nontarget organisms, including insect pollinators, reptiles and amphibians, waterfowl, shore birds, raptors, and insect pollinators and threatened and endangered species, and a lack of information to adequately address these concerns. For more information, see Appendix 2.

In two meetings, the SAP reviewed the OPP risk assessment and American Cyanamid's probabilistic risk assessment. In the first meeting, the SAP generally agreed with OPP's risk assessment. However, the SAP also concluded that the OPP risk assessment may have underestimated risk to birds for the following reasons: insect residues may have been underestimated, degradates and metabolites were not included, the 10% estimate of diet from treated fields may be too low (50% may be more appropriate), and there was no estimate of the following important variables: pesticide drift to adjacent habitats, gorging behavior, higher food intakes by young birds, or dermal and drinking water exposure.

In a second meeting, the SAP specifically considered American Cyanamid's probabilistic risk assessment, in which American Cyanamid concluded that the risks to birds were negligible. The SAP concluded that the exposure model used in the American Cyanamid risk assessment was not correctly constructed, the probabilistic assessment was unreliable and American Cyanamid's conclusion of negligible risk was not supported for any geographic scale. Particular areas of concern are listed below:

- The level of chlorfenapyr exposure in birds from treated cotton fields was inappropriately diluted by numeric factors erroneously used in an effort to account for large regional scale populations of birds.

- A properly conducted field-level probabilistic risk assessment is likely to come to similar conclusions as OPP's deterministic risk assessment.

- The SAP encouraged OPP to develop a protocol for future probabilistic risk assessments. The SAP stated, however, that OPP would need additional data to make a probabilistic risk assessment a useful tool for evaluating risk. OPP believes it would take about 2-3 or more years for these data to be developed, submitted and reviewed. It is our belief that if the data recommended by the SAP are included, the estimates of risk would likely increase. For more detailed information on the SAP's findings, refer to Appendix 3.

In conclusion, therefore, OPP has reviewed several studies that indicate that birds exposed to low doses of chlorfenapyr will experience reproductive effects. EPA has further concluded that the widespread use of chlorfenapyr in accordance with the proposed label instructions would pose widespread risks to birds. These risks include serious impacts on avian reproduction in treated areas. There appears to be an extensive opportunity for avian species to be exposed to chlorfenapyr in the diet at more than sufficient dose levels to produce adverse reproductive effects. In the proposed label application scenarios, OPP believes that avian exposures will likely be above a level at which adverse effects will occur. OPP has also reviewed bird monitoring data that indicates that many species of birds feed in cotton fields and are likely to be present and feeding in fields at times when chlorfenapyr would be used and still present at hazardous levels. These studies and EPA's analyses, contained in the docket nos. OPP-34162, 30464, 612 and 620 are incorporated by reference into this document. The January 1999 and January 2000 benefits assessments are also incorporated by reference into this document.

Based on the findings set forth above, OPP believes the peer reviewed data submitted by the applicant supports its decision on the application for registration.

Benefits Findings.

OPP has two sources of information regarding the benefits of chlorfenapyr: The first is qualitative information based on discussions with extension and state entomologists, state agricultural officials and formal and informal comment from growers and grower groups. The second source is the compilation, review, and assessment of comparative product performance data available in journals, other published reports and in some unpublished data available to OPP. The pictures presented by these two sources of information present somewhat different conclusions about the benefits of this compound. OPP has chosen to use a weight of the evidence approach in making its conclusions about the benefits.

Qualitative Assessment. OPP has been evaluating the value of chlorfenapyr for the control of cotton pests since 1994 when the initial applications for emergency exemptions (Section 18s) for

beet armyworm control were submitted by several cotton states. In a qualitative benefits assessment based on discussions with entomologists, state agricultural officials and growers, published on the OPP homepage in January, 1999, OPP concluded that:

- The beet armyworm is a very erratic pest, generally most severe following mild winters and summers with above average temperature and below average rainfall. The pest has a history of causing sporadic, but large losses ranging from 700 to 368,000 bales during the period from 1991 to 1998.

- Chlorfenapyr was viewed as one of the most effective materials available for beet armyworm control.

- In 1995, the year that Sec. 18s were approved late in the growing season, losses were large, and for a number of producers, they were catastrophic. Thus, the beet armyworm's ability to damage bolls and strip a cotton field of foliage, and thereby wipe out a crop for an individual producer, was indicated through abundant anecdotal evidence. For more information on the events that brought about the Sec. 18 applications, refer to Appendix 4.

- OPP was also aware that the demand for chlorfenapyr to control this pest was increased by the initiation of boll weevil eradication programs in several mid-South states. During the start-up years of a boll weevil eradication program, multiple insecticide applications reduce parasites and predators which can result in more severe beet armyworm outbreaks than might happen in the absence of the program. However, OPP is very supportive of the boll weevil eradication program because once the boll weevil is eradicated, the number of insecticide applications per acre, per growing season is reduced. Reduction of pesticide usage also saves growers money.

- OPP found that the other effective compound registered against beet armyworm was spinosad (Tracer®). In January, 1999, in OPP's judgment, spinosad appeared to be at least as good as chlorfenapyr. OPP believes that since beet armyworm has a well-documented capacity to develop resistance to pesticides, it is important that there be more than one alternative to control it. Tebufenozide (Confirm®) was found to be less effective than chlorfenapyr, and works best at lower populations of beet armyworm.

- Some unregistered compounds were also evaluated. Two compounds were believed to be as effective as chlorfenapyr. Another compound was believed to be effective on beet armyworm on vegetables and probably effective for cotton as well. Two compounds passed the reduced risk screen and another compound, not reduced risk, was less toxic to birds than chlorfenapyr.

For these reasons, in January 1999, OPP concluded there was a very high benefit for chlorfenapyr use against beet armyworm.

OPP received numerous comments in response to the notice of availability of risk and benefits assessments published in January 1999. As of April 2, 1999, 179 comments were received

from growers or groups representing the grower community. These comments largely confirmed the conclusions of the January1999 benefits assessment.

Review of Comparative Data. In addition to the qualitative assessment described, OPP has completed a comparative data assessment based on comparative efficacy trials. These comparative efficacy trials, 70 in number, compared chlorfenapyr's performance in controlling beet armyworm to a number of alternatives. Claims of confidentiality have been waived for these data or the data came from published sources. The conclusions are as set forth:

Comparative Efficacy of Chlorfenapyr and Alternatives for Control of Beet Armyworm on Cotton

Insecticide	% control[1]	Yield loss[2]	# tests	Toxicity to beneficials	Comments
chlorfenapyr	88.6%	0	15	med-high	Majority of studies from Louisiana
spinosad	80.7%	1.6%	14	low	Worked better than chlorfenapyr in Alabama, nearly as well in Louisiana, poorly in South Carolina and Texas
tebufenozide	67%	4.3%	14	low	Worked well in Texas , poorly in South Carolina and Louisiana
chlorpyrifos	61.6%	5.4%	8	high	
profenofos	22.4%	13%	3	high	
methoxyfenozide	77.3%	2.3%	3	low	Not currently registered
emamectin benzoate	88.1%	0.1%	10	low-med	Not currently registered. Worked better than chlorfenapyr in AL, slightly worse in AR, LA, TX, and SC.
indoxacarb	87.8%	0.2	5	high	Not currently registered. Worked a little better than chlorfenapyr in Louisiana, and a little worse than chlorfenapyr in South Carolina

1/ since each of the alternatives were included in a different subset of comparisons, percent control figures presented here are relative to the average percent control achieved by chlorfenapyr and may not agree with the actual average percent control from the particular study subset.

2/ Yield loss relative to chlorfenapyr treated cotton. Assumes 20 percent yield loss from untreated beet armyworm infestation and that there is a linear relationship between efficacy and yield loss.

- Limited comparative efficacy and product performance data precluded definitive evaluation of claims relating to beet armyworm control. The majority of the studies OPP reviewed were

conducted in Louisiana and thus OPP has more confidence in OPP's conclusions for Louisiana than for other states. With these limitations in mind, OPP reviewed studies comparing chlorfenapyr to the following compounds: tebufenozide (Confirm®), spinosad (Tracer®), chlorpyrifos (Lorsban®), profenofos (Curacron®) and thiodicarb (Larvin®). OPP also reviewed the limited available studies of compounds in the registration pipeline, including methoxyfenozide (Intrepid®), indoxacarb (Steward®) and emamectin benzoate (Denim®). These studies showed that chlorfenapyr is more effective in controlling beet armyworms than the currently registered alternatives (spinosad, tebufenozide, chlorpyrifos, and profenofos) and three insecticides in the registration pipeline (methoxyfenozide, emamectin benzoate and indoxacarb). In these tests, chlorfenapyr averaged 88.6% control of beet armyworm. Spinosad, tebufenozide, and chlorpyrifos, the most effective registered alternatives, averaged 80.7%, 67%, and 62% control respectively while profenofos, the least effective alternative, averaged only 22%. Three compounds in the registration pipeline, methoxyfenozide, emamectin benzoate, and indoxacarb averaged 77.3%, 88.1% and 87.8% control, respectively. On average, indoxacarb and emamectin benzoate treatments were only one percent less effective than chlorfenapyr. Indoxacarb and emamectin benzoate appeared to be the most effective of the unregistered insecticides in controlling beet armyworms.

- The comparative product efficacy data indicates that, in the absence of chlorfenapyr, growers will likely apply spinosad during years of low to moderate beet armyworm infestations and may experience yield losses averaging roughly 2 percent relative to those which would have been achieved using chlorfenapyr. According to the criteria in the Qualitative Benefits Characterization Model (Brassard and Grube, 1998), a 2% yield loss is considered to be minor. The individual grower's impacts associated with a minor loss is predicted not to significantly affect the profitability of owner operated farms.

- During periods of high beet armyworm activity and in southern areas of the cotton belt where beet armyworms can survive the winter, growers are likely to alternate between spinosad and tebufenozide or chlorpyrifos (for resistance management purposes) and suffer yield losses on average of 3 to 5 percent (when compared to yields with chlorfenapyr). Yield losses of 3-5 percent are considered to be moderate according to the criteria set forth in the above cited model.

