August 31, 1999

PROFILE SHEET
FIFRA SCIENTIFIC ADVISORY PANEL

SESSION TITLE: Review of American Cyanamid Company's Probabilistic Assessment for Chlorfenapyr and Request for Guidance On Problem Formulation

SAP MEETING DATE: September 24, 1999

LEAD DIVISION/LEAD PRESENTER AND OTHER OPP PANEL PARTICIPANTS:

See attached draft agenda.

DESCRIPTION/PURPOSE OF SESSION (very brief description to be used for press releases, Federal Register Notice, etc):

In December of 1994 the Office of Pesticide Programs (OPP) received a request for a FIFRA Section 3 Registration for the use of the pyrrole insecticide chlorfenapyr on cotton. In response, the Environmental Fate and Effects Division (EFED) conducted a series of increasingly refined ecological risk assessments. On July 22, 1999, OPP presented the results of the completed risk assessments to the SAP to obtain guidance on potential further refinements. The comments and recommendations from the Panel will be included in the background documents for this SAP session at a later date.

The first ecological risk assessment, conducted in 1994, was qualitative in nature and based solely on the limited data available in support of an experimental use permit application for chlorfenapyr. This risk assessment was conducted pursuant to emergency use requests (FIFRA Section 18). In this assessment, EPA found that the acute levels of concern were exceeded for birds, fish, and aquatic invertebrates. The assessment concluded that birds were expected to be at high acute risk (no chronic toxicity data were yet available) and the exceedance of the levels of concern warranted a refined risk assessment.

In 1995, OPP conducted a screening level risk assessment of the use of this compound on cotton. In this assessment, EPA estimated chlofenapyr residues in wildlife food items based on assumptions of maximum application rates and frequencies of application and no dissipation. This was a typical EFED screening level risk assessment. The assumption of maximum application rate and frequency of application combined with the assumption of no dissipation meant that EPA's estimates of residues on avian food items would be relatively high and that avian exposure would, accordingly, also be estimated to be relatively high. In this assessment, EPA concluded that chlorfenapyr was persistent, and risk quotients for acute toxic effects exceeded high risk level of concern by 20X and chronic effects level of concern by 504X. Aerial application of chlorfenapyr was concluded to also present a high acute risk to aquatic organisms.

In 1996, OPP refined the avian exposure component of its ecological risk assessment to rely on

mean or typical assumptions of chlorfenapyr residues in wildlife food items rather than estimates based on maximum application rates and frequencies of application. Both the 1995 and 1996 assessments assumed no dissipation of chlorfenapyr residues in food items. In this assessment, EPA found that avian acute risk quotients exceeded the acute high risk level of concern by factors ranging from 0.5X to 6X (depending on application rate) and chronic levels of concern were exceeded by factors of 4x to 53X.

In 1997, OPP further refined the avian risk assessment to account for potential residue dissipation. However, food item residue dissipation data was not available, and the 1997 risk assessment relied on environmental fate data to estimate the fate of residues in the soil as a surrogate for the fate of residues in wildlife food items. In this refinement, EPA found that soil half-life assumptions of 2 to 4 years resulted in modeled soil concentrations that exceeded the 0.5 ppm dietary avian reproduction effects threshold for multiple years.

Subsequent to the 1997 refinement of the avian risk assessment, the registrant provided the Agency with data regarding the residues of parent chlorfenapyr in vegetation, seed, and insects over time to address the need for dissipation of residues in wildlife food items. In addition, new data were supplied for aerobic soil metabolism and field soil dissipation of chlorfenapyr that indicated the persistence of chlorfenapyr in soils was less than previously assumed.

OPP's 1998 further refinement of the avian risk assessment incorporated registrant-supplied data regarding measured chlorfenapyr residues in wildlife food items, avian species assemblages in cotton agroenvironments, and selected biological characteristics of these avian species as they relate to dietary exposure and effects data for selected passerine species. Although OPP's techniques for assessing avian exposure and effects were modified from historic practice in order to incorporate the measured residue data, the avian risk assessment generally followed current EFED risk assessment approaches. In addition to refinements in the avian risk assessment, OPP's 1998 assessment included refinements in the aquatic risk assessment. The 1998 assessment includes the use of the MUSCRAT probabilistic model for aquatic exposure as well as effects data for sediment-dwelling invertebrates.

