United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508P)

EPA OPP-2006-XXX
June XX, 2006

Reregistration Eligibility Decision for Pentachloronitrobenzene

List A

Case No. 0128

CERTIFIED MAIL

Dear Registrant:

The Environmental Protection Agency (EPA, or the Agency) has completed its review of the available data and public comments received related to the risk assessments for the organochlorine fungicide, pentachloronitrobenzene, or PCNB. Based on this review, we have made a determination that many of the uses of PCNB are not eligible for reregistration and have additionally identified a number of measures that the Agency believes are necessary to mitigate risks associated with the remaining uses of PCNB. The uses of PCNB that are eligible for reregistration are: cole crops (labeled for treatment of clubroot only), ornamental bulbs in commercial production, and seed treatments. The Agency is now publishing its reregistration eligibility and risk management decisions for the uses of PCNB, along with the technical bases for these decisions, for a 60-day public comment period. The enclosed "Reregistration Eligibility Decision for Pentachloronitrobenzene," which was approved on July 11, 2006, contains the Agency's decisions.

A Notice of Availability for the Reregistration Eligibility Decision (RED) for PCNB has been published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket (7502P), 1200 Pennsylvania Ave, NW, Washington, DC 20460, Electronic copies of the RED and all supporting documents also are available at http://www.regulations.gov/ in Docket Number OPP-2004-0202.

This document and the process used to develop it are the result of EPA's program to facilitate greater public involvement and participation in the Agency's pesticide reregistration and tolerance reassessment decision making. Since the enactment of the Food Quality Protection Act of 1996 (FQPA), EPA has undertaken to increase transparency, to consult with stakeholders, and to engage the public in developing pesticide reregistration and tolerance reassessment decisions. The revised human health and environmental risk assessments for PCNB were placed in the public docket and opened for public comment through a *Federal Register* notice on March 2, 2005. Other supporting documentation has been added since that time, and is likewise available to the public via the docket.

To mitigate the risks associated with the uses of PCNB that are eligible for reregistration, product labels must be revised by the registrants to adopt the changes set forth in

Section V of this document. Instructions for registrants on submitting revised labeling and the time frame for doing so can be found in Section V.

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, Jill Bloom, at (703) 308-8019. For questions about product reregistration and/or the Product data call-in (DCI) that accompanies this document, please contact Bonnie Adler at (703) 308-8523.

/s/

Debra Edwards, Ph.D.
Director, Special Review and
Reregistration Division

Attachment

Reregistration Eligibility Decision

for

Pentachloronitrobenzene

List A
Case 0128

Approved By:

_____/s/_____
Debra Edwards, Ph.D.
Director, Special Review and
Reregistration Division

_____July 11, 2006_____
Date

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration.
EP	End-Use Product
EPA	Environmental Protection Agency
ESA	Endangered Species Act
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MUP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate

OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PCA	Percent Crop Area
PAD	Population Adjusted Dose
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Pentachlorobenzene Reregistration Eligibility Decision Team

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Executive Summary

This document presents EPA's decision on the tolerance reassessment and reregistration eligibility of the registered uses of pentachloronitrobenzene (PCNB). In making its decisions, the Agency considered data previously required of and submitted by the registrants, current guidelines for conducting acceptable studies to generate such data, published scientific literature, and public comments on the human health and environmental risk assessments. The Agency has reassessed the fourteen tolerances established for PCNB. The Agency has determined that the currently registered uses of PCNB for cole crops (for control of clubroot only), commercial production of flowering bulbs, and seed treatment are eligible for reregistration, provided changes are made to product labels as specified in this document. Data requirements associated with these uses are detailed in the RED. The remaining uses of PCNB are ineligible for reregistration.

PCNB is an organochlorine fungicide used to control diseases on vegetables (predominantly green beans and cole crops), field crops (cotton, potatoes, and peanuts), turf, ornamentals, and seeds (seed treatments of barley, beans, corn, cotton, oats, peas, peanut, potato, rice, safflower, sorghum, soybean, sugar beet, and wheat). The Agency estimates total usage of PCNB at 770,000 to 1,000,000 lbs/year, with the greatest agricultural use on cotton (400,000 lbs/year) and potatoes (60,000 lbs/year); turf applications are estimated at 250,000-500,000 lbs/year (90-95% of which is used on golf courses).

The Agency assessed the human health and environmental risks of PCNB as currently registered. The Agency also assessed the benefits associated with the currently registered uses of PCNB. The reregistration eligibility decision for PCNB is based on these assessments. The risk assessments went through several iterations based on public comments, proposed mitigation, and the correction of an error in and refinements to the dietary assessment. A chronology of the Agency risk reassessments and registrant responses may be helpful in tracking the risk conclusions discussed in this document.

Chronology

The Agency released risk assessments revised to address public comments (mostly technical in nature) on March 2, 2005, and determined at that time that the dietary, residential, aggregate, ecological, and some occupational risks associated with the uses of PCNB were of concern. The risks discussed in Section III of the RED reflect the assessments made public in March 2005.

On June 10, 2005, the two registrants of technical grade PCNB, Amvac and Chemtura, proposed a risk mitigation plan focused mainly on reducing dietary and worker risk. Measures proposed by the registrants included:

- reduction of maximum seasonal application rates on several use sites
- restriction of golf course use to tees, greens, and fairways
- terminations of the use on garlic
- prohibition of some application methods and formulation types

- additional PPE for workers

The Agency determined that the registrant proposal, if implemented, would adequately address most of the occupational risks, but that dietary, residential, and ecological risks would still be of concern.

After the Agency evaluated the proposal, Amvac and Chemtura informally supplemented their original mitigation plan by proposing that all turf uses of PCNB except golf course tees, greens, and fairways be terminated. The Agency initiated a review of this addition to the proposal. At the same time, the Agency corrected an error in its dietary risk assessment related to how PCNB residues partition in the liquid and fat portions of milk, refined the theoretical composition of the diet for lactating cows to more realistically reflect its contribution to residues in milk, and incorporated a new adsorption coefficient to better represent estimated water concentrations associated with the turf use. The risks discussed in Section IV of the RED reflect these changes and the Agency's assessment of the registrants' complete risk mitigation proposal.

The Agency concluded that the registrants' complete proposal, together with the correction and refinement of the dietary assessment, would decrease estimates of dietary risk below levels of concern, and eliminate occupational risks from PCNB use on turf sites the registrants proposed for termination. The dietary risk conclusions are captured in an October 20, 2005 assessment. The residential and aggregate risks would also be reduced by the proposal, although the residential risk posed by the use of PCNB on ornamentals in residential settings would continue to be of concern.

Although the registrants' proposal would also reduce wildlife exposures to PCNB, the Agency did not find it adequate to address ecological risk concerns. The ecological risk quotients associated with the registrants' proposal are captured in documents dated July 7 and August 9, 2005. Of particular concern are the widespread use of PCNB and the contribution of the environmental fate and transport characteristics of PCNB and its metabolites to ecological risk. These characteristics, particularly persistence, bioaccumulative potential and the potential for long-range atmospheric transport, are discussed in a synopsis dated April 26, 2006; the synopsis also captures the Agency's conclusions about their impact on environmental risk. The environmental risks associated with the registrants' complete mitigation are discussed in Section IV of the RED.

The risks summarized in this document are those that result only from the use of PCNB. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is to account for the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for PCNB. Chlorothalonil and pentachlorophenol, two pesticides in the same general family as

PCNB, do not appear to result in the same health endpoints. The endpoints used to assess human health risks for PCNB are primarily thyroid hypertrophy and hepatocellular hypertrophy and hyperplasia. The endpoints for chlorothalonil have been identified as various kidney and forestomach effects, and the endpoints identified for pentachlorophenol are carcinogenicity and developmental effects. The Agency has not undertaken a comprehensive assessment of organochlorine pesticides with respect to common mechanism. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

Environmental Fate and Ecological Risk

The fate characteristics of PCNB and its metabolites, their ecotoxicity and estimated concentrations in the environment, and the ecological risks posed by the currently labeled uses of PCNB are detailed in Section III of the RED. The persistence, bioaccumulative potential, and potential for long-range transport of PCNB and its metabolites are key to understanding the extent and scope of ecological exposures associated with the use of PCNB.

Persistence

Over 80 metabolites have been identified for PCNB. The predominant metabolites of PCNB in the environment are PCA, PCTA, and pentachlorobenzene. PCNB and its metabolites are very persistent in the environment. PCNB alone has a measured aerobic soil metabolism half-life of over six months; PCNB and its metabolites combined have an aerobic soil metabolism half-life of close to three years. Field data show that PCNB residues can be found in rotational crops several years after the last application of PCNB. The persistence of PCNB limits the effects of depuration (an organism's ability to remove accumulated toxins from its system) and increases opportunities for exposure. PCNB and its metabolites have persistence properties that exceed national and international thresholds for identifying persistent chemicals.