- There is a considerable amount of uncertainty regarding the distribution of yield losses caused by beet armyworm. OPP's review of beet armyworm yield loss statistics for the worst year (1995) and in the states with the highest infestation (Alabama and Florida) suggests that average yield losses are about 10 percent on the untreated acreage (Spenkel and Austin, 1996). In addition, a six year anthology of comparative performance studies taken to yield in Louisiana on multiple infestations of beet armyworm, bollworm, and tobacco budworm reported yield losses in the untreated plots ranging from 0 to 38 percent and averaging around 20 percent (Leonard et. al., 1996). However, some growers will experience higher yield losses, and some lower.

- Except for tebufenozide, which is significantly more expensive than chlorfenapyr, the alternatives are comparably priced. See table 8 in attachment 3.

- According to an article entitled "Pest Patterns - The Impact of Bollgard® Technology and Boll Weevil Eradication on Cotton IPM" (Smith, 1998), insecticide applications are lowered following completion of the boll weevil eradication program, which, in turn, reduces the impacts on beet armyworm predators. Therefore, under these conditions, "the beet armyworm is not expected to be an economic pest of cotton in the southeastern United States in the foreseeable future."(Smith, 1998).

- The alternatives spinosad and tebufenozide are much less toxic to beneficial arthropods than chlorfenapyr, and thus would be a better fit in integrated pest management systems.

OPP believes it is appropriate to balance the qualitative findings with the comparative data findings. The qualitative findings, based on comments from the user community and several years of informal communications with state and extension entomologists, state agricultural officials and users, provide valuable insight into what is actually being experienced by some cotton growers. Relying completely on this information, however, may overstate the economic benefits due to the very dynamic situation with respect to the registration of alternatives. Similarly, the comparative data assessment, which is a more systematic evaluation of the benefits, may understate the value of chlorfenapyr in the control of beet armyworm in some situations. Due to limitations in the number of studies available, it is very plausible the comparative data assessment does not capture the full spectrum of chlorfenapyr benefits. In particular, it may not fully explain the high infestation scenarios in areas under the boll weevil eradication program. Thus, OPP feels that it is appropriate to attempt to integrate the findings of the qualitative and comparative data assessments. In so doing, OPP finds, that the benefits of chlorfenapyr in controlling beet armyworm in cotton may range from moderate to high, depending on the specific situation, although overall the alternatives will provide adequate control in most situations.

Risk/Benefit Determination.

FIFRA section 3(c)(5) provides that "the Administrator shall register a pesticide if the administrator determines that, [among other things]... it will perform its intended function without unreasonable adverse effects on the environment..." Unreasonable adverse effects are defined as "(1) any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide." Under section 3(c)(7)(C), the Administrator may conditionally register a pesticide containing a new active ingredient, "for a period reasonably sufficient for the generation and submission of required data . . . on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed the risk criteria enumerated in the regulations issued under this Act, and on such other conditions as the Administrator may prescribe. A conditional registration . . . shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest." OPP believes that if these conditions cannot be met, neither type of registration is permissible.

Balancing the qualitative findings with the comparative product performance data, which had not been included in the January 1999 benefits assessment, OPP concludes that the benefits of chlorfenapyr may be somewhat lower than estimated in previous assessments. However, based on

the weight of the evidence, OPP continues to believe the benefits of chlorfenapyr to control beet armyworm may be in a range from moderate to high depending on the specific situation. Even if the benefits are assumed to be on the high end, OPP has determined that these benefits do not outweigh the risks that we believe would be posed by this chemical if registered as proposed. EPA has further concluded that widespread use of chlorfenapyr in accordance with the proposed label instructions would pose widespread risks to birds. These risks include serious impacts on avian reproduction in treated areas.

OPP continues to be concerned about chlorfenapyr's potential for adverse ecological effects, including terrestrial and aquatic effects, persistence and build-up in the environment following repeat applications and effects on threatened and endangered species. Refinements of the risk assessment, including a probabilistic risk assessment presented by the registrant have not reduced this concern. These findings have been confirmed by the Scientific Advisory Panel.

OPP therefore believes and recommends that you make the following findings at this time:

I. The ecological risks of chlorfenapyr use on cotton are extremely high.

II. The widespread use of chlorfenapyr on cotton as proposed by the registrant would pose widespread risks to birds. These risks include serious impacts on avian reproduction in treated areas..

III. The ecological risks of chlorfenapyr use on cotton outweigh its benefits.

IV. Chlorfenapyr does not meet the standard for registration under FIFRA Sec. 3, and

V. Therefore, the Agency should deny this application for registration.

Human Health. OPP is not recommending denial on human health grounds. Refer to Appendix 5 for a detailed discussion.

Other Concerns. OPP is mindful of its responsibilities under the Migratory Bird Treaty Act and the Bald and Golden Eagle Protection Act. The Endangered Species Act (ESA) prohibits takings of species designated by the Department of the Interior as endangered or threatened. Due to the serious reproductive risks posed by this chemical, OPP is concerned that threatened and endangered species would be harmed if chlorfenapyr were registered for use on cotton. OPP also believes that threatened and endangered species exist in cotton-growing states. Taken together, the provisions of these three statutes provide additional support for OPP's recommendation to deny this application for registration.

Outstanding Environmental Fate and Effects Data Requirements. A number of data requirements remain unfulfilled. Even if these data requirements were met, OPP believes that the environmental risk picture would not be improved. Based on the SAP review of the available data as

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decreased risk. Therefore, OPP believes it has sufficient data to recommend the denial of this registration. Appendix 6 contains a list of outstanding studies.

RECOMMENDATIONS. We recommend that you deny American Cyanamid's application for registration of chlorfenapyr for use on cotton in accordance with FIFRA section 3(c)(6). The Office of General Counsel has expressed the opinion that our recommended approach is legally defensible. Our analysis of the factors specified in section 3 of FIFRA is described below.

A. We believe that the data submitted by the applicant, OPP's review of that data, the peer review of submitted data, and OPP's consideration of peer review comments, support a decision to deny this application for registration.

B. Risk/Benefit Balancing. We have weighed the risks and benefits of the pesticide taking into account the economic, social, and environmental costs and benefits of the use of this chemical. We believe that the risks of this chemical for use on cotton outweigh its benefits. The applicant has not demonstrated that chlorfenapyr use on cotton will not cause unreasonable adverse effects. For the reasons listed above, we believe that chlorfenapyr does not meet the statutory requirements for registration under FIFRA Sec. 3. Therefore, we recommend that you deny this application for registration under FIFRA Section 3.

C. Public Interest Finding. We also believe that it is not in the public interest to register this chemical, as there are efficacious and less environmentally toxic alternatives.

✓ [Yes] After considering the above information and recommendations, I hereby determine that the risks of this chemical to the environment outweigh its benefits. In so doing, I determine that American Cyanamid's application for registration of chlorfenapyr for use on cotton should be denied. I will notify American Cyanamid of this decision.

____ [No] After considering the above information and recommendations, I have decided to grant American Cyanamid's application for registration of chlorfenapyr for use on cotton.

DATED: 3/13/00

Susan H. Wayland

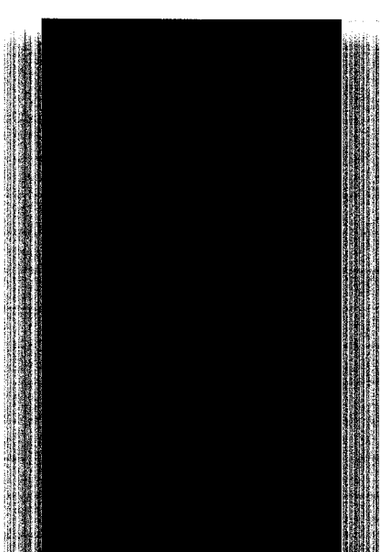
Susan H. Wayland, Acting Assistant Administrator
Office of Prevention, Pesticides, and Toxic Substances

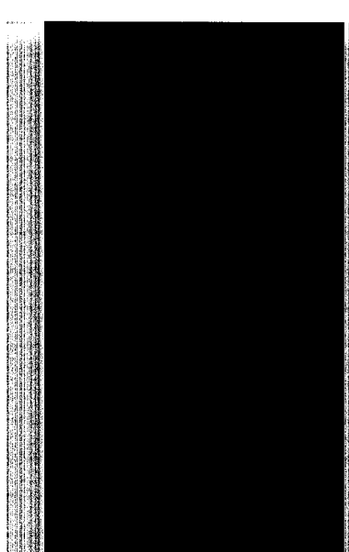
Attachments: Appendices with Table Attachments and Table of Federal Register Documents
Scientific Reviews
SAP Reports
Benefits Assessment

[redacted]

[redacted]

Appendices





Appendix 1

Ecological Effects: Since 1994, OPP has conducted several increasingly refined assessments of the risks to terrestrial and aquatic organisms resulting from chlorfenapyr use on cotton. Extensive data provided by American Cyanamid have been central to allowing OPP to move from generalized assumptions that are part of the screening level assessment to more complex and precise assessments of the potential ecological risks associated with this use.

OPP's most refined risk assessment (August, 1998) built upon previous OPP risk assessments for this chemical and use site, but incorporated proposed changes in chlorfenapyr labeling, additional exposure data, and refinements to the exposure modeling.

1. Hazard Identification. Chlorfenapyr is a member of the chemical family "pyrroles" and is the first pyrrole submitted for U.S. registration. Chlorfenapyr has a unique mode of action. It is a pro-insecticide that is converted (or metabolized) to the active form by mixed function oxidases (MFOs) in the target pest. The active form acts on the mitochondria and uncouples oxidative phosphorylation which stops the production of adenosine triphosphate (ATP), the primary source of cellular energy. This action causes cell death, and ultimately, death of the target organism, the insect. However, the interrupted metabolic process is common to all living organisms, and so is of concern for non-target organisms.