EFED recognizes the limitations of the Division's current deterministic approach with respect to characterizing assessment uncertainty and the potential utility of a probabilistic approach in helping risk assessors and risk managers to better understand the potential magnitude and severity of ecological impacts. EFED is, in fact, actively engaged in an initiative to develop probabilistic risk assessment methods, approaches, and tools for purposes of ecological risk assessment of pesticides. However, at present EFED lacks peer reviewed guidance and standard operating procedures for probabilistic ecological risk assessments of pesticide use. In order to obtain additional scientific guidance, OPP included a series of questions in the July 22nd SAP targeted to discuss data requirements, data quality, and probabilistic procedures and assumptions applicable to the chlorfenapyr Section 3 registration on cotton.

During the July 22nd SAP discussion of probabilistic approach questions, a number of comments were made with respect to an American Cyanamid assessment of chlorfenapyr risks to avian reproduction as a result of the chemical's use on cotton. This assessment, submitted to OPP in

April of 1999 and included in the July 1999 SAP background information package at the request of the registrant, uses probabilistic techniques to generate probability distributions of chronic exposure Risk Quotients. EFED has conducted a preliminary review of this assessment (not included in the July SAP information package at the request of the registrant), which focuses on (1) consistency with generic Agency acceptance criteria for probabilistic risk assessments (available at **www.eap.gov/nceaw1/mcpolicy**) , (2) general assumptions associated with the geographic and population scales incorporated into the exposure characterization, and (3) use of available data for establishment of distributions of variable important to the exposure characterization. However, a number of the comments made by SAP panel members in July suggest that the Agency would benefit from a more thorough discussion of this assessment as well as a discussion of problem formulation for this compound.

OVERALL OBJECTIVES

1. EFED is seeking SAP input regarding the probabilistic risk assessment submitted on April 22, 1999 to the Agency by American Cyanamid Company ("Avian Probabilistic Ecological Risk Analysis for Chlorfenapyr (AC 303630) in Cotton. MRID No. 448098-01") and the ability of the assessment to predict the probability and magnitude of risks to avian species from chlorfenapyr use on cotton.

   Specifically, EFED is seeking guidance on whether the initial probabilistic risk assessment adequately considers the implications of geographic scale and population definitions in the assessment, and whether the existing data available on chlorfenapyr fate, residues, and effects and cotton agroenvironments can accommodate extrapolations of risks to scales beyond the treated agroenvironment to larger scales.

2. EFED is also interested in comments on EFED's review of American Cyanamid Company's probabilistic assessment. This review is entitled "Evaluation of 'Avian Probabilistic Ecological Risk Analysis for Chlorfenapyr (AC 303630) in Cotton. MRID No. 448098-01' " and was conducted by Ed Odenkirchen and Alex Clem, EFED.

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Questions to the Scientific Advisory Panel

1. American Cyanamid Company's probabilistic risk assessment defines a bird population as "*a group of individuals belonging to the same species inhabiting the southern and western U.S. where cotton agroenvironments exist. Natural populations of birds are not geographically bound to arbitrary spatial areas, nor can they be realistically be assigned temporal boundaries.*" (Avian Probabilistic Ecological Risk Analysis for Chlorfenapyr (AC 303630) in Cotton. Submitted by American Cyanamid Company to the Agency April 22, 1999. MRID No. 448098-01. Study completion date: December 9, 1998.)

   A. Does the SAP agree that populations o concerned f bird species associated with cotton agroenvironments are not geographically bound to spatial areas?
   B. Since the Agency is with how birds on cotton fields treated with chlorfenapyr are affected, would a scale by acre or field be more appropriate?
   C. Can the SAP suggest further refinements in the scale of probabilistic assessments?
   D. Are there important ecological impacts not accounted for in using the population definition and geographic scales assumed in the probabilistic risk assessment?
   E. If so, are there sufficient data to address these effects at smaller geographical scales for more limited definitions of populations?

2. Given the scale established for American Cyanamid Company's probabilistic risk assessment, are the data used in the probabilistic risk assessment sufficient in geographic scope and technical rigor to establish the probability distributions for the wildlife food residue and dietary proportions (field and buffer) assumed in the probabilistic risk assessment with reasonable scientific certainty? If not, would a smaller geographical scale be more appropriate for use with the available data, and what scale would be recommended?