Bioaccumulation

The fate characteristics of PCNB and its metabolites indicate that they have the potential to bioaccumulate, or increase in concentration the food chain. Bioconcentration data for PCNB are limited, with Bioconcentration Factors up to 1100 in whole fish and 3100 in algae. Modeling suggests that the aquatic food chain is a likely mechanism for bioaccumulation of PCNB. PCNB exceeds national thresholds for identifying chemicals with bioaccumulative potential.
The extent to which PCNB and its metabolites may bioaccumulate in humans (at the top of the food chain) is a source of uncertainty and concern in the consideration of human health risks also, and the Agency is requiring data to help resolve this uncertainty.

Long-range Transport

PCNB is a moderately volatile compound. Both PCNB and PCA show a potential for long-range atmospheric transport. Field data demonstrate that significant quantities of PCNB can volatilize from the field and will undergo long-range atmospheric transport. Monitoring data are limited, but PCNB has been detected at sites in Canada distant from areas where it could have been applied. EPA's environmental exposure models do not account for long-range transport and so may underestimate risks.

Environmental Loading

The combined effect of these fate characteristics on the amount of the pesticide and its metabolites entering and remaining in the environment is referred to in this document as "environmental loading." Environmental loading varies with the different use sites for a pesticide, and is a function of how much of the pesticide is introduced into the environment, as measured by usage (pounds applied on an annual basis), percent crop treated (the proportion of a given use site that is treated in a year), application rates, and application methods (for a volatile pesticide like PCNB, a foliar application may result in more volatilization and a greater potential for long-range transport).

The Impact of Fate Characteristics on Ecological Risk

The Agency believes that the persistence, bioaccumulative potential, potential for long-range transport and other fate characteristics of PCNB and its metabolites contribute to ecological risk in ways that cannot be accounted for by modeling risk quotients, that ecological risk quotients derived from these models are likely to underestimate the magnitude of risk, and that the environmental fate characteristics of PCNB result in increased numbers and wider distribution of organisms at risk. The Agency has conducted a qualitative analysis of the effect of these characteristics on risk.

Wildlife Exposures

The Agency utilized the Tier II screening Pesticide Root Zone Model and the Exposure Analysis Model System (PRZM/EXAMS) to estimate surface water exposures for aquatic wildlife from PCNB and its metabolites.

Water concentrations were originally assessed for currently labeled uses of PCNB, and then again after the registrants proposed their risk mitigation plan. Under the original assessment, the scenario that resulted in the greatest estimated environmental exposures (EECs) in surface water was a turf scenario modeled using Pennsylvania soil and weather conditions. EECs from the original assessment are found in Section III, Table 17; EECs modeled on the registrants' mitigation proposal are found in Section IV, Table 38.

The Agency used several different methods to estimate exposures to terrestrial wildlife. Models were used to estimate exposures from ingestion of treated seed and from ingestion of a variety of food items contaminated via spray and chemigation applications of PCNB. In the original assessment, estimated concentrations on terrestrial forage items were based on the ELL-

FATE model; a more recent version of that model, the TREX model, subsequently was used to assess estimated concentrations based on the registrants' mitigation proposal. The Agency views TREX to be a more refined terrestrial exposure model than ELL-FATE. The registrants' mitigation proposal would not reduce seed treatment application rates, so the Agency did not reassess exposures to treated seed. EECs for terrestrial food items from the original assessment are found in Section III; terrestrial EECs modeled based on the registrants' mitigation proposal are found in several support documents ("Environmental Fate and Ecological Risk Assessment for the Re-registration of Pentachloronitrobenzene," February 15, 2005; "Revised Tier II Surface Water Exposure Values and Terrestrial Exposure Values for PCNB Based on Proposed Lower Application Rates (Risk Mitigation Phase)," August 9, 2005) and are summarized in Section IV. The support documents can be accessed via http://www.regulations.gov/, Docket Number OPP-2004-0202).

Toxicity to Non-target Organisms

PCNB is highly toxic to freshwater fish and invertebrates and is very highly toxic to estuarine/marine fish and invertebrates on an acute exposure basis. The Agency uses measures of toxicity in freshwater fish as surrogates for toxicity to aquatic-phase amphibians. Chronic effects in freshwater fish and invertebrates include reduced number of eggs produced and reductions in the number of young which survive. No chronic toxicity data are available for estuarine/marine animals. Since estuarine/marine invertebrates appear to be much more sensitive to PCNB than their freshwater counterparts on an acute exposure basis, it is reasonable to assume that they also may be more sensitive on a chronic basis.

PCNB is practically non-toxic to birds and mammals on an acute basis. For birds, chronic effects include reproductive and growth effects. The Agency uses measures of toxicity in birds as surrogates for toxicity to reptiles and terrestrial-phase amphibians. For mammals, laboratory studies conducted in rodents to facilitate the assessment of chronic health effects for humans provide the data that were used to assess risks to terrestrial mammals, but the relevance of the endpoints from the selected study (liver and thyroid effects in a 2-generation reproduction study in rats) to wildlife is not clear. An alternate and more sensitive endpoint for chronic mammalian exposures (reduced pup weight, from a different 2-generation rat reproduction study submitted to the Agency) may be more relevant to wildlife than the endpoint selected for the ecological risk assessment. The alternate endpoint was identified by the Agency after the ecological effects assessment was completed and so is not a part of the posted risk assessments. Estimates of mammalian risk based on this alternate endpoint would be much greater than those cited in the assessment.

PCNB is practically nontoxic to bees on an acute exposure basis. Few data are available for aquatic or terrestrial plants, although growers have reported phytoxicity to some grass species and varieties, and there is one reported adverse effect incident in which PCNB was implicated in poor germination of cottonseed.

Risk Quotients

Risks to wildlife typically are estimated by the Agency as the ratio of estimated exposures of the subject pesticide in water (for aquatic life) and food (for terrestrial life) to toxicity as measured by adverse effects endpoints. The Agency compares these risk quotients (RQs) to levels of concern (LOCs) for the relevant categories of terrestrial and aquatic organisms and time frames of exposure. The Agency has calculated RQs for acute and chronic exposures of birds and mammals of several sizes (for a number of food sources), and freshwater fish and invertebrates. No chronic toxicity data are available for estuarine/marine fish or invertebrates, so the Agency cannot calculate chronic RQs for these taxa. Since estuarine/marine invertebrates appear to be much more sensitive to PCNB than their freshwater counterparts on an acute exposure basis, it is reasonable to assume that they would be more sensitive on a chronic basis, with higher RQs. Risk Quotients associated with the currently registered uses of PCNB exceed levels of concern for most species type-use site combinations that have been assessed.

Based on the registrants' mitigation proposal, RQs would still exceed LOCs for birds, reptiles, terrestrial-phase amphibians, and mammals for chronic risks and chronic risk to endangered species in association with several use sites, and also for acute, acute endangered species, and chronic risks and chronic risk to endangered species for fish, invertebrates, and aquatic-phase amphibians. Although some of the RQs would be reduced, risks of concern would persist, particularly based on consideration of the persistence, bioaccumulation, and long-range transport potential of PCNB and its metabolites, and the potential for wildlife exposures from unincorporated applications of PCNB on sites such as turf and potatoes.

A detailed discussion of the Risk Quotients associated with currently labeled PCNB uses is found in Section III of the RED; discussion of the RQs that would be associated with the registrants' mitigation proposal may be found in Section IV.

Endangered Species

Endangered species LOCs associated with the use of PCNB are exceeded for aquatic and terrestrial species.

To address concerns about risks to Federally-listed endangered and threatened species from pesticide use, the Agency has developed the Endangered Species Protection Program. Through this program, EPA will use toxicity and exposure data developed for Reregistration Eligibility Decisions and consider ecological parameters, use information, geographic relationships between specific pesticide uses, as well as biological requirements and behavioral aspects of a particular species for a species-specific analysis of PCNB use. The Agency's species-specific analysis will take into consideration any risk mitigation measures implemented as part of the RED decision for PCNB. Following this future species-specific analysis, a determination whether there is a likelihood of potential effects to a listed species may result in additional limitations on the use of PCNB, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries as appropriate. Until a species-specific analysis is completed, the ecological risk mitigation measures being implemented through the RED will reduce the likelihood that endangered and threatened species may be exposed to PCNB. Information about the Agency's assessment process for threatened and endangered species is

posted at www.epa.gov/espp. Once an Endangered Species assessment is completed, further changes to the PCNB registrations may be necessary as explained in Section III B.8 of the RED.