It appears that various species metabolize chlorfenapyr differently. For example, it appears that insects are more efficient in converting chlorfenapyr to its active form (and thus are more susceptible) than are vertebrate species. Data supplied by American Cyanamid for rats, goats, and poultry indicate that the active form is produced in all these species. However, there are differences in sensitivity to chlorfenapyr between mammals and birds. One possible explanation for this difference comes from metabolism data that show the active form is metabolized in mammals to compounds which are more water soluble (or excretable in urine), but in birds less of these soluble metabolites of the active form are found. This information does not suggest chlorfenapyr is not excreted from poultry, merely that the pathways for metabolism and elimination from the body may differ between mammals and birds. This explanation for differences in toxicity is tentative, as specific metabolic rates have not been researched for different species.

OPP uses ecological toxicology studies on select species to identify the toxicity to nontarget organisms, such as birds. Because of the persistence of chlorfenapyr (1.4 year half-life), repeat applications (2 applications permitted on label), and evidence that it can be found in avian food items, OPP required chronic toxicity studies for this compound. In a chronic toxicity study for birds, over a period of 22 weeks, the test species was subjected to continuous exposure to a pesticide at predetermined test levels, before and during its breeding season. The following biological effects (endpoints) are measured: eggs laid, eggs cracked, eggs set, viable embryos, live 3-week embryos, normal hatchlings, 14-day-old survivors, weights of 14 day old survivors, egg shell thickness, total food consumption, and initial and final body weights by sex. These measures

[redacted]

are statistically analyzed to determine the level of exposure at which no adverse effects were observed (NOAEL, or no observed adverse effect level) , and the threshold level at which adverse effects are observed (the LOAEL, or lowest observed adverse effect level).

In a chronic reproductive study using mallard ducks (the most sensitive species tested), four groups of birds were fed chlorfenapyr at concentrations of 0 (control group), 0.5, 1.5 and 2.5 ppm respectively in their diet. The no observed adverse effect level (NOAEL) was identified as 0.5 ppm and is the value used in the risk assessment. The lowest observed adverse effect level (LOAEL) for systemic effects was 1.5 ppm for reduced body weight in adult females. The lowest observed adverse effect concentration for reproductive effects was 2.5 ppm. At that level, there were significant differences in the 2.5 ppm group compared to the control group: total number of eggs laid (-41%), the number of eggs set (-42%) the number of viable embryos (immediately after laying) (-44%), the number of viable embryos at 21 days of age (just prior to hatch) (-33%), the number of normal hatchlings (-56%), the number of hatchlings surviving 14 days (-56%), and a decrease in body weight of adult males and females (males: -14%; females: -15%). The data upon which these results are based are presented in Table 1.

Table 1. Study of Chronic Reproduction in the Mallard: Mean (Average) Values for Specified Biological Effects (Endpoints) by Treatment Group

Biological Effect (Endpoint)	**Control Group**	**0.5 ppm Group NOAEL**	**1.5 ppm Group LOAEL**	**2.5 ppm Group LOAEL**
Eggs laid	50.75	49.25	35.28	30.13
Eggs set	47.31	44.75	31.86	27.38
Viable embryos	39.56	40.38	27.21	22.18
Live 3-week embryos	30.06	38.75	26.21	20.00
Normal hatchlings	33.00	31.88	21.14	14.50
14-day-old survivors	32.88	31.75	21.07	14.43
Final weight of males (grams)	1251.00	1207.44	1144.81	1072.06
Final weight of females (grams)	1155.75	1124.13	977.64	983.4

Unlike human health assessments, EPA does not use uncertainty factors to account for

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intraspecies or interspecies differences in sensitivity in ecological risk because conservative assumptions are supposed to be built into the models. If, however, OPP were to incorporate uncertainty factors, the assessment would be much more conservative, and the calculated risks would be much higher than described in this document. It is possible, and has been suggested by peer review, that there are bird species that were not tested that are more or less sensitive than the mallard duck.

2. Environmental Fate.

a. Persistence/Rate of Degradation. Chlorfenapyr's persistence is typified by a laboratory aerobic soil metabolism half-life of 1.4 years

b. Degradates. Because of the persistence of the parent compound and relatively short study durations, only small amounts of structurally similar metabolites or degradates, some of which exhibit ecotoxicity, were identified in soil, in field and lab studies.

c. Accumulation in the Physical Environment. Because of chlorfenapyr's persistence, uniform annual use in a given area would be expected to result in significant build-up in the environment. Further details on the fate and persistence of chlorfenapyr can be found in Appendix 2.

3. Exposure Characterization. The characterization of exposure is the area of the ecological risk assessment that has been most substantially refined over the course of the chlorfenapyr review. The initial risk assessment in 1994 used a standard screening-level exposure scenario commonly used in all OPP terrestrial exposure assessments. This standardized approach relies on pesticide residue data for wildlife food items and food item surrogates generated from numerous field studies and summarized by Hoerger and Kenaga (1972) and modified by Fletcher et al. (1994) [see August 1998 risk assessment for references]. This approach allows for a calculation of potential residue values on/in wildlife food and feed. The result is a single maximum residue concentration. The screening approach considered upper bound estimates of exposure to residues in wildlife food items (95th percentile). This conservative approach addresses uncertainty by providing for a wide margin between known effects and estimated exposure. The screening assessment, however, did not attempt to account for degradation/dissipation of chlorfenapyr residues in wildlife food items.

With the primary ecological risk focused on chlorfenapyr's persistence and avian reproduction effects, OPP risk assessors proceeded with additional exposure analyses that refined the risk assessment, using progressively less conservative assumptions. The next level of analysis substituted "typical" (50th percentile) food item residue values for the upper bound value. A 50th percentile assumption may be more typical exposure scenario; it reflects mean or average exposure. It is less conservative than a 95th percentile exposure. However, even when the conservative assumptions are replaced with less conservative/less protective assumptions, the results for chlorfenapyr still substantially exceeded levels of concern.

The analysis was further refined as follows: Although chlorfenapyr is a persistent

[redacted]

compound, OPP expected that some level of dilution/dissipation could occur in the environment. Therefore, an exposure characterization that would provide for some assumed level of dilution/dissipation was tested. A "ubiquitous soil model" was devised as an exposure scenario in an effort to account for field dilution/dissipation of chlorfenapyr residues. This model accounted for dilution and dissipation by assuming that the avian diet was contaminated at a level that was equal to that accumulated in soil. The level was assumed to be equivalent to the application amount of pesticide evenly dispersed in a 15 cm depth of soil plus residual carryover (based on a range of half-lives in soil) from previous years of application (present years application + previous accumulated value/15 cm soil). This resulted in exposure values in the range of 0.7-1.4 ppm in the avian diet. These exposure values were then compared to the reproduction toxicity threshold (0.5 ppm). Again, the results substantially exceeded levels of concern. American Cyanamid suggested that the exposure values still substantially overestimated true wildlife exposure in the field. Accordingly, American Cyanamid undertook studies to better estimate chlorfenapyr persistence in soil and residues in wildlife food items.

American Cyanamid has provided actual residue data for chlorfenapyr in avian food items, including weed seeds, weed seed heads, and insects (both adults and larvae). [MRIDs 444526-08 and 444642-01]. These measured residues in avian food items were an important component of the exposure estimation models used in the current August 1998 OPP risk assessment.

Much of the registrant's wildlife food item residue data reflected multiple applications of the compound at rates that would exceed the proposed application rates. In order to use these data in a manner that would not be overly conservative, residue data were normalized to application rate for tested rates that were closest to label rates and limited to only those consecutive applications that would be in compliance with the proposed labels. This avoided situations where modeled exposures would have been based on unrealistic application scenarios. Thus, the actual duration of residue monitoring was truncated to one, two, or three weeks, depending upon the tested application rate. This therefore limited the duration of exposure modeling, which was truncated to a maximum of 4 weeks following initial pesticide application.

Food intake rates were calculated for bird species known to be in cotton fields (on the basis of registrant-supplied avian census data (MRIDs 444642-02 and 444526-16). The mixtures of food items comprising the diet were species-specific. Exposures were calculated based on caloric intake necessary for normal avian activity. Calculated exposures for assessment of reproduction risks assumed either 100 % or 10 % of the avian diet originating from the fields. The 10 % assumption was based on the frequency of observations of birds in cotton fields from census data on sites across the Cotton Belt region of the United States. (Subsequently, based on the recommendation of the September, 1999 Scientific Advisory Panel (SAP), an assumption was added that 50% of the diet originated in cotton fields. This assumption is not incorporated in the August 1998 risk assessment).

OPP recognized that the assumption of 100% of diet originating in cotton fields was likely to be conservative for long-term exposures associated with observed reproductive effects. The avian census data showed that avian use of Arizona fields ranged from 60% to 69% of

observations. In Texas, avian use ranged from 21% to 27% of observations. Use of Alabama and Mississippi fields ranged from 11% to 24% of observations. In a field study performed to investigate the acute effects of chlorfenapyr treatment of cotton on birds (MRID 444526-16), birds occurred in chlorfenapyr treated and untreated fields for a total of 13% of the observations. These data do not provide sufficient information on the actual proportions of avian diet that originate in cotton fields. It is possible birds may actually consume food from cotton fields at a greater or lesser rate than these numbers may indicate. However, for the purpose of evaluating the impact of data concerning avian use of fields on the outcome of the risk assessment an assumed minimum proportion of the avian diet (10%) from treated cotton fields was used. This assumption of 10% is lower than the minimum number of observations of birds in cotton fields. Note that this does not include contribution of chlorfenapyr residues from off-field food sources contaminated by drift. (At the recommendation of the September 1999 Scientific Advisory Panel (SAP), OPP also included an assumption that 50% of diet comes from cotton fields).

4. Risk Conclusions. OPP used risk quotients (RQs) to measure risk. A risk quotient compares the level of exposure (generally the levels of pesticide residue in the diet) to the critical toxicity concentration (the highest concentration at which toxicity does not occur -- the "no observed adverse effect concentration or level" (NOAEC or NOAEL) set forth in the hazard identification). This is expressed as set forth below:

$$RQ = \frac{\text{exposure level}}{\text{toxicological endpoint NOAEL}}$$

Risk quotients are then compared to OPP's established Levels of Concern (LOCs). These levels of concern are critical values indicating potential risk to nontarget organisms, such as birds. When risk quotients exceed the levels of concern, the potential exists for risk to nontarget organisms. More specifically, the criteria indicate whether a pesticide, when used as directed, has the potential to cause adverse effects to nontarget organisms. For birds, the level of concern for chronic effects is equal to or greater than "1". This means that the level of pesticide residues that the birds consume is equal to or greater than the highest dose or level at which no effects were observed.