3. Based on the registrant's definition of population, American Cyanamid's probabilistic risk assessment concludes that the "*results of the present probabilistic risk analysis demonstrate that the risks to birds from recommended use of chlorfenapyr applied to cotton are negligible.*" Does the SAP believe that this conclusion can be reasonably extrapolated from the registrant's probabilistic risk assessment to populations and geographic scales intermediate to nationwide and individual treated fields? If not, can the SAP recommend appropriate modifications to the assessment approach and any additional data requirements to facilitate such an extrapolation?

4. Referring to EFED's evaluation of the registrant's probabilistic risk assessment ("Evaluation of 'Avian Probabilistic Ecological Risk Analysis for Chlorfenapyr (AC 303630) in Cotton. MRID No. 448098-01 ' by Ed Odenkirchen and Alex Clem, EFED) and the exposure model used by the registrant:

   1. Are EFED's concerns regarding the modification of exposure distributions through

the use of the variables $P_{CAforage}$ and $P_{treatment}$ reasonable? Can the SAP suggest other quantitative methods of assessing population risks from reproductive effects in birds using treated cotton agroenvironments in the context of larger populations that would afford less uncertainty?

2. Does the SAP agree with the Agency's concerns regarding the variable P_{infest}?

3. American Cyanamid's probabilistic risk assessment relies on avian census data from a series of field studies described in MRID No. 444642-02. These data will be forwarded at a later date and are presented as being illustrative of avian use of inside and outside of cotton agroenvironments (cotton field and buffer as defined in the probabilistic risk assessment). EFED's review has suggested that the nature of the study plots established in these field studies results in census data limited only to questions of avian use of in-field and buffer areas (i.e. the cotton agroenvironment only) and are not applicable to questions of avian use outside of cotton agroenvironments as defined by American Cyanamid's probabilistic risk assessment. Does the SAP agree with the EFED position?

4. Given that American Cyanamid's probabilistic risk assessment is concerned with risk quotients for time-zero (after application) residues, does the SAP agree with EFED that the approach for selecting peak values underestimates residues because of the total mass applied normalization of the third applications?

5. Referring to the discussions of probabilistic approaches from the July 22nd SAP:

   1. Does American Cyanamid's probabilistic risk assessment attempt to quantify uncertainty associated with interspecies extrapolations of avian reproduction toxicity endpoints?. Given that the majority of birds observed in cotton agroenvironments are passerines, can the SAP propose an appropriate extrapolation uncertainty factor to account for differences in sensitivity between the tested mallards and quail to the untested passerines?

   2. The SAP discussed approaches for investigation dependancy or covariance between variables. The registrant's response to questions regarding testing for such confounding factors is presented in the document included in this package entitled "CHLORFENAPYR: Avian Probabilistic Ecological Risk Analysis for Chlorfenapyr in Cotton: Response to Questions by EFED Reviewers". Given that a number of residue studies for different wildlife food items were conducted on different fields and that there appears not to have been plot-pairing of food item analyses for those studies with multiple food items investigated, does the SAP believe that investigations of covariance or dependancy between variables conducted for the registrant's probabilistic risk assessment are adequate?

6. Based on Mr. Jim Jones' presentation on the problem formulation for chlorfenapyr use on cotton, do you have any guidance and suggestions for improving the problem

formulation?

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Friday, September 24, 1999

Session 5: Review of American Cyanamid Company's Probabilistic Assessment for Chlorfenapyr and Request for Guidance on Problem Formulation

9:00 - 9:45 Presentation: Introduction, Background and Objectives – Ms. Denise Keehner, EPA, Office of Pesticide Programs

9:45 - 10:15 Presentation: Overview of Chlorfenapyr Chemical Characteristics and Properties - Dr. Edward Odenkirchen, EPA, Office of Pesticide Programs

10:15 - 10:30 Break

10:30 - 11:00 Presentation: Problem Formulation - Mr. Jim Jones, EPA, Office of Pesticide Programs

11:00 - 12:00 Presentation: Overview of American Cyanamid Company's Probabilistic Risk Assessment (April 22, 1999, MRID #448098-01) – American Cyanamid Company

12:00 - 1:00 Lunch

1:00 - 1:15 Presentation: Review of SAP Questions - Denise Keehner, EPA, Office of Pesticide Programs

1:15 - 2:15 Public Comments

2:15 - 2:30 Break

2:30 - 5:45 Panel Discussion