Human Health Risks

Dietary Risk

The PCNB dietary risk assessment quantifies chronic risks only. An acute health risk endpoint has not been identified for PCNB, so an acute dietary risk assessment has not been conducted. The method for predicting chronic dietary risk associated with PCNB is also appropriate for assessing the cancer risk, so no separate assessment of carcinogenic risk is necessary. The chronic dietary (food only) risk assessment is considered to be a highly refined assessment utilizing all available monitoring data, percent-crop-treated information, and processing factors from residues in food based on field trials. The screening models PRZM/EXAMS and SCI-GROW were used to estimate the drinking water concentrations of PCNB and PCA in surface water and groundwater.

Dietary risk was originally assessed for currently labeled uses of PCNB, and then again after the registrants proposed their risk mitigation plan. The registrants' proposal to eliminate the broadcast application of PCNB to bulbs would greatly reduce estimates of concentrations in groundwater, and the proposal to terminate all turf applications of PCNB except to tees, greens, and fairways allowed the Agency to reassess surface water concentrations based on a Golf Course Adjustment Factor (GCAF) of 34%, to account for that portion of golf course turf on which PCNB could be used. As a result of this proposal, estimates of surface water concentrations would be reduced relative to those in the original assessment. The highest modeled surface water drinking water concentration from the original assessment was 65.5 µg/L for turf, and the highest estimate from the assessment based on the risk mitigation proposal would be 10.3 µg/L, for cabbage. Food-only dietary exposures are based on field trials and currently labeled use rates, and the impact of proposed reductions in application rates on residues in food cannot be estimated.

The chronic dietary risks for food plus water were initially assessed at greater than 100% of the chronic Population Adjusted Dose (cPAD) for several population subgroups (children less than one year, 173%; children one to two years, 214%; children three to five years, 154%), and were of concern. Mitigation measures proposed by the registrants, and the correction and refinement of the dietary assessment relating to the contribution of milk to dietary risk were incorporated into the subsequent dietary assessment, yield dietary risk estimates below levels of concern for the general population and all subgroups. A more detailed discussion of the original dietary risk assessment is found in Section III of the RED, and discussion of the dietary risks that would be associated with the registrants' mitigation proposal and the correction and refinement of the dietary assessment may be found in Section IV.

Inadvertent Residues

For a number of use sites not registered for PCNB use, associated commodities show detectable levels of PCNB residues. The Agency believes that the persistence of PCNB in soil

results in uptake of residues by growing plants for several years after PCNB is applied. The dietary risk assessment was conducted both for residues from registered crops only, and for residues from registered crops plus residues from crops for which PCNB is not registered. Carrots, spinach, cucumber, and ginseng, for which PCNB is not registered, contribute to the latter of these. Other food sources (fresh winter squash, asparagus, pears, celery, aquaculture-raised tilapia, and ginger root) also appear to contribute to dietary residues, but data are insufficient to support their use in quantifying risk. The Agency anticipates that implementation of risk mitigation measures for PCNB and the consequent reduction in overall usage, will result in fewer commodities with inadvertent residues of the pesticide and its metabolites.

Tolerances

The fourteen tolerances established for residues of PCNB have been reassessed, and found to satisfy the requirements for a safety finding under FIFRA and FQPA, based on implementation of the requirements of this RED. The tolerances could change at a later time based on the new analytical method required by the RED, residue data currently in review, or product cancellations resulting from implementation of the terms of the RED.

Non-occupational Risk

PCNB products are marketed for homeowner use on residential lawns and ornamental plants. PCNB products are also marketed for use by professional applicators on residential turf, golf courses, and commercial/industrial and recreational turf, as well as non-turf ornamentals. Residential handlers may be exposed to PCNB during applications to home lawns and ornamental plants. Adults and children alike may be exposed after these applications; other post-application exposures may take place at golf courses, parks, and schools. Post-application non-occupational exposures from treatment of commercial/industrial and recreational turf, and turf at parks and schools, are not assessed individually, but are expected to be similar to residential exposure from lawns after application of PCNB. Residential post-application exposures to treated ornamentals could not be assessed because the Agency lacks a methodology for estimating such exposures.

The residential handler exposures to PCNB are considered to be short-term in nature due to the episodic use associated with homeowner products. For PCNB, residential handler margins of exposure (MOEs) of less than 1000 represent risks of concern. MOEs were estimated for both dermal and inhalation exposures. Based on the currently labeled uses of PCNB, some residential handler scenarios pose risks of concern, with MOEs ranging from 12 to 490 for certain application methods.

After application to turf and ornamentals, short- to intermediate-term dermal exposures are anticipated for adults and children in residential settings, and in parks and other public areas. Incidental oral exposure is also expected to occur for small children, and is combined with their dermal exposures where applicable (i.e., playing on turf). Exposure is also expected in golfers playing on courses treated with PCNB. Post-application MOEs of less than 1000 represent risks of concern. Based on the Agency's initial assessment, practically all residential turf post-application and golfer scenarios pose risks of concern. Of these scenarios, MOEs for post-

application exposures on lawns are as low as <10 (for hand-to-mouth and object-to-mouth exposures of children). Golfer MOEs were not estimated to increase above 1000 until nine days after application.

The registrants' proposal to terminate residential turf use would eliminate the risks associated with residential turf. Risks associated with the use of PCNB on residential ornamentals would be unaffected by the proposal, and the Agency remains concerned about them. The registrants' mitigation proposal would not affect exposures for golfers after application of PCNB to golf course turf, but recently submitted data from the ARTF have been reviewed in the context of golfer reentry, and the Agency now believes that risks for golfers are not of concern even on the day of application. The Agency's review of the ARTF data is found in "PCNB: HED Revision of Golfer Risk Assessment," dated March 6, 2006 and can be accessed at http://www.regulations.gov/, Docket Number OPP-2004-0202.

Aggregate Risk

The aggregate risk assessment for PCNB estimates combined risks from exposure to PCNB via all means other than occupational exposures. Risks from dietary exposure (food and drinking water) and exposures from non-occupational sources (e.g., residential uses) are aggregated.

Acute Aggregate Risk**.** No acute human health risk endpoint has been identified for PCNB, so an acute aggregate risk assessment was not conducted.

Short- and Intermediate-term Aggregate Risk. This measure of aggregate risk combines estimated chronic dietary exposure plus any applicable residential, recreational, incidental oral, dermal, and inhalation exposures. For PCNB, residential risks from contact with treated lawns by themselves are of concern. These risks, combined with residential handler and dietary risks, yield aggregated risk estimates of even greater concern. Mitigation proposed by the registrants and correction and refinement of the dietary assessment focusing on the contribution of milk to dietary exposure would reduce the dietary risk below levels of concern for the general population and all subgroups. Mitigation proposed by the registrants would eliminate the risk from residential application and post-application exposures related to the turf use; risks from applications to residential ornamentals have not been quantified, but the Agency remains concerned about them. The original aggregate risk assessment is discussed in Section III of the RED; the aggregate assessment based on the registrant risk mitigation proposal is discussed in Section IV.

Chronic Aggregate Risk. Since none of the residential or recreational exposures to PCNB are considered to be chronic in length and duration, the chronic aggregate risk assessment addresses only chronic dietary exposures to PCNB in food and water. As noted above, dietary risks from food plus water were of concern for several highly exposed subpopulations. Mitigation measures proposed by the registrants and correction and refinement of the dietary assessment would reduce the chronic dietary risk below levels of concern for the general population and all subgroups.

Cancer Aggregate Risk. PCNB is classified as a possible human carcinogen (Group C). The dose-response relationship is unquantified. The Agency believes that the cPAD chosen for predicting chronic dietary risk is also appropriate for quantifying human carcinogenic risk, so a separate assessment of aggregate cancer risk is not necessary.

Occupational Risk

PCNB is used to treat seed, and for soil and foliar applications. Risks to handlers for all types of applications are assessed. Post-application risks to workers are assessed for those workers thought to have the highest potential for exposure.

Occupational Risk (excluding seed handlers)

The Agency assessed potential occupational exposures to workers for exposure scenarios derived from the various use sites, formulation types, application methods and rates, and tasks performed by workers. The Agency assessed 103 different non-seed handler exposure scenarios for occupational use.

Handler MOEs were calculated for short- and intermediate-term exposures. The intermediate-term duration is intended to represent commercial applicators who may make repeated applications of PCNB over the course of the growing season, while the short-term duration is representative of private growers, whose exposures during the season are likely to be more limited. The occupational risk assessment includes MOE calculations for progressively more protective levels of personal protective equipment (PPE) and engineering controls, using surrogate data from the Pesticide Handlers Exposure Data (PHED). The occupational risk assessment is described in more detail in Section III of this document. Although the registrants' risk mitigation proposal would be expected to decrease some occupational risks below levels of concern, no formal reassessment of occupational risk was conducted.