For chlorfenapyr, the no observed adverse effect concentration from the mallard duck reproduction study (0.5 ppm, converted to 0.059 mg/kg-bw/day) was compared to exposures resulting from residues in the estimated diets of several species of birds known to inhabit cotton fields. Sample results of the risk assessment for uses of chlorfenapyr on cotton are presented below in Table 2 using the white-eyed vireo. Of the species investigated for this risk assessment, the white-eyed vireo had the highest potential for exposure.

Table 2. Reproductive Risk Quotients for the White-eyed Vireo: by how much does Dietary Exposure exceed the "No Observed Adverse Effect Level," assuming varying percentages of the diet come from treated cotton fields

Days After 1st Treatment	Reproduction RQ (using 0.2 lb ai/A x 2 applications) and a NOAEL of 0.059 mg/kg-bwt/day		
	100% of diet from treated cotton field	50% of diet from treated cotton field*	10% of diet from treated cotton field*
0.1	52.77	26.39	5.28
3.1	16.80	8.40	1.68
7	9.03	4.52	0.90
7.1	67.60	33.80	6.76
14	20.53	10.27	2.05

* assumes no chlorfenapyr residues in off-field food items (i.e., no drift of chemical off treated field)

Table 2 shows that dietary residues associated with an application rate typical for beet armyworm substantially exceed the NOAEL for reproductive effects. Predicted dietary exposure levels (based on measured residues in avian food items) for a typical application rate exceed the threshold for reproductive effects for one species, the white eyed vireo, by 68 times the threshold level. These exposure estimates were based on measured data for 14 days (the limit of the measured data available to OPP from field studies with applications typical for certain cotton pests). However, the rates of decline for chlorfenapyr in bird food items suggest that, for application rates typical for pests in cotton, the dietary exposure may exceed toxicological thresholds for birds for up to five weeks after initial chlorfenapyr application. Even when assumed use of cotton fields by birds is reduced to below those demonstrated from cotton field data (i.e., assumptions of 50% and 10% of diet originating from cotton fields), risks to reproduction still exceed levels of concern in many instances. In addition, the reproduction toxicology data was based on a study using the mallard duck as the test species.

Table 3. Reproductive Risk Quotients: by how much does Dietary Exposure exceed the "Lowest Observed Adverse Effect Level," assuming varying percentages of the diet come from treated cotton fields: White-Eyed Vireo

Days After 1st Treatment	Reproduction RQ (using 0.2 lb ai/A x 2 applications) and a LOAEL of 0.24 mg/kg-bw/day*		
	100% of diet from treated cotton field	50% of diet from treated cotton field**	10% of diet from treated cotton field**
0.1	12.96	6.48	1.30

Days After 1st Treatment	Reproduction RQ (using 0.2 lb ai/A x 2 applications) and a LOAEL of 0.24 mg/kg-bw/day*		
3.1	4.13	2.06	0.41
7	2.21	1.10	0.22
7.1	16.63	8.31	1.66
14	5.04	2.52	0.50

* 0.24 mg.kg-bw/day = $\frac{\text{(LOAEL of 1.5 mg/kg-diet)(mean food consumption of 0.16225 kg/day)}}{\text{mean body weight of 1.03448 kg}}$

** assumes no chlorfenapyr residues in off-field food items (e.g., no drift of chemical off treated field)

Table 3 shows that in most instances, dietary exposures exceed levels at which reproductive effects have been observed.[1]

Our confidence in the present avian risk findings is greater than in previous assessments because the recent assessment utilized less conservative assumptions than previous assessments regarding potential exposure, but nonetheless continued to indicate that avian species will likely be exposed to amounts of chlorfenapyr that will cause serious adverse effects.

The current assessment incorporated the following:

- measured residue values in seeds, insects, and forage
- assessment of risks to specific species known to occur in cotton fields, including species-specific considerations of life history information, dietary preferences, and metabolic requirements
- incorporation of information specific to the use of cotton fields as a food resource by wildlife
- use of conservative and less conservative (less protective) assumptions. These assumptions are discussed below.

The following are the conservative exposure parameter values and assumptions used in the August 1998 assessment:

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[1]Tables 2 and 3 represent information and analysis that go beyond the August 1998 risk assessment.

- Maximum lepidopteran larvae residues used in exposure (however, not the highest possible insect residues from available information). The peak residue values for adult beet armyworm moths measured in these studies were higher than the measured levels for larvae. Furthermore, data provided by the registrant regarding insect residues for other pesticide applications suggest that the maximum residues used in the exposure model were within the upper bounds of these other data sets.

- 100% of diet from cotton field

- Use of seed residue data as surrogate for fruit residues (consistent with other OPP exposure assessment approaches, no data on weed fruits available). The July SAP agreed with the Agency that large fruits are not useful surrogates.

The less conservative assumptions in the August 1998 assessment are as follows:

- An assumption of 10% of diet from treated fields still poses reproduction risks

- Use of composite weed seed residues for exposure (no accounting for acute effects associated with hot-spots)

- No adjustment of toxicity endpoints for nestlings that may be more sensitive than adults.

- No adjustment of toxicity endpoints for inter-species differences in sensitivity

- Use of mean biological parameters in exposure models (body weights, metabolic requirements, food intake rates)

- No quantitation of dietary exposure from soil invertebrates in the diet

- No quantitation of other exposure routes (dermal, inhalation, drinking water)

- No quantitation of the contributions of multiple year residues to exposure (single season exposure only)

- No quantitation of additional toxicological risks from biologically active metabolites known to occur in soil and in insects.

The confidence in the August 1998 ecological risk assessment was enhanced by the FIFRA SAP who indicated that the Agency had done a good job of characterizing the potential risk of chlorfenapyr to birds.

OPP's concerns regarding the risks of chlorfenapyr use on cotton to birds are based on the following issues:

- **Chlorfenapyr disrupts energy production in insects and very likely disrupts energy production in birds and other non-target animals:** Chlorfenapyr is a pyrrole insecticide-miticide that kills insects by disrupting energy production at the cellular level. Laboratory testing has shown that the chemical causes a wide variety of reproductive effects in birds. It is likely that these effects in birds are occurring as a result of disruption of energy production at critical periods in egg production, embryo formation, and hatchling development.

- **Chlorfenapyr causes a wide variety of significant reproductive effects in birds:** Laboratory testing of mallard ducks and bobwhite quail show reduced eggs laid, reduced viable embryos, reduced embryo survival, reduced normal hatchlings and reduced hatchling survival -- all associated with exposure to chlorfenapyr. These effects occurred at very low concentrations of chlorfenapyr in the diet.

- **Chlorfenapyr is persistent, environmental levels will build up quickly in the environment:** The half-life of chlorfenapyr in soil is more than one year. OPP has concerns for pesticides with such persistence, particularly in light of accurately predicting the full extent of on-site accumulation and off-site transport. To the extent that predictions of on-site accumulation can be made, environmental levels of chlorfenapyr can be expected to reach levels approximately two and ½ half times the annual application rate after only a few years of continued use.

- **Chlorfenapyr residues have been measured in avian food items:** The applicant has provided data regarding the concentrations of chlorfenapyr in avian food items including adult and larval insects, weed seeds, weed seed heads, and forage from treated areas. These data show that chlorfenapyr is detectable in avian food items on the day of application and that residues in potentially toxic concentrations persist following application.

- **Chlorfenapyr residues in food items are well in excess of levels that could produce adverse effects on bird reproduction:** A comparison of the threshold for reproductive effects in birds with residues in avian food items indicated that for all application scenarios proposed by product labels, dietary exposure would exceed levels required for reproduction impairment. Furthermore, the pattern of decline of chlorfenapyr residues in food items suggested that dietary exposures would exceed thresholds for reproduction impairment following a single application. Multiple applications, as allowed on the label, would extend the period over which residues would be above reproduction effects thresholds to many weeks.

- **Birds are associated with cotton fields and surrounding habitats:** The applicant has provided avian census data for cotton agroenvironments (the cotton field and surrounding habitat) in Arizona, Texas, and the Southeastern U.S. These data show more than 130 bird species occur within cotton fields or in an area within 50 meters of the field edge.

- **Birds use cotton fields and have been observed to feed in these fields:** The applicant-supplied avian census data of cotton agroenvironments show birds actually occurring within the planted portions of cotton fields. In Arizona, 60% to 69% of observations in cotton agroenvironments were for birds in the actual cotton field. Similarly, in Texas, bird observations in actual cotton fields ranged from 21% to 27% of observations while in Alabama and Mississippi fields observations of birds in the planted cotton ranged from 11% to 24% of observations. These avian census data primarily are concerned with presence or absence of species within fields and surrounding buffer. However, there are data for 72 hours of observation of bird activities within the planted portions of the cotton fields. In both Arizona and southeastern cotton field sites, perching and foraging accounted for more than 50% of the observations. In Texas, foraging activities comprised 35% of the observations.

  In a field study performed to investigate the acute effects of chlorfenapyr treatment of cotton on birds, birds occurred in chlorfenapyr-treated and untreated cotton fields for a total of 13% of the observations made. Chlorfenapyr treatment had no impact on the degree to which cotton fields were used by birds. Observations from this study indicated that cardinals and morning doves were actively seeking patches of weeds within the cotton crop and the authors concluded that the birds were feeding on Johnson grass seed dropped on the soil.