Potential handler risk for each exposure scenario was assessed using the endpoints selected from the toxicology database for PCNB and the appropriate uncertainty factor. Risks associated with different levels of PPE and engineering controls were assessed independently of what is currently required by PCNB labels, and the assessment indicates what level of PPE or engineering controls would be required to adequately mitigate the risks associated with the various scenarios.

The target MOE for the occupational uses of PCNB is 100. Based on the currently labeled uses of PCNB, many scenarios do not achieve MOEs greater than 100 at any level of PPE or engineering controls, or data are not available to assess the risk reduction associated with higher levels of protection. In other cases, the use of engineering controls is not feasible and was not assessed. The formulation type and use site combinations corresponding to MOEs less than 100 at the highest level of protection assessed or feasible are:

Mixer/loaders

- dry flowables/chemigation/sod farms (MOEs 39-80)
- liquids/chemigation/sod farms (inhalation MOE 74)
- wettable powders/chemigation/soil banding cole crops (inhalation MOE 28)
- wettable powders/chemigation/sod farms (inhalation MOE 20)
- wettable powders/groundboom/sod farms (inhalation MOE 89)

Applicators
- dry flowables as spray/high-pressure handwand/ornamentals (MOEs 0.59-39)
- emulsifiable concentrates /high-pressure handwand/industrial lawn (inhalation MOE 59)
- wettable powders/high-pressure handwand/industrial lawns (inhalation MOE 18)

Mixer/loader/applicators or loader/applicators
- liquids/handgun sprayer/ornamentals (MOEs 36-77)
- granules/push-type spreader/industrial lawn (inhalation MOE 44)
- granules/belly grinder/ornamentals (dermal MOE 21)
- granules/push-type spreader/ornamentals (inhalation MOE 88)
- wettable powders/low-pressure hand-wand/ornamentals (MOEs 0.58-3.1)
- wettable powders/low-pressure hand-wand/shade trees (MOEs 3.4-18)

The occupational scenarios with MOEs less than 100 include most of the scenarios assessed for sod farms. Six of the eight mixer/loader/applicator or loader/applicator scenarios for which occupational risk were assessed have MOEs of 100 or less; these scenarios all involve the use of PCNB on ornamentals and lawns, with liquid, granular, and wettable powder formulations. Occupational risks associated with these scenarios cannot be adequately mitigated with PPE or engineering controls. Risk mitigation measures needed to address other risk concerns will mitigate most of the occupational risks associated with use of PCNB on ornamentals, and any remaining risks will be addressed with labeling required by the RED.

Occupational Risk for Seed Handlers

Seed handler exposures vary with application rates, the activities in which handlers engage, whether closed systems are used in the seed treatment facility, and the amount of seed handled. These latter factors are, in turn, related to whether PCNB is applied commercially or on-farm. Activities assessed by EPA are loading/applying, bagging, sewing bags of seed closed, planting, and multiple seed handling tasks performed by the same individual. This assessment does not account for high-efficiency air-handling systems facilities that remove air laden with pesticide residues from the workspace. The Agency lacks a methodology to assess such systems, but believes they can reduce occupational exposures for seed handlers. The Agency considers seed-handling tasks to result in short- and intermediate-term exposures.

There are four scenarios in which risks were estimated to be below the target MOE of 100; all four are the result of inhalation exposures at commercial seed treatment facilities for handlers engaged in multiple treatment activities, with barley (MOE 50), peas (75), rice (50), and soybeans (75). These scenarios were assessed for handlers wearing long pants, long-sleeved shirts, gloves, but no respirator, and using open systems. While data are lacking to quantify risks

for seed-handlers engaged in multiple treatment activities on the farm, it is reasonable to assume that those handlers might also be exposed above levels of concern. The Agency has determined that the labels of PCNB seed treatment products must be amended to require seed handlers to wear respirators while seed handling tasks are performed. The type of respirators differs by the type of task.

Post-application Worker Risks

The Agency assessed risks for the workers expected to be most highly exposed after application of PCNB—golf course maintenance workers and sod farm workers. There were no risks of concern associated with their exposures.

Benefits of PCNB use

EPA assessed the benefits and costs associated with the use of PCNB and alternatives for the major uses of PCNB. This assessment is described in the document, "Benefits and Cost Analysis of PCNB and Alternatives for Use on Golf Course Turf (Tees, Greens, Fairways), Cotton, Potatoes, Green Beans, and Cole Crops (Cabbage, Brussels Sprouts, Cauliflower), " May 22, 2006, which has been posted to the PCNB Docket at http://www.regulations.gov/. EPA has also sought to characterize the benefits of the minor uses of PCNB by soliciting information through the USDA from the Regional IPM Centers, and by examining Crop Profiles posted at http://www.ipmcenters.org/Crop Profiles/, anecdotal information about how users value PCNB, and usage and percent crop treated information. The benefits assessments are detailed in Section IV of this RED.

The Agency has concluded that of the major use sites, only the use of PCNB to combat clubroot on cole crops has substantial benefits. PCNB appears to be the only available chemical treatment that is feasible for effective management of clubroot where the pathogen occurs in soil. Both methyl bromide and metam sodium are effective in controlling the pathogen, but both pose risks of concern. A six- or seven- year rotation to crops in another plant family may be effective for controlling the pathogen on infested acreage, but may not be a practical alternative for growers.

While acknowledging that additional information not already available to the Agency could be used to refine the benefits assessment for the minor uses of PCNB, the Agency additionally has identified only commercial production of flowering bulbs and seed treatments as uses with potentially high benefits from the use of PCNB. The Agency is actively soliciting comments on the need for PCNB on some other minor use sites, in order to determine if amendments should be made to this eligibility decision.

Risk Mitigation Summary

EPA has assessed the risks associated with the uses of PCNB as currently labeled, and also as associated with the mitigation measures proposed by the technical registrants. While implementation of the registrants' proposal would adequately reduce or eliminate dietary and

most residential and occupational risks, other residential and occupational risks and ecological risks would continue to be of concern. As noted, the Agency has evaluated the benefits of PCNB use, and has made a determination on each of the uses of PCNB based on the relationship of risks to benefits. In order to adequately address the full complement of PCNB risks, and in consideration of the benefits, the Agency has decided that a number of measures are necessary. In summary:

- The uses of PCNB on turf, residential ornamentals, green beans, cotton, potatoes, dry beans and peas, garlic, peanuts, tomatoes, peppers, and ornamentals in commercial production (except for flowering bulbs) are not eligible for reregistration and must be deleted from product labels. Products labeled exclusively for one or more of these ineligible uses will not be eligible for reregistration.

- Application to flowering bulbs in commercial production must be limited to in-furrow, banded, drench, and bulb soak applications. Broadcast application to ornamental bulbs is prohibited. Wettable powder formulations must not be labeled for this use.

- Products which are eligible for reregistration must be labeled to require adequate PPE and engineering controls, as detailed in this RED. For example, seed handlers will be required to wear PPE for respiratory protection.

- Application to cole crops must be limited to a maximum rate of 22.5 lb ai/A. Application via chemigation is prohibited. Products for use on cole crops must bear labeling prohibiting their use on cole crops except for treatment of clubroot. The only products labeled for use on cole crops which are eligible for reregistration are those which are limited to the cole crop/clubroot combination, and no other pests may be added to the label of a registered product either by amendment or through the notification process (PR Notice 98-10).

- All aerial applications of PCNB are prohibited.

These eligibility decisions, and the risk mitigation measures for the uses which have been designated as eligible for reregistration, are discussed in detail in Section IV of this RED.

Conclusions

The risk assessments for PCNB, which support the Agency's reregistration decision, are based on the best scientific data and methodologies available to the Agency at this time and are adequate for determining the reregistration eligibility of the uses of PCNB and reassessing tolerances. The benefits associated with the currently labeled uses for PCNB are also a factor in the Agency's decision. Due to residual uncertainty associated with the benefits of the minor uses of PCNB, the Agency is issuing this Reregistration Eligibility Decision for PCNB for a 60-day public comment period, as announced in a Notice of Availability published in the *Federal Register*. The RED announces the Agency's decision that the following uses of PCNB are eligible for reregistration: cole crops (for treatment of clubroot only), ornamental bulbs in

commercial production, and seed treatments. Other uses of PCNB are not eligible for reregistration. The RED includes guidance and time frames for complying with required label changes for products containing PCNB and developing data required to support the eligible uses.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984, and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, and a review of all submitted data by the U.S. Environmental Protection Agency. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. This Act amends FFDCA to require that by August 3, 2006, EPA must reassess all tolerances in effect at the time of the enactment. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity.

PCNB is an organochlorine fungicide used to control diseases on vegetables (especially green beans and cole crops), field crops (cotton, potatoes, and peanuts), turf, ornamentals, and seeds (seed treatments of barley, beans, corn, cotton, oats, peas, peanut, potato, safflower, sorghum, soybean, sugar beet, and wheat). It is applied to soil, foliage (for turf and some ornamental uses), and seeds.

The Agency has concluded that the FQPA Safety Factor of 10X must be retained for PCNB dietary and residential risk estimates because there are residual uncertainties in the databases for pre- and/or postnatal toxicity. The decision to retain the 10X factor takes into account these potential effects and the incompleteness of the data with respect to exposure and toxicity to infants and children. The safety factor has been retained for the assessment of dietary, residential, and aggregate risk.

Risks summarized in this document are those that result only from the use of PCNB. FQPA requires that the Agency consider available information concerning the cumulative effects of a pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for PCNB and any other substances. Chlorothalonil and pentachlorophenol, pesticides in the same family as PCNB, do not appear to result in the same endpoints. The endpoints used to assess human health risks for PCNB are primarily thyroid hypertrophy and hepatocellular hypertrophy and hyperplasia. The endpoints for chlorothalonil

have been identified as various kidney and forestomach effects, and the endpoints for pentachlorophenol are carcinogenicity (hemangiosarcomas, hepatocellular tumors, and adrenal tumors) and developmental effects (increased resorptions of fetuses, reduced fetal weight, skeletal malformations of fetuses). The Agency has not undertaken a comprehensive assessment of organochlorine pesticides with respect to common mechanism. For the purposes of this action, EPA assumes that PCNB does not share a common mechanism of toxicity with other substances. Information on EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals is found in the policy statements released by EPA's Office of Pesticide Programs at http://www.epa.gov/pesticides/trac/science/#common.

This document presents the Agency's reregistration eligibility decision for the registered uses of PCNB, including the consideration of risk to infants, children and adults for any potential food and drinking water exposures, and dermal, inhalation or oral exposures from residential uses. The information presented herein is summarized from more detailed information which can be found in the technical supporting documents for PCNB referenced in this document. The preliminary and revised risk assessments and supporting documents for PCNB may be accessed via http://www.regulations.gov/, the Federal-wide electronic docket management and comment system. To find the correct docket and documents associated with it, select the Advanced Search function, and then select Docket Search. Enter the Docket Number OPP-2004-0202 in the Docket ID field and submit. Click on the Docket ID link, and icons for viewing and downloading the supporting documents will appear. Your computer's "pop-up blocker" function must be turned off for you to view or download documents in the docket.

This document consists of six sections. Section I is this *Introduction*. Section II provides a *Chemical Overview*, a profile of the use and usage of PCNB, and its regulatory history. Section III, *Summary of the PCNB Risk Assessments*, outlines the human health and environmental risks associated with PCNB. Section IV discusses the Agency's *Risk Management, Reregistration, and Tolerance Reassessment Decisions*. Section V, *What Registrants Need to Do*, summarizes changes to be implemented based on the risk mitigation measures discussed in Section IV and generic data required to support continued registration of the eligible uses of PCNB. Finally, the Appendices in Section VI list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and provide the Data Call-In notices (DCIs) associated with this RED.

II. Chemical Overview

A. Regulatory History

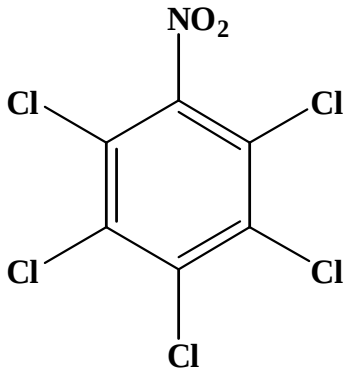
PCNB was first registered in the United States in l964. There are 74 active registrations for products containing PCNB registered under Section 3 of FIFRA. There are also four long-standing Section 18 Emergency Exemptions and eight Section 24(c) (Special Local Needs) registrations. This RED document evaluates risks from all currently registered uses, including agricultural food and non-food crops and non-agricultural uses such as ornamentals and turf.

PCNB has been identified by EPA as one of 177 Hazardous Air Pollutants. The Agency is assisting State and local agencies in their efforts to prioritize these pollutants for further investigation. PCNB has also been designated as toxic air contaminant by California, and so is subject to an evaluation of potential control measures and an effort to foster public awareness of potential exposures and control measures.

In Canada, PCNB is a candidate for reevaluation (akin to our reregistration). In 2000, the sole European registrant of PCNB, Uniroyal (now Chemtura), withdrew support for the fungicide following a determination by the European Commission that risk to non-target organisms could not be excluded by evaluation of the current data base. Uniroyal elected not to develop the data needed to support the registration, primarily ecotoxicology and environmental fate data.

B. Chemical Identification

- **Chemical Structure:**



- **Common name:** PCNB, quintozene
- **Chemical name:** pentachloronitrobenzene
- **Chemical Family:** organochlorine, substituted aromatics class
- **Empirical formula:** $C_6Cl_5NO_2$
- **CAS Registry No.:** 82-68-8
- **Case number:** 0128
- **OPP Chemical Code:** 056502
- **Molecular weight:** 295.3 g/mol
- **Trade names:** Terraclor, Turfcide, Terrazan, Terra-Coat, Parflo, Win-Flo, Blocker
- **Basic manufacturers:** Amvac, Chemtura (formerly Crompton Corp. or Uniroyal)

Technical PCNB is a colorless to pale yellow to cream-colored crystalline solid of fine needles. It is practically insoluble in water (0.44 mg/l at 25° C). PCNB has a melting point of 141-145° C, a boiling point of 328° C, and a relatively high vapor pressure (1.13×10^{-4} mmHg at 25°C).

C. Use Profile

Use information for PCNB is detailed in Appendix A.

Type of Pesticide: Fungicide

Summary of Use: PCNB is a non-systemic fungicide applied to soil, foliage (mainly turf), and seeds to control plant diseases. PCNB may be formulated with other fungicides or an insecticide, e.g., thiram, metalaxyl, carboxin, or malathion.

Food Uses: PCNB is used on vegetables (predominantly green beans and cole crops), field crops (cotton, potatoes, and peanuts), and seeds (seed treatments of barley, beans, corn, cotton, oats, peas, peanut, rice, safflower, sorghum, soybean, sugar beet, and wheat). There are tolerances for PCNB on cottonseed, collards, kale, mustard, beans, broccoli, Brussels sprouts, cabbage, cauliflower, garlic, pepper, potato, tomato, and peanuts.

Non-Food: PCNB is used on turf (golf courses, sod farms, commercial and industrial turf, and lawns) and ornamentals.

Residential: PCNB is used on lawns and broadleaf ornamentals.

Target Pests: Cole crops: clubroot (*Plasmodiophora brassicae*), wirestem (*Rhizoctonia solani*)
Cotton: Rhizoctonia seedling disease or damping-off (*R. solani*)
Green beans: Rhizoctonia root/stem rot or damping-off (*R. solani*), white mold (*S. sclerotiorum*).
Peanuts: seedling diseases (*R. solani*, *Fusarium* and *Pythium* spp.)
Potatoes: stem canker/black scurf (*R. solani*), white mold (*Sclerotinia sclerotiorum*)
Tomatoes and peppers: Southern blight (*Sclerotium rolfsii*)
Turf: Fusarium patch (pink snow mold), Typhula blight (gray snow mold), dollar patch, Rhizoctonia brown patch, large patch of Zoysia, leaf spot/melting-out dollar spot

PCNB works by suppressing the growth of plant pathogens.

Formulation Types: Flowable concentrate, water dispersible granular, wettable powder, emulsifiable concentrate, granular, dust, and ready-to-use formulations

Application Methods: Seed treatment, pre-plant incorporated applications, in-furrow, broadcast banding, drenches, foliar sprays

Application Rates: Maximum application rates for field and vegetable crops are generally 2-30 lb. ai/A with one application/season. The maximum label rate for turf is 33 lb. ai/A per application, with a maximum of two applications/season. PCNB may be applied as an unincorporated broadcast application to ornamental bulbs at 213 lb. ai/A, the highest yearly application rate for PCNB.