- **Even assumption of minimal field use by birds does not eliminate concerns for reproductive effects:** A large variety of avian species use cotton fields with appreciable frequency and the observed instances of bird use of cotton fields include a substantial number of foraging behavior observations. However, the available avian census data do not provide sufficient information on the actual proportions of a bird's diet that is obtained from cotton fields. It is possible that cotton fields may contribute to avian diets out of proportion to the time birds have been observed in the fields. It is also possible that pest outbreaks in cotton fields may result in higher foraging rates in cotton fields. However, for the purposes of evaluating the impact of data concerning avian use of fields on the outcome of the risk assessment, an assumed minimum proportion of the avian diet of 10% from treated cotton fields was used to test the impacts on calculations of avian chronic Risk Quotients ("RQs"). This assumption of 10% is lower than the minimum number of observations of birds in cotton fields (11% to13% as reported in the applicant's avian census data.). To simplify the evaluation of avian use effects on risk assessment, no contributions of chlorfenapyr residues from off-field food sources contaminated by drift were included in the recalculation of avian RQs.

  Reducing the intake of food from treated fields to 10% of the total diet and assuming all off-field dietary residues are zero, still resulted in dietary doses that exceed the chronic level of concern for the proposed label application rates.

  It must be stressed that an assumed 10% factor for the proportion of bird diet originating from treated cotton field areas is lower than all avian census data reported by the applicant

and does not account for the presence of chlorfenapyr residues in avian food resources in off-field habitats.

- **Routes of exposure in addition to diet and chlorfenapyr metabolites may contribute to risk:** Because of considerations of dietary exposures only, the actual exposure of a given bird in a treated cotton field could be higher than estimated in OPP's risk assessment. If evaluated, we believe the combined burdens associated with dermal, inhalation, and drinking water exposures would have increased the potential risk for birds in and around cotton fields treated with chlorfenapyr. Furthermore, the available residue data in wildlife food items do not include measurements of chlorfenapyr metabolites of known toxicity to non-target organisms. It has been suggested that exposure to chlorfenapyr metabolites may also increase the risks to birds in and around treated cotton fields.

- **Chlorfenapyr application periods coincide with avian reproduction periods**: The applicant provided information on the reproduction periods of all avian species reported to occur in cotton fields. These reproduction periods are likely to coincide with time of chlorfenapyr application to cotton fields. For southern cotton fields (Texas and eastward), 37 species are profiled, with 33 species (89%) exhibiting egg laying and/or nestling periods overlapping with the proposed time period for chlorfenapyr application. For the southern United States cotton areas and windows for application to control mites, 33 species were profiled, with the species' egg-laying and/or nestling periods overlapping the mite-control application window. For western cotton fields, 34 species were profiled, with the species' egg-laying and/or nestling periods overlapping the mite-control application window, and 31 species (91%) with egg-laying and/or nestling periods overlapping the armyworm-control application window.

  The applicant argued that much of this overlap of reproductive periods with chlorfenapyr application periods is for second and third clutching attempts by birds, and suggested that effects at these periods may not be ecologically important. However, other information presented by the applicant states that standard cotton agricultural practice in the early season (i.e., early cultivation for weed control) is likely to cause a large number of nest failures or abandonments. It is therefore logical to expect that second and third clutch attempts at reproduction would be ecologically significant in the face of early reproduction disruption.

- **Populations of many bird species in states where cotton is grown are declining:** Although specific causes cannot be identified in all cases, available data from the United States Biological Survey for bird populations indicates that many species have declining trends in states where cotton is grown. OPP is concerned that introduction of pesticide chemicals with demonstrable effects of bird reproduction, may further stress bird populations in areas where chemical exposure is in excess of levels required for reproduction impairment.

- In addition to toxicity to birds, chlorfenapyr is highly toxic to honeybee and small

mammals using cotton fields as sources of dietary materials also may be at risk for reproductive impairment and mortality.

The aquatic risk characterization from the August 1998 risk assessment for aquatic effects is summarized below:

- Using water column estimates of chlorfenapyr concentrations, chlorfenapyr applications to cotton present acute risks to freshwater fish and invertebrates in cotton growing regions.
- Acute and chronic risks are predicted for estuarine and marine organisms.
- Through the screening level assessment, there appears to be a high acute risk for freshwater fish and freshwater invertebrates.
- Data and risk profiles taken together indicate a high potential for fish kills and depletion of invertebrate communities to occur in waterways near treated fields.

Other Ecological Concerns

OPP also has concerns for acute avian exposure and concerns for acute and chronic exposures for certain aquatic, sediment dwelling, estuarine, and marine organisms. These concerns are based largely on the persistence of the chemical in aquatic environments, and a concern for potential accumulation in invertebrates. There are a number of data gaps for these scenarios and the uncertainty surrounding any estimates is very large.

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Appendix 2

Endangered Species Risk Characterization. The Fish and Wildlife Service (FWS) has reviewed the Agency's risk assessment and in a letter dated 12/21/1999 concluded as follows:

- FWS expressed concern about risks to nontarget organisms, including insect pollinators, reptiles and amphibians, waterfowl, shore birds, raptors, and insect pollinators and threatened and endangered species, and a lack of information to adequately address these concerns.

- The FWS's greatest concern is the risk that chlorfenapyr use on cotton poses to birds for acute and chronic effects, including reproduction impairment. In addition, residual concentrations may exceed thresholds for reproductive effects for several weeks following application. The FWS finds this particularly worrisome in view of the fact that more than 510 species of birds are known to occur in cottonbelt states and may forage in cotton fields. FWS states that even minimal time in treated cotton fields could result in adverse impacts on birds.

- The persistence and potential for surface runoff of parent chlorfenapyr and its degradates heighten concerns for waterfowl and shorebirds and raptors which may be exposed through contaminated prey.

Appendix 3

External Review of OPP's Ecological Risk Assessment and American Cyanamid's Probabilistic Risk Assessment

The applicant has argued that OPP's risk assessment overestimated the likelihood of exposures that would cause avian reproductive effects. In response, OPP asked the FIFRA Scientific Advisory Panel (SAP) to review OPP's risk assessment.

The SAP was composed of several internationally recognized experts in fields such as statistics, avian and aquatic biology as well as probabilistic risk assessment. The SAP held two meetings to discuss and evaluate OPP's risk assessment as well as the applicant's probabilistic assessment. The July 1999 meeting reviewed OPP's risk assessment and the September 1999 meeting reviewed the applicant's probabilistic assessment. The SAP generally agreed with OPP's assessment and conclusions concerning the probabilistic assessment.

The following summarizes the July SAP meeting and panel members' concerns:

- The use of residue data for weed seeds, seed heads, insects, and forage in OPP's exposure calculations for assessing bird risks were technically appropriate. The SAP suggested that this data may underestimate insect residues, subsequent bird exposures from consumption of these insects, and bird risks.

- Degradates and metabolites of chlorfenapyr were not evaluated (this would have likely increased the overall bird exposure to chlorfenapyr and toxicologically significant metabolites).

- The lower bound assumption that 10% of bird diet originates from the treated areas of cotton agroenvironments may be an underestimate. The SAP suggested that a higher assumption of the diet originating from cotton field areas might be appropriate (such as 50% of the diet from treated field areas). This would increase the predicted bird exposure levels.

- OPP's exposure estimate did not account for drift of chlorfenapyr from the treatment site on cotton fields to adjacent habitats. OPP lower bound assumption of zero residues in adjacent habitats should be modified to include residue scenarios for habitat areas adjacent to treated fields. This would increase the predicted bird exposure levels.

- OPP's assumptions for the food intake for birds did not consider the potential for gorging behavior (short-term consumption of food at levels higher than the typical daily intake), nor did OPP's food intake assumptions consider potentially higher food intakes by young. Incorporation of these higher food intake rates would increase the predicted bird exposure

levels.

- OPP's assessment quantified exposures from consumed residues from food intakes. Dermal contact and drinking water exposures were not quantified. Incorporation of these other routes of exposure would likely increase the predicted bird exposure levels.

In summary, the comments suggest that OPP's assessment may have underestimated risk. There has not been a refined assessment performed since the SAP meetings, accordingly, the risks to avian species are likely higher than stated in this document.

The September SAP concluded that American Cyanamid's conclusion of negligible risk is not supported for any geographic scale. For more detail on the SAP's conclusions for both meetings, refer to SAP Report No. 99-04C and SAP Report No. 99-05E. Refer to Appendix 4 for a more detailed breakdown of suggested data and OPP's approximation on the length of time to complete the studies.

The SAP indicated that additional data would be needed, as follows:

- Additional residue data for dietary items, collected from several regions (about 2 years to complete).

- Additional data on wildlife use of cotton fields (about 2 years to complete).

- Actual measures of wildlife exposure from dietary analysis (about 2 years to complete).

- Dose response data for reproduction effects (more than 2 years to complete).

During the discussions about probabilistic risk assessment, OPP also refined its approach to problem formulation for avian risk assessment. OPP has concluded that probabilistic risk assessment may have many steps. The first step would be to calculate risk at a small scale, that is, at the field or community level. If the conclusion is that the probability that significant effects are not likely at the local or field level, then no larger scale risk assessments are necessary. However, if the assessment concludes that the probability that significant effects on local bird populations are likely to occur at the field level, then it may be appropriate to conduct a risk assessment at a broader scale, that is at the state or regional level. OPP may, however, regulate at the field level, especially when threatened and endangered species may be affected.

Appendix 4

Events that brought about the issuance of Section 18 for Beet armyworm Control. The repeated use of malathion in the boll weevil eradication program, and the intense use of organophosphate insecticides prior to the inception of this program, is believed to have caused a sufficient decline in the cotton eco-system predator and parasite populations that reduced their effectiveness in controlling lepidopterous cotton pests, including beet armyworm.

The boll weevil eradication program has affected predatory organisms, which would normally control the beet armyworm, for the following reasons. Malathion, the chemical used in the boll weevil eradication program, is applied at ultra low volume in oil sprays which can drift to nontarget areas that act as reservoir for parasites and predators. In addition, the boll weevil eradication program calls for all fields in an area to be treated even if treatment is concurrent with other insecticide applications.

The beet armyworm was not a significant economic pest prior to the first full season of boll weevil eradication in 1988. Not a single field has had economic levels of beet armyworm infestations since area-wide applications of insecticides in the boll weevil eradication program were reduced after the 1995 season. Many cotton growers and experts believe that drought is the primary factor causing beet armyworm outbreaks. Extreme drought has occurred in the deep sandy soils of southeast Alabama in both 1996 and 1997, but no outbreaks occurred, leading OPP to believe that it is the boll weevil eradication program which largely influences the beet armyworm.