Timing: Primarily at or near planting; for snow mold on turf, in cool, damp weather

Use Classification: General Use

Registrants: Include Amvac and Chemtura (registrants of technical material), Bayer Cropscience LP, Scotts, Lebanon Seaboard, Syngenta, VPG, Drexel, The Andersons, Gowan, Lesco, Marman

D. Estimated Usage of Pesticide

Table 1 summarizes PCNB usage on major sites in the United States.

Table 1. PCNB Usage Summary

Site	Lbs. Active Ingredient Applied	Maximum Percent Crop Treated
Cotton	400,000	10%
Turf	250,000-500,000	no information
Potatoes	60,000	5%
Green beans	30,000	20%
Cabbage	10,000	<2.5%
Cauliflower	6,000	5%
Brussels sprouts	7,000	10%
Peanuts	5,000	<2.5%
Total	770,000-1,000,000	

For more detail, see the Screening Level Usage Assessment of May 10, 2005, posted to http://www.regulations.gov/, Docket Number OPP-2004-0202.

III. Summary of PCNB Risk Assessments

This section's summary of EPA's human health, environmental fate, and ecological effects risk findings and conclusions for PCNB has been drawn from the more-detailed documents: "Pentachloronitrobenzene (PCNB): 2nd Revised HED Chapter of the Reregistration Eligibility Decision Document" dated February 3, 2005 (the chapter was revised to address error-only comments solicited from the registrants), and "Environmental Fate and Ecological Risk Assessment for the Re-registration of Pentachloronitrobenzene," February 15, 2005, and associated supporting documents available at http://www.regulations.gov/, Docket Number OPP-2004-0202. The risk estimates presented in this Section reflect the Agency's best estimates as of February 2005, and are presented here for reference purposes. Based on public comments, technical corrections, and risk mitigation measures proposed by the registrants, the Agency subsequently revised many of its risk assessments for PCNB. These changes are fully discussed, and citations for supporting scientific documents provided, in Section IV of this RED.

A. Human Health Risk Assessment

1. Toxicity of PCNB

a) Acute Toxicity

The database for acute toxicity of the technical grade PCNB products is complete. PCNB has relatively low acute toxicity to the test animals. Data for materials produced by both Chemtura and Amvac are presented in Table 2. These materials differ somewhat, and data indicate that the Chemtura product is a sensitizer while the Amvac product is not.

Table 2. Acute Toxicity of PCNB

Guideline Number Study Type	Registrant	MRID #	Results	Tox Category
81-1/ 870.1100 Acute Oral	Chemtura	43198201	LD_{50} = >5000 mg/kg	IV
	Amvac	41443101	LD_{50} = >5050 mg/kg	IV
81-2/ 870.1200 Acute Dermal	Chemtura	43198202	LD_{50} = >5000 mg/kg	IV
	Amvac	41443102	LD_{50} = >2020 mg/kg	III
81-3/ 870.1300 Acute Inhalation	Chemtura	43118201	LC_{50} = > 1.7 mg/L	III
	Amvac	41443103	LC_{50} = > 6.49 mg/L	III
81-4/ 870.2400 Primary Eye Irritation	Chemtura	43198203	Slight irritant	III
	Amvac	41443109	Slight irritant	III
81-5/ 870.2500	Chemtura	43198204	Non irritant	IV

Primary Skin Irritation	Amvac	41443105	PII = 0.0175	IV
81-6 /870.2600 Dermal Sensitization	Chemtura	40609001	Weak sensitizer	n/a
	Amvac	40734001	Non sensitizer	n/a

b) Endpoint Selection

The toxicological endpoints used for the human risk assessment are presented in Table 3 below. Further details on the toxicity database of PCNB can be found in the Docket item "Revised Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision," dated January 7, 2005, and posted to http://www.regulations.gov/.

Table 3. Endpoints for PCNB Risk Assessment

Exposure Scenario	Dose Used in Risk Assessment (FQPA Safety Factor)	Levels of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary	N/A	N/A	None selected
Chronic Dietary	NOAEL= 1.0 mg/kg/day (10X) cPAD is 0.001 mg/kg/day	Target is ≤100% of cPAD	Chronic/Oncogenicity Study (rat) LOAEL = 150 mg/kg/day based on hepatocelluar hypertrophy and hyperplasia, thyroid hypertrophy
Short-Term Incidental Oral (1-30 days)	NOAEL= 1.0 mg/kg/day (10X)	Target MOE ≥ 1000	90-Day Subchronic (rat) LOAEL = 1.0 mg/kg/day, based on no toxicity at 30d
Intermediate-Term Incidental Oral (1- 6 months)	NOAEL= 1.0 mg/kg/day (10X)	Target MOE ≥ 1000	90-Day Subchronic (rat) LOAEL = 1.0 mg/kg/day based on threshold effects (liver and thyroid lesions) seen at lowest dose tested
Short- and Intermediate-Term Dermal	NOAEL= 300 mg/kg/day (10X, residential)	Residential target MOE ≥ 1000; Occupational target MOE > 100	21-Day Dermal (rat) LOAEL = 1000 mg/kg/day based on hypertrophy of the thyroid follicular epithelium and dilation of the thyroid follicles in males
Long-Term Dermal (>6 months)	Oral NOAEL= 1.0 mg/kg/day; dermal absorption 33% of oral	Target MOE ≥ 100	Chronic/Oncogenicity Study (rat) LOAEL = 150 mg/kg/day based on hepatocelluar hypertrophy and hyperplasia, thyroid hypertrophy

Exposure Scenario	Dose Used in Risk Assessment (FQPA Safety Factor)	Levels of Concern for Risk Assessment	Study and Toxicological Effects
Short-Term Inhalation	Oral NOAEL= 1.0 mg/kg/day; inhalation absorption 100% of oral (10X, residential)	Residential target MOE ≥ 1000; Occupational target MOE > 100	90-Day Subchronic (rat) LOAEL = 1.0 mg/kg/day based on no toxicity at 30 days
Intermediate-Term Inhalation	Oral NOAEL= 1.0 mg/kg/day; inhalation absorption 100% of oral (10X, residential)	Residential target MOE ≥ 1000; Occupational target MOE ≥ 100	90-Day Subchronic (rat) LOAEL = 1.0 mg/kg/day based on threshold effects (liver and thyroid lesions) seen at lowest dose tested
Long-Term Inhalation	Oral NOAEL= 1.0 mg/kg/day with inhalation absorption rate = 100% of oral	Target MOE ≥ 100	Chronic/Oncogenicity Study (rat) LOAEL = 150 mg/kg/day based on hepatocelluar hypertrophy and hyperplasia, thyroid hypertrophy
Cancer	PCNB is classified as a Group C (possible human) carcinogen. For the purpose of risk characterization, the chronic dietary risk assessment approach is used to quantify cancer risk.		

c) FQPA Safety Factor

There is no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses after *in utero* exposure, or after pre- or postnatal exposure to rats in multigeneration reproduction studies.

Because thyroid weights were increased in a number of chronic and subchronic studies in rats; thyroid histopathology effects including neoplasia were observed in some studies; and TSH, T3, and T4 levels were affected in a 90-day special oral study in male rats, the Agency determined that a comparative thyroid assay in young and adult rats (which would report hormonal measurements for thyroid function) would be required. The DCI associated with this RED requires that such a study be undertaken in support of continued registration of the eligible uses of PCNB.

The absence of comparative thyroid study data at this time introduces an extra uncertainty in the risk assessment. Thus, the Agency has determined that an FQPA safety factor of 10X should be retained for the dietary (chronic) and all residential exposure (incidental oral, dermal, and inhalation) scenarios, based on the concern about thyroid effects.

d) Population Adjusted Dose

Dietary risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the Reference Dose (RfD) divided by the FQPA Safety Factor, and for non-cancer effects, is of concern for PCNB at or above 100%.

(1) Acute PAD

No appropriate acute endpoint attributed to a single dose was identified; therefore, an acute PAD has not been calculated.

(2) Chronic PAD

The endpoint for the chronic dietary assessment was identified in a combined chronic toxicity and oncogenicity study in rats, in which the NOAEL was 1.0 mg/kg/day (adverse effects observed at higher doses were hepatocelluar hypertrophy and hyperplasia, and thyroid hypertrophy). With incorporation of the intra- and interspecies uncertainty factors (totaling 100X), the chronic RfD is then 0.01 mg/kg/day. The FQPA Safety Factor is 10X, as discussed above, producing a chronic PAD of 0.001 mg/kg/day (cPAD = cRfD/FQPA SF).

e) Uncertainties in the Toxicology Database to be Addressed with New Data Requirements

The fate characteristics of PCNB and its metabolites indicate that they have the potential to bioaccumulate. The extent to which PCNB and its metabolites may bioaccumulate in humans is a source of uncertainty and concern in the consideration of both human health and ecological risks. Data are required to address this uncertainty. In addition, data are required to address concerns about the impact of contaminants in PCNB test materials on toxicity testing, and additional toxicity endpoints. Data requirements are tabulated in Section IV of this RED.