Under present conditions, the beet armyworm is not expected to be an economic pest of cotton in the southeastern United States in the foreseeable future. The beet armyworm is a secondary pest resulting from intense organophosphate insecticide usage (such as used in the boll weevil eradication program), and it will likely be almost nonexistent after the boll weevil eradication program ends. The beet armyworm disappeared following the reduction of organophosphate usage after completion of the boll weevil eradication program in the southeastern states. Several other armyworm species and insects are being detected in fields under this reduced insecticide input regime, but most of these have little or no potential to become economic pests.

OPP knows that the cotton producing states in the mid-south- Louisiana, Mississippi, Arkansas, Texas, Oklahoma and Tennessee- will soon engage in the boll weevil eradication program, and will face the potential threat from beet armyworm outbreaks. OPP also recognizes that the oil mixed, ULV-applied Malathion, used in the eradication program, poses a threat to the reservoirs of beneficial arthropods in the cotton agro-ecosystem.

Appendix 5

Human Health. OPP completed a risk assessment for chlorfenapyr use on cotton. OPP made the requisite FQPA finding. Human health risks do not exceed levels of concern. Occupational exposures also did not exceed levels of concern. A developmental neurotoxicity study was required. To date the applicant has not submitted a developmental neurotoxicity study. The findings are summarized below.

Chlorfenapyr has been used on cotton under the authority of Sec. 18 of FIFRA. A time limited tolerance, which expires January 31, 2001, has been established under Sec. 408 of FFDCA to accommodate the emergency exemption use.

Human health risk assessments have been completed for cotton and for citrus and are summarized below. A chronic dietary exposure analysis for cotton and citrus showed that exposure for non-nursing infants less than 1 year old (the subgroup with the highest exposure) would be 26% of the RfD, while the exposure for the general U.S. population would be 12% of the RfD. The combined exposure of chronic dietary and drinking water exposure to chlorfenapyr residues resulting from cotton and citrus use would be no greater than 100% of the RfD for children or the general U.S. population.

Based on the existing toxicological database for chlorfenapyr, the acute dietary level of concern has been established at Margins of Exposure (MOEs) below 1000. For use of chlorfenapyr, acute dietary MOEs ranged from 4,500 to 9,000. Potential residues in drinking water (resulting from use on cotton and citrus) are not above levels of concern.

FQPA findings. As required by FQPA, OPP has made a determination of safety for the U.S. Population, Infants, and Children and has concluded that there is a reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to chlorfenapyr residues (cotton and citrus use). OPP relied on the following information to reach this conclusion: The percentage of the RfD that will be utilized by chronic dietary (food only) exposure to residues of chlorfenapyr ranges from 5 percent for nursing infants less than one year old, up to 26 percent non-nursing infants less than one year old. Despite the potential for exposure to chlorfenapyr in drinking water, OPP does not expect the chronic aggregate exposure to exceed 100% of the RfD. Since there are no residential uses of chlorfenapyr, no chronic residential exposure is anticipated.

OPP has further concluded that there is a reasonable certainty that no harm will result to infants and children from acute aggregate exposure to chlorfenapyr residues. The acute dietary (food only) MOE for females 13+ years old (accounts for both maternal and fetal exposure) is

4500. This risk assessment assumed 100% crop treated for all treated crops consumed, resulting in a significant over-estimate of dietary exposure. Despite the potential for exposure to chlorfenapyr in drinking water, OPP does not expect the acute aggregate exposure to exceed the level of concern. The large acute dietary MOE calculated for females 13+ years old provides assurance that there is a reasonable certainty of no harm for both females 13+ years and the pre-natal development of infants.

For chlorfenapyr, acceptable prenatal toxicity studies in rats and rabbits have been submitted to OPP. There are no data gaps for the assessment of the effects of chlorfenapyr following *in utero* exposure. However, a developmental neurotoxicity study has been required. An acceptable reproductive toxicity study in rats with chlorfenapyr is also available. There are no data gaps for the assessment of the effects of chlorfenapyr to young animals following early postnatal exposure. The existing data demonstrated no indication of increased sensitivity of rats and/or rabbits to in utero exposure to chlorfenapyr. The no observed adverse effect levels for maternal toxicity (in the existing developmental studies) were always less than or equal to the no observed adverse effect levels for fetal toxicity. The existing data demonstrated no indication of increased sensitivity of rats and/or rabbits to early post natal exposure to chlorfenapyr. The no observed adverse effect levels for systemic toxicity was always less than the no observed adverse effect levels for reproductive toxicity. However, since this chemical has a demonstrated potential for central nervous system lesions, OPP determined that there was inadequate evidence to be sure that increased sensitivity to infants or children did not exist.

OPP determined that for chlorfenapyr, the additional 10-fold FQPA Factor for the protection of infants and children should be retained for lack of understanding of the cause, and possible further unknown neurotoxicity with regard to the developing young. OPP considered that "unusual toxic properties raise concerns regarding the adequacy of the standard (i.e., 100-fold) margin/factor." OPP has required that a developmental neurotoxicity study be conducted based upon the effects of a spongyform myelopathy and/or vacuolation seen in the brain and spinal cord of treated rats and mice.

Health Effects Characteristics. The toxicology data base is complete. However, because of concerns about some nervous system effects seen in submitted studies, the registrant has been required to submit a developmental neurotoxicity study. The results of the hazard assessment are summarized below.

Carcinogenicity. The carcinogenicity of this chemical has been found to be "cannot be determined, suggestive." This determination is based on increases in tumors that occurred in the rat only. The evidence was not considered to be persuasive but could not be dismissed. In addition, the acceptable doses for the RfD would provide adequate protection for a cancer risk if it exists.

Other chronic effects. For other chronic effects, a Reference Dose (RfD) has been

established at 0.003 mg/kg/day based on decreased body weight gains and brain lesions (vacuolation) observed in the 1-year rat neurotoxicity study. An uncertainty factor (UF) of 1000 was applied to account for interspecies extrapolation, intraspecies variability and the additional FQPA Factor of 10. The FQPA factor has been retained because chlorfenapyr has produced central nervous system lesions in several studies in both rats and mice. It will be reevaluated after the developmental neurotoxicity study has been submitted.

Acute effects. The end point of concern (lethargy in males) for acute dietary risk assessment was taken from the acute neurotoxicity study in rats. An uncertainty factor (UF) of 1000 is based on 100 to account for interspecies extrapolation and intraspecies variability plus the 10-fold FQPA Factor described above.

Appendix 6

Outstanding Ecological Data Requirements

- Analytical methods validations. The applicant did not submit soil and water methods of analysis suitable for detecting about one-tenth of the trace concentrations with observed ecological effects for OPP laboratory validation. Using this criterion, present procedures for water need to be improved by a factor of five or ten for sensitive species. Additionally, depending on marine, chronic sediment toxicity testing, improvements for sediment/soil may be necessary.

- Spray drift data [Droplet Size Spectrum and Drift Field Evaluation]: The applicant had the option to satisfy requirements through the Spray Drift Task Force according to PR Notice 90-3.

- Modified avian reproduction test data: In an April 1998 oral presentation before OPP, the registrant presented preliminary results of an avian reproduction toxicity test that utilized a modified exposure regime. This study used variable dietary concentrations to simulate the decreasing concentrations of chlorfenapyr observed for weed seed head, cotton plant, and insect residues. The oral presentation of the resultant data suggested that some information from the study may be applicable to assessing the risks of field residues of chlorfenapyr to avian reproduction. However, written presentation of these data was not submitted to OPP.

- Chronic sediment toxicity testing: At the time OPP requested sediment toxicity testing, the only protocol which had been fully developed was a 10-day acute sediment toxicity test. However, OPP now has developed a guideline protocol for a 28-day chronic sediment testing. Although specific criteria for a chronic toxicity test have yet to be published, one criterion would include the persistence of the compound. Because chlorfenapyr has been characterized as an extremely persistent compound, OPP would have required a chronic sediment toxicity test with freshwater invertebrates. Furthermore, because of the risk assessment indicates the potential for acute toxic effects in marine/estuarine sediment-dwelling invertebrates, a chronic toxicity test with these organisms was also required.

Other toxicity testing: Invalid acute and/or chronic aquatic tests:

- LC50 Rainbow trout Optional. Invalid test due to failure to measure test concentration on photolytic degradate (Cl 357,806). The LC50 of 2.6 ppb implies that this compound is more toxic than the parent.

- EC50 Oyster Shell Deposition Study. Invalid study due to inadequate shell growth in controls. An embryo-larvae study was not conducted.

- Sheepshead minnow Early life (marine/estuarine). Invalid study due to low Dissolved Oxygen level throughout the experiment. The required fish full life-cycle study listed directly below would have satisfied this requirement.

- Sheepshead minnow Life-cycle Study. The EEC is greater than 0.1 of the NOEL in the fish early life and invertebrate Life-Cycle study. The studies submitted should have been repeated due to control contamination. It should be noted that limited tests were performed on two different degradates of AC 303,630. The major degradate CL 312,094 (the *des*-bromo derivative of AC 303,630), was tested only on bluegill sunfish. The photolytic degradate in water, CL 357,806, however, was tested on rainbow trout and Daphnia magna. The purpose of testing these two degradates on different species was not revealed in any of the material submitted. The registrant should have explained this selectivity before conducting additional testing on degradates.

Appendix 7

The applicant proposed mitigation measures through revised labels dated December 1997 and April 1999. Most of the proposed measures are designed to mitigate or reduce direct acute concerns associated with chlorfenapyr use, although they may also affect chronic concerns. OPP considered these mitigation measures. OPP believes that the field residue data show that these mitigation measures still yield avian dietary exposure estimates that exceed chronic toxicity thresholds for birds. In addition, the nature of the concern -- chronic reproductive effects combined with the persistence of chlorfenapyr -- make this a difficult problem to mitigate. Based on our analyses, OPP believes the above mitigation measures will have a limited effect on the risks posed by chlorfenapyr.