2. Dietary Risk Assessment

a) Assumptions and Uncertainties

The Agency considers the dietary risk assessment for PCNB to be a highly refined assessment that utilizes all available monitoring data, percent crop treated information, and processing factors. Nevertheless, several important assumptions add uncertainty to the findings.

Because monitoring data do not include analysis of all the PCNB metabolites of concern (there are more than 80), estimates of total residues of concern are based mainly on the ratio of total radioactive residues (TRR) to PCNB from available metabolism studies in combination with monitoring residue data on PCNB.

USDA's 1994-1998 Continuing Surveys of Food Intake by Individuals were used as the consumption database for the dietary exposure assessment. PCNB and/or its metabolites were widely detected in monitoring of unregistered food uses, often at levels higher than in registered food uses. The Agency believes that the presence of PCNB and/or its metabolites on unregistered crops is due primarily to its uptake from soil by crops planted to areas where other crops were legally and previously treated with PCNB (rather than illegal use) and the very long half-lives of

PCNB and its metabolites in soil. To account for these residues, the Agency assessed dietary risk for residues associated with registered food uses only and for residues from registered food uses plus residues from crops for which PCNB is not registered. The Agency views that this latter set of residues as a more accurate representation of dietary exposure. The estimates for dietary risk from food found in this document are based on residues from registered crops plus residues from crops for which PCNB is not registered, unless otherwise noted.

PCNB and/or some of its metabolites have been found at detectable levels in some crop parts grown from treated seeds, particularly wheat (straw) and peas. Residues have also been found in these same crops grown from untreated seeds. The source of the PCNB residues in such commodities is not clear and may vary. Because of this uncertainty and the expectation that residues resulting from seed treatments are lower than those resulting from soil and foliar applications, PCNB residues that originate with seed treatments are not included in the dietary risk assessment, with the exception of such residues correlating to animal feed items. The seed treatment residues are an important component of residues of PCNB and metabolites in meat and milk because the seed treatment uses are major contributors to residues in animal diets (animal feed items are mainly associated with crops for which PCNB is applied to seeds only).

The dietary exposure assessment for food only was conducted using the Dietary Exposure Evaluation Model-Food Consumption Intake Database (DEEM-FCID™).

b) Acute Dietary Risk

Since no acute endpoint was identified for PCNB, an acute dietary risk assessment was not conducted.

c) Chronic (Noncancer) Dietary Risk

Table 4 shows, that in February 2005, chronic dietary risk from food alone was estimated at over100% of the cPAD for the population subgroups children 1-2 years old and children 3-5 years old. These risk estimates are associated with the currently registered uses of PCNB plus residues in commodities associated with uses that are not registered.

Table 4. Chronic Dietary Risk Estimates, February 2005

Population Subgroup	cPAD (mg/kg/day)	Food only risk (no water)		Total risk including risk from water	
		Exposure (mg/kg/day)	% cPAD	Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.001	0.000338	34	0.000703	70
All Infants (< 1 year old)	0.001	0.000539	54	0.001734	**173**
Children 1-2 years old	0.001	0.001597	**160**	0.002138	**214**
Children 3-5 years old	0.001	0.001035	**104**	0.001542	**154**
Children 6-12 years old	0.001	0.000614	61	0.000964	96
Youth 13-19 years old	0.001	0.000281	28	0.000544	54
Adults 20-49 years old	0.001	0.000194	19	0.000535	54
Adults 50+ years old	0.001	0.000206	21	0.000565	56
Females 13-49 years old	0.001	0.000203	20	0.000542	54

Chronic dietary risks now have been reassessed based on proposed mitigation and technical revisions to correct an error related to how PCNB residues partition in the liquid and fat portions of milk and to refine the dietary assessment by more accurately reflecting the composition of the diet for lactating cows and its contribution to residues in milk. These risk estimates are discussed in Section IV of this document.

d) Cancer Dietary Risk

PCNB is classified as an unquantified Group C (possible human) carcinogen, with a threshold effect observed in test animals. The Agency believes that the cPAD chosen for predicting chronic dietary risk is also appropriate for quantifying human carcinogenic risk from PCNB exposure.

e) Dietary Exposures from Drinking Water

The Agency uses physical-chemical property data and representative high-application rate use scenarios to model potential concentrations of pesticides in surface water and groundwater, or Estimated Drinking Water Concentrations (EDWCs). For drinking water, the Agency was able to model potential contributions from PCNB and one metabolite, PCA. Of the numerous degradates of PCNB, only PCA is expected to be present at >10% of the original parent concentration.

To assess concentrations of PCNB and PCA in drinking water, the Agency approximated half-lives by summing the concentration of the parent and PCA; half-lives were calculated normally (using first-order linear regression). Degradation kinetics for the parent and PCA were not determined separately and then combined. This approach is conservative, but should not overestimate half-lives relative to estimates determined using individual kinetic rates for each compound. The continuous formation and decline of degradates in a sequential manner does not affect the half-lives calculated using this approach, as the other major degradate, PCTA, is formed from PCA.

The drinking water exposure assessment is based on the uses of PCNB as currently labeled. Other features of the drinking water exposure assessment are detailed in "Pentachloronitrobenzene, Second Revised Drinking Water Assessment**:** New Tier II Drinking Water EDWCs for Use in the Human Health Risk Assessment," July 15, 2004, accessible via http://www.regulations.gov/.

Dietary exposures from surface water are incorporated into the "Total risk including risk from water" column of Table 4. The Agency believes that surface water sources are more likely to be contaminated with PCNB and its metabolites than are groundwater sources, since PCNB is relatively immobile in soil.

(1) Surface Water Concentrations

Surface water EDWCs were determined using the Tier II screening models PRZM/EXAMS. Applications to turf, peanuts, cabbage, potatoes, and cotton were modeled, with the turf scenario assessed at 32.67 lb ai/A/application, and two applications, for the highest rate overall. This scenario produced the highest EDWCs, as seen in Table 5 below. Dietary exposures from surface water-source drinking water are incorporated into Table 4. Estimated drinking water concentrations don't reflect an alternate adsorption coefficient used in the later drinking water assessment that was conducted to assess the registrants' risk mitigation proposal. The Agency used a different coefficient at that time based on technical comment from the registrants; the new coefficient decreased estimates of PCNB getting to surface water to a small degree relative to the impact of the risk mitigation measures themselves.

(2) Groundwater Concentrations

Groundwater EDWCs for the drinking water assessment were generated using the Tier 1 screening model SCI-GROW. The highest application rate from PCNB product labels was used as an input in the model. That rate is the application to bulb crops at 213.4 lb ai/A/application in a single application.

Results for the PRZM/EXAMS and SCI-GROW modeling are shown in Table 5 below.

Table 5. Chronic (1-in-10-year annual mean) EDWCs, February 2005

Source	Scenario Modeled	EDWC
Surface water	Turf	65.5 µg/L (ppb)
Groundwater	Bulbs	30.6 µg/L (ppb)

Drinking water concentrations have been reassessed based on mitigation measures proposed by the registrants. These concentrations are discussed in Section IV of this document.

3. Residential and Other Nonoccupational Exposures

PCNB is used on residential turf, and to a lesser extent, broadleaf ornamentals. Individuals who apply PCNB in their yards (residential handlers) and adults and children who do yard work, or walk, sit, play, or exercise on turf to which PCNB is applied may be exposed to residues. The Agency has assessed the potential exposures and risks associated with PCNB applications to residential turf. PCNB is also used extensively on golf courses, and the Agency has assessed the potential exposure of golfers to PCNB residues and the associated risks.

a) Residential Handlers

(1) Exposure, Scenarios, and Assumptions

Residential handler exposures are a function of the formulation type, application equipment and rate, and area treated or volume applied. The Agency assessed eight different scenarios deemed to be representative of residential applications and supported by exposure data.

For PCNB, the Agency relied on assumptions typical to most residential handler assessments:

- Homeowner use of the pesticide is episodic; exposures are short-term
- Shorts, short-sleeved shirts, socks, and shoes are worn during application
- One person mixes, loads, and applies the pesticide
- Area treated or volume applied is based on typical lawn sizes
- Unit exposure values from PHED or from Outdoor Residential Exposure Task Force (ORETF) data were used to calculate risk, based on scenarios that are similar but not identical to the actual scenarios.