The applicant proposed the following risk mitigation measures on a proposed label dated December 1997:

- Restricted use Pesticide. The registrant has proposed that the product be "Restricted Use" due to aquatic and avian concerns. As a restricted use product, it could be applied only by certified applicators.

- Drift and runoff hazard statements. To limit drift and runoff to water bodies, the user would be directed to avoid inadvertent application to water.

- Bee statement. Since this product is toxic to bees, the user is directed to take measures to avoid exposing bees.

- Endangered Species. The user would be directed to avoid use in areas where threatened or endangered species are likely to be, and to notify authorities and American Cyanamid if adverse environmental effects are observed.

- Economic thresholds. The proposed label states that application should not begin until target pest populations have reached local economic threshold levels. The user should consult with the Cooperative Extension Service or crop advisor to determine recognized local economic threshold levels. The directions for use for beet armyworm specify applications only after an economic threshold, such as 5 active "hits" per 100 row feet, is met. For tobacco budworm, higher rates should be used only when pest pressure is heavy or large larvae (greater than 1/4 inch) predominate.

- Resistance and Pest Management statement. Directions are included to use in a pest management program which coordinates different chemical classes of insecticides in spray schedules, provides thorough coverage of targeted crops and pests, uses proper chemical rates per label directions, and monitors pest populations.

- Pests. For states other than California and Arizona the label lists four species of spider mites, beet armyworm and tobacco budworm and cotton bollworm. Loopers and other

armyworms are listed as secondary, not primary, pests (if they are present in the field at time of application for control of tobacco budworm and cotton bollworm, they also will be controlled). The label for use in California and Arizona is similar.

Additional mitigation was proposed in a Sec. 3 label dated April 1999.

- Label language stating that the product must not be used in areas where impact on threatened or endangered species is likely. Applicators would be directed to contact the U.S. Fish & Wildlife Service to determine whether occupied habitat for any listed species is located on or adjacent to the property to be treated with chlorfenapyr. Application was prohibited within one mile of bald eagle nests, within 100 yards for ground application and 1/4 mile for aerial application for other terrestrial endangered species. Application prohibited within one mile of Federal (or designated National) wildlife refuges. Applicators directed to notify state and/or Federal authorities and American Cyanamid immediately if any adverse environmental effects due to chlorfenapyr use were observed.

- Pests were limited to resistant tobacco budworm in Texas, Louisiana, Mississippi, and Arkansas; beet armyworm in Oklahoma, Alabama, Tennessee, Florida, George, North Carolina, and South Carolina; and spider mites in California.; loopers, boll worms, other armyworms and spider mites were listed as secondary pests that would also be controlled at appropriate rates

- Treatment thresholds for resistant tobacco budworm were defined. Applicators would be directed to apply only in the event of field failures with synthetic pyrethroids, or after a treated vial test showed that 50 - 60% of the collected adults survived exposure to pyrethroid residue.

- Applicators were directed to make no more than two consecutive applications of chlorfenapyr. Then they were to rotate to another product from a different class based on mode of action.

- The label would establish buffer zones of 25 feet (ground application) or 150 feet (aerial application) from surface water bodies or commercial fish farm ponds

- Aerial applicators directed to comply with drift management requirements and use the information covered in the Aerial Drift Reduction Advisory. The label would provide specific guidance on avoiding spray drift during aerial and ground application.

- Applicators directed to avoid drift to adjacent sensitive areas

- Users directed to avoid cultivating within 25 feet of aquatic areas to allow growth of a vegetative filter strip.

Attachments

Attachment 1

Documents Appearing in the Federal Register

File Symbol	Product	Type of Notice	Date of Publication	Comments
PP5F4456	petition for tolerance for chlorfenapyr residues	Notice of Filing	Feb 5, 1997	4 comments: 2 from cotton grower groups supported registration comments addressed in BEAD benefits assessment. 2 raised concerns about endocrine disruptors. Comments will be addressed elsewhere.
241-GAA	Technical Chlorfenapyr	Notice of Receipt	Dec. 2, 1998	no comments
241-GAT	Pirate	Notice of Receipt	Dec. 2, 1998	ditto
241-GAI	Alert	Notice of Receipt	Dec. 2, 1998	ditto
241-GAT 241-GAI	Pirate and Alert	Notice of Availability of Risk/Benefit Assessment	January 20, 1999	many (about 400)

Table 1.Summary of Efficacy and Yield Comparisons between Chlorfenapyr (Pirate®) and Spinosad (Tracer®) applied for Controlling Beet Armyworm on Cotton.

Study ID	Application rate (lb ai/A)		Yield (lbs/A or kg/ha)			Efficacy (Number of larvae)			Performance relative to chlorfenapyr	
	chlorfenapyr	spinosad	Chlorfenapyr	spinosad	Control plot	Chlorfenapyr	spinosad	Control Plot	Yield Index[2]	Efficacy Index[3]
ALABAMA										
Novartis 95b	0.2	0.025				15	2.5	45.75	??	127.3
LOUISIANA										
AMT 24:F58	0.2	0.067				2.15	2.15	20.75	??	100.0
AMT 22:42F-2	0.18	0.067				1.4	1.5	14.4		99.3
AMT 22:65F	0.2	0.067				0.52	0.51	2.07	??	100.5
PBCC 96:830a	0.2	0.067				0.5	0.5	6.7		100.0
PBCC 96:830b	0.2	0.067				0.5	0.5	6.7		100.0
PBCC 96:1045a	0.2	0.067				0.42	0.38	4.1		101.0
PBCC 96:1045b	0.2	0.067				1.22	2.05	5.2		84.0
Novartis 95c	0.35	0.067				0.6	0.1	12.1		104.1
Average Relative Performance (n = 8)						86.6%	84.4%	0%	ERR	98.6
SOUTH CAROLINA										
PBCC 99:1035a	0.25	0.089				0.27	1.93	5.1		67.5
PBCC 99:1036	0.25	0.075				0.95	2.4	14.1		89.7
Average Relative Performance (n = 2)						94%	72.6%	0%	??	78.6
TEXAS										
PBCC 96:845a	0.2	0.062				4	14.8	26.6	??	59.4
PBCC 96:845b	0.2	0.062				0.9	3.15	18.4	??	87.8
Novartis 95d	0.2	0.062				2.45	8.15	18		68.3
Average Relative Performance (n = 3)						90%	63.6%	0%	0.0	71.8

Study ID	Application rate (lb ai/A)		Yield (lbs/A or kg/ha)			Efficacy (Number of larvae)			Performance relative to chlorfenapyr	
	chlorfenapyr	spinosad	Chlorfenapyr	spinosad	Control plot	Chlorfenapyr	spinosad	Control Plot	Yield Index[2]	Efficacy Index[3]
TOTAL US										
Average Relative Performance (n = 14)						88.6%	80.7%	0%	ERR	92.1

2/ Yield relative to Chlorfenapyr: where Chlorfenapyr = 100

3/ Efficacy relative to chlorfenapyr: where Chlorfenapyr = 100. For example, if Chlorfenapyr achieved 90% control and spinosad achieved 80% control then spinosad would have an efficacy index of 90. Differences measured are absolute percentage point differences.

AMT = Arthropod Management Tests IAT = Insecticide and Acaricide Tests
PBCC = Proceedings of the Beltwide Cotton Conference, National Cotton Council (PBCC year:page)
Novartis: Efficacy Data Submitted in support of emmamectin benzoate on cotton

Table 2. Summary of Efficacy and Yield Comparisons between Chlorfenapyr (Pirate®) and Tebufenozide (Confirm®) applied for Controlling Beet Armyworm on Cotton.

Study ID	Application rate (lb ai/A)		Yield (lbs/A or kg/ha)			Efficacy (Number of larvae)			Performance relative to chlorfenapyr	
	chlorfenapyr	tebufenozide	Chlorfenapyr	tebufenozide	Control Plot	Chlorfenapyr	tebufenozide	Control Plot	Yield Index[2]	Efficacy Index[3]
LOUISIANA										
AMT 24:F58	0.2	0.125				2.15	3.9	20.75	??	91.6
AMT 22:42F-1	0.18	0.07				0.25	2.15	8.4		77.4
AMT 22:42F-1	0.18	0.13				0.25	1.15	8.4		89.3
AMT 22:42F-3	0.18	0.07				0	0.8	2.8		71.4
AMT 22:42F-3	0.18	0.13				0	0.3	2.8		89.3
AMT 22:65F	0.2	0.125				0.52	1.44	2.07	??	55.6
PBCC 96:1045a	0.2	0.125				0.42	1.1	4.1		83.4
PBCC 96:1045b	0.2	0.125				1.22	4.25	5.2		41.7
AMT 20:66F-1	0.25	0.125				0	0.55	5.25		89.5
AMT 20:66F-2	0.25	0.125				0.5	2.0	9.25		83.8
Average Relative Performance (n = 10)									ERR	77.3
TEXAS										
PBCC 96:845a	0.2	0.125				4	6.9	26.6	??	89.1
PBCC 96:845b	0.2	0.125				0.9	2.5	18.4	??	91.3
Average Relative Performance (n = 2)									??	90.2
SOUTH CAROLINA										
PBCC 96:878b	0.2	0.125				0.17	0.44	2.6	??	89.6
PBCC 99:1036	0.25	0.125				0.95	7.25	14.1		55.3
Average Relative Performance (n = 2)									0.0	72.5
TOTAL US										
Average Relative Performance (n = 14)						88.6%	67%		ERR	78.4

2/ Yield relative to Chlorfenapyr: where Chlorfenapyr = 100

3/ Efficacy relative to chlorfenapyr: where Chlorfenapyr = 100. For example, if Chlorfenapyr achieved 90% control and tebufenozide achieved 80% control then spinosad would have an efficacy index of 90. Differences measured are absolute percentage point differences.

AMT = Arthropod Management Tests IAT = Insecticide and Acaricide Tests
PBCC = Proceedings of the Beltwide Cotton Conference, National Cotton Council (PBCC year:page)

Table 3. Summary of Efficacy and Yield Comparisons between Chlorfenapyr (Pirate®) and Emmamectin Benzoate (Proclaim®) applied for Controlling Beet Armyworm on Cotton.

Study ID	Application rate (lb ai/A)		Yield (lbs/A or kg/ha)			Efficacy (Number of larvae)			Performance relative to chlorfenapyr	
	chlorfenapyr	emmamectin	Chlorfenapyr	emmamectin	Control Plot	Chlorfenapyr	emmamectin	Control Plot	Yield Index[2]	Efficacy Index[3]
ALABAMA										
Novartis 94a	0.2	0.01	2962	2864	2722	7.03	3.67	23.6	96.7	114.2
Novartis 95b	0.15	0.01				16.8	8.2	45.75	??	118.8
Novartis 95b	0.2	0.01				15	8.2	45.75	??	114.9
Average Relative Performance (n = 3)									96.7	116.0
ARKANSAS										
Novartis 95a	0.15	0.01				0.65	1.65	13.15	??	92.4
Novartis 95a	0.15	0.0075				0.65	1.3	13.15	??	95.1
Average Relative Performance (n = 2)									??	93.8
LOUISIANA										
Novartis 95c	0.35	0.0075				0.6	0.26	12.1		102.8
AMT 24:F58	0.2	0.01				2.15	5.3	20.75	??	84.8
Average Relative Performance (n = 2)									??	93.8
TEXAS										
Novartis 95d	0.2	0.008				2.45	3.65	18		93.3
PBCC 96:845a	0.2	0.0075				4	5.5	26.6	??	94.4
Average Relative Performance (n = 2)									??	93.9
SOUTH CAROLINA										
PBCC 99:1036	0.25	0.0125				0.95	3.28	14.1		83.5
Average Relative Performance (n = 1)									??	83.5
TOTAL US										
Average Relative Performance (n = 10)						88.6%	88.1%		ERR	99.5

2/ Yield relative to Chlorfenapyr: where Chlorfenapyr = 100

3/ Efficacy relative to chlorfenapyr: where Chlorfenapyr = 100. For example, if Chlorfenapyr achieved 90% control and emmamectin benzoate achieved 80% control then emmamectin benzoate would have an efficacy index of 90. Differences measured are absolute percentage point differences.

AMT = Arthropod Management Tests IAT = Insecticide and Acaricide Tests
PBCC = Proceedings of the Beltwide Cotton Conference, National Cotton Council (PBCC year:page)
Novartis: Efficacy Data Submitted in support of emmamectin benzoate on cotton

Table 4. Summary of Efficacy and Yield Comparisons between Chlorfenapyr (Pirate®) and Methoxyfenoazide (Intrepid®, RH 2485) applied for Controlling Beet Armyworm on Cotton.

Study ID	Application rate (lb ai/A)		Yield (lbs/A or kg/ha)			Efficacy (Number of larvae)			Performance relative to chlorfenapyr	
	chlorfenapyr	methoxyfenozide	Chlorfenapyr	methoxyfenozide	Control Plot	Chlorfenapyr	methoxyfenozide	Control Plot	Yield Index[2]	Efficacy Index[3]
LOUISIANA										
AMT 22:42F-1	0.18	0.05				0.25	1.4	8.4		86.3
AMT 22:42F-1	0.18	0.10				0.25	1.15	8.4		89.3
AMT 22:42F-1	0.18	0.15				0.25	1.3	8.4		87.5
Average Relative Performance (n = 3)									??	88.7
TOTAL US										
Average Relative Performance (n =3)						88.6	77.3		??	88.7

2/ Yield relative to Chlorfenapyr: where Chlorfenapyr = 100

3/ Efficacy relative to chlorfenapyr: where Chlorfenapyr = 100. For example, if Chlorfenapyr achieved 90% control and methoxyfenozide achieved 80% control then spinosad would have an efficacy index of 90. Differences measured are absolute percentage point differences.

AMT = Arthropod Management Tests IAT = Insecticide and Acaricide Tests
PBCC = Proceedings of the Beltwide Cotton Conference, National Cotton Council (PBCC year:page)

Table 5. Summary of Efficacy and Yield Comparisons between Chlorfenapyr (Pirate®) and Chlorpyrifos (Lorsban®) applied for Controlling Beet Armyworm on Cotton.

Study ID	Application rate (lb ai/A)		Yield (lbs/A or kg/ha)			Efficacy (Number of larvae)			Performance relative to chlorfenapyr	
	chlorfenapyr	chlorpyrifos	Chlorfenapyr	chlorpyrifos	Control Plot	Chlorfenapyr	chlorpyrifos	Control Plot	Yield Index[2]	Efficacy Index[3]
LOUISIANA										
PBCC 96:1045a	0.2	1.0				0.42	0.78	4.1		91.2
PBCC 96:1045b	0.2	1.0				1.22	2.45	5.2		76.3
PBCC 96:830b	0.2	1.0				0.5	0.75	6.7		96.3
AMT 22:42F-1	0.18	0.75				0.25	1.8	8.4		81.5
AMT 22:65F	0.2	1.0				0.52	1.22	2.07	??	66.2
AMT 20:66F	0.25	1.0				0	1.9	5.25		63.8
FLEnt 77:457b	0.25	1.0				1.2	5.9	9.5	??	50.5
Average Relative Performance (n = 7)									??	75.1
TEXAS										
PBCC 96:845a	0.2	1				4	15	26.6	??	58.6
Average Relative Performance (n = 1)									??	58.6
TOTAL US										
Average Relative Performance (n = 8)						88.6	61.6		ERR	73.0

2/ Yield relative to Chlorfenapyr: where Chlorfenapyr = 100

3/ Efficacy relative to chlorfenapyr: where Chlorfenapyr = 100. For example, if Chlorfenapyr achieved 90% control and chlorpyrifos achieved 80% control then spinosad would have an efficacy index of 90. Differences measured are absolute percentage point differences.

AMT = Arthropod Management Tests IAT = Insecticide and Acaricide Tests
PBCC = Proceedings of the Beltwide Cotton Conference, National Cotton Council (PBCC year:page)
FLEnt = Florida Entomologist (Volume: page)

Table 6. Summary of Efficacy and Yield Comparisons between Chlorfenapyr (Pirate®) and Profenofos (Curacron®) applied for Controlling Beet Armyworm on Cotton.

Study ID	Application rate (lb ai/A)		Yield (lbs/A or kg/ha)			Efficacy (Number of larvae)			Performance relative to chlorfenapyr	
	chlorfenapyr	profenofos	Chlorfenapyr	profenofos	Control Plot	chlorfenapyr	profenofos	Control Plot	Yield Index[2]	Efficacy Index[3]
LOUISIANA										
FLEnt 77:457a	0.2	1.0				0.1	2.6	3	??	16.7
Average Relative Performance (n = 1)									??	16.7
TEXAS										
PBCC 96:845a	0.2	1				4	23.25	26.6	??	27.6
Average Relative Performance (n = 1)									??	27.6
SOUTH CAROLINA										
PBCC 99:1036	0.25	1.0				0.95	6.98	14.1		57.2
Average Relative Performance (n = 1)									??	57.2
TOTAL US										
Average Relative Performance (n = 3)						88.6	22.4		ERR	33.8

2/ Yield relative to Chlorfenapyr: where Chlorfenapyr = 100

3/ Efficacy relative to chlorfenapyr: where Chlorfenapyr = 100. For example, if Chlorfenapyr achieved 90% control and profenofos achieved 80% control then spinosad would have an efficacy index of 90. Differences measured are absolute percentage point differences.

AMT = Arthropod Management Tests IAT = Insecticide and Acaricide Tests
PBCC = Proceedings of the Beltwide Cotton Conference, National Cotton Council (PBCC year:page)
FLEnt = Florida Entomologist (Volume: page)

Table 7. Summary of Efficacy and Yield Comparisons between Chlorfenapyr (Pirate®) and Indoxacarb (Steward®, Avaunt®, DPX MP062 applied at 0.09 to 0.11 lb ai/A[1]) applied for Controlling Beet Armyworm on Cotton.

Study ID	Application rate (lb ai/A)		Yield (lbs/A or kg/ha)			Efficacy (Number of larvae)			Performance relative to chlorfenapyr	
	chlorfenapyr	indoxacarb	Chlorfenapyr	indoxacarb	Control plot	Chlorfenapyr	indoxacarb	Control Plot	Yield Index[2]	Efficacy Index[3]
LOUISIANA										
AMT 24:F58	0.2	0.09				2.15	0.55	20.75		107.7
AMT 24:F58	0.2	0.11				2.15	0.15	20.75		109.6
Average Relative Performance (n = 2)						89.4%	98.1%	0%		108.7
SOUTH CAROLINA										
PBCC 99:1035a	0.25	0.11				0.27	0.87	5.1		88.2
PBCC 99:1036	0.25	0.09				0.95	1.9	14.1		93.3
PBCC 99:1036	0.25	0.11				0.95	1.4	14.1		96.8
Average Relative Performance (n = 3)						93.7%	86.5%	0%		92.8
TOTAL US										
Average Relative Performance (n = 5)						92%	91.2%	0%		99.2
Compared to all Chlorfenapyr tests						88.6	87.8			

1/Proposed label rate of 0.09-0.11 lb ai/A from: Mitchell, W. 1999 in Proceedings of the Beltwide Cotton Conferences, p. 73.

2/ Yield relative to Chlorfenapyr: where Chlorfenapyr = 100

3/ Efficacy relative to chlorfenapyr: where Chlorfenapyr = 100. For example, if Chlorfenapyr achieved 90% control and spinosad achieved 80% control then spinosad would have an efficacy index of 90. Differences measured are absolute percentage point differences.

AMT = Arthropod Management Tests IAT = Insecticide and Acaricide Tests
PBCC = Proceedings of the Beltwide Cotton Conference, National Cotton Council (PBCC year:page)

Table 8. Comparative Costs

Compound	Cost
Chlorfenapyr	$11 per acre treatment
spinosad	$12 per acre treatment
tebufenozide	$33 per acre treatment
chlorpyrifos	$8 per acre treatment
profenofos	$6 per acre treatment
thiodicarb	$8 per acre treatment

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