(2) Residential Handler Risk Estimates

The risk estimates are presented in Table 6 below. Exposure scenarios are described in greater detail in the document “Pentachloronitrobenzene (PCNB): Revised Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document, November

11, 2004." The residential handler risk assessment is based on the uses of PCNB as currently labeled. MOEs representing risks of concern (<1000) are shown in bold.

Table 6. Summary Short Term Residential Handler Risk for PCNB

Exposure Scenario	Application Rate	Area Treated or Amounted Applied per Day	Dermal MOE	Inhalation MOE
Applicator				
Applying Granulars for Hand application	32.67 lb ai /A	0.023 A	**65**	**200**
Mixer/Loader/Applicator				
Liquids for Low Pressure Handwand application	0.15 lb ai /gal	5 gal	**280**	3100
Liquids for Backpack sprayer application	0.15 lb ai /gal	5 gal	5500	3100
Liquids for Garden hose-end sprayer	32.67 lb ai /A	0.5 A	**120**	**250**
Loader/Applicator				
RTU Liquids for Garden hose-end sprayer	32.67 lb ai /A	0.5 A	**490**	**390**
Granulars for Belly Grinder application	32.67 lb ai /A	0.5 A	**12**	**69**
Granulars for Push-type spreader	32.67 lb ai /A	0.5 A	1900	4900
	43.56 lb ai /A	0.5 A	1400	3700

b) Residential Post-application Risk

(1) Exposure, Scenarios, and Assumptions

Residential post-application exposures result primarily from contact with lawn grass after treatment. They are a function of the type of activity taking place on the lawn (children playing, adults doing yard work), the route of exposure (dermal, hand-to-mouth), application rate, and time since treatment. The type of activity and the route of exposure combine to describe the scenario.

Exposure estimates are based on standard Transfer Coefficients (TCs) representing the amount of treated surface an individual is likely to come into contact with during an hour of a particular type of activity. The coefficients used in this assessment are based on the Policy Memos and Standard Operating Procedures cited below. Activities (on turf) selected as the basis for the residential post-application risk assessment and the relevant TCs for the short-term endpoint are:

- Adults in a low exposure activity (e.g., golfing or mowing); TC = 500 cm^2/hour; Policy Memo # 003.1 "Agricultural Transfer Coefficients," Revised August 7, 2000.

- Adults in a high exposure activity (e.g., heavy yard work); TC = 14,500 cm^2/hour; "Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments," Feb. 22, 2001.

- Toddlers in a high exposure activity (playing); TC = 5200 cm^2/hour; SOPs of February 22, 2001.

The proportion of residues which may be transferred to humans from treated foliage, designated "Turf Transferable Residues" (or TTRs) is assumed to be 5% of the PCNB application rate, as prescribed by the February 22, 2001 SOP.

(2) Post-application Risk Estimates

Dermal risk estimates for adults and children exposed to PCNB on turf, and associated with the use of PCNB as currently labeled, are shown in Table 7. MOEs representing risks of concern (<1000) are in bold.

Table 7. Risks for Residential Short-Term Post-Application Activities

Activity	Application Rate (lb ai/A)	TC (cm^2/hr)	MOE on day of treatment
high contact lawn activities: adults	32.67	14500	**40**
high contact lawn activities: toddler	32.67	5200	**110**
mowing turf: adults	32.67	500	1145

The MOEs for all but one of the assessed residential post-application scenarios are of concern. In the February 2005 assessment, MOEs calculated for reentry of treated golf courses by golfers did not rise above 1000 until the ninth day after treatment. However, based on ARTF data received after this assessment was completed, golfer reentry risks now appear to be acceptable (MOE >1000) even on the day of application. The ARTF data allowed the Agency to use an empirical value for the amount of residue on turf which is available for transfer to human skin (Turf Transferable Residue or TTR) rather than a default value which is 5% of the pesticide application rate. The empirical value was less than the default value. This new assessment is documented in "PCNB: HED Revision of Golfer Risk Assessment," March 6, 2006, which has been posted to http://www.regulations.gov/ in Docket Number OPP-2004-0202, and discussed in Section IV of this RED.

The Agency also assessed oral, non-dietary exposure to toddlers on treated turf. Exposures were calculated based on the methodology presented in the residential SOPs. Post-application risk estimates for PCNB are described in greater detail in the November 15, 2004

document “Revised Occupational and Residential Exposure Assessment for the [PCNB] Reregistration Eligibility Decision Document,” and summarized in Table 8. These risks were assessed based on the use of PCNB as currently labeled. MOEs representing risks of concern (<1000) appear in bold.

Table 8. Residential Short-term Post-application Risks for Toddlers

Exposure Scenario	Application Rate	MOE
Hand to Mouth Activity on Turf	32.67	**2**
Object to Mouth Activity on Turf	32.67	**8**
Incidental Soil Ingestion	32.67	**612**

Residential post-application risks have been reassessed based on a risk mitigation proposed by the registrants, as discussed in Section IV of this RED.

4. Aggregate Risk

Short-term (1-30 day) aggregate exposure combines the chronic estimated dietary exposure with estimated short-term residential/recreational/incidental oral, dermal, and inhalation exposures resulting from the registered uses of the chemical. Residential handler exposures to PCNB are considered to be short-term due to episodic use. Likewise, post-application exposures are considered to be short-term. For PCNB, residential exposures are already of concern, so aggregating them with dietary exposures would yield risks of even greater concern. Aggregate risks have been reassessed based on proposed mitigation, as discussed in Section IV of this RED.

5. Cumulative Assessment

FQPA requires EPA to consider available information concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals.

Guidance for conducting cumulative risk assessments on substances that have a common mechanism of toxicity is available at http://www.epa.gov/pesticides/trac/science/#common. In the guidance, it is stated that a cumulative risk assessment of substances that cause a common toxic effect by a common mechanism will not be conducted until an aggregate exposure assessment of each substance has been completed. Before undertaking a cumulative risk assessment, HED will follow procedures for identifying chemicals that have a common mechanism of toxicity as set forth in the "*Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity*" (64 FR 5795-5796, February 5, 1999).

PCNB is a member of the substituted aromatics class of pesticides (*George W. Ware, The Pesticide Book, Fourth ed., 1994*). Other members of this class include chlorothalonil and pentachlorophenol. The Agency did not perform a cumulative risk assessment as part of this risk assessment for PCNB. Chlorothalonil and pentachlorophenol do not appear to result in the same endpoints as PCNB. The endpoints used to assess human health risks for PCNB are primarily thyroid hypertrophy and hepatocellular hypertrophy and hyperplasia. The endpoints for chlorothalonil have been identified as various kidney and forestomach effects, and the endpoints identified for pentachlorophenol are carcinogenicity (hemangiosarcomas, hepatocellular tumors, and adrenal tumors) and developmental effects (increased resorptions of fetuses, reduced fetal weight, skeletal malformations of fetuses). The Agency has not undertaken a comprehensive assessment of organochlorine pesticides with respect to common mechanism.

6. Occupational Risk

Occupational handlers of PCNB may be exposed through seed treatment activities or the use of PCNB for soil and foliar applications. Occupational exposure was assessed based on maximum allowable label rates. The Agency relied on surrogate data from the Pesticide Handlers Exposure Database (PHED) Version 1.1.; chemical specific post-application exposure data have not been submitted by the registrants in support of the reregistration of PCNB.

a) Toxicological Endpoints for the Occupational Assessment

Table 3 above shows the endpoints used in the PCNB occupational risk assessment.

b) Seed Handler Exposure Information

The information used by the Agency to assess exposures to handlers of treated seed comes from several sources:

- The amount of seed treated or planted daily is based on information from an Agency database and from registrants.
- The seed treatment exposure SOP unit exposure values generally range from the geometric mean to the median for the selected data set.
- The seed treatment surrogate exposure database is relatively small.

c) Soil and Foliar Application Exposure Information

The information used by the Agency to assess exposures to handlers from soil and foliar application of PCNB also comes from several sources:

- The numbers of acres treated daily are standard values from Exposure Policy Number 9.1, “Standard Values for Daily Acres Treated in Agriculture,” September 25, 2001, except for airblast acreage for magnolia trees. For this assessment, magnolia acreage is assumed at 20 acres.

- The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set.

- To enhance consistency and quality control, the Agency has developed a set of grading criteria to characterize the quality of the original study data from the PHED database, based on the number of observations and the available quality control data.

- While data from PHED provides the best available information on handler exposures, some aspects of the included studies may not accurately represent labeled uses in all cases.

d) Occupational Handler Risk Summary

(1) Seed Treatment Handler Risk

Seeds may be treated with PCNB on the farm or at a commercial seed treatment facility. Seed treatment activities that may result in exposure are loading/applying PCNB to seed; bagging treated seed; sewing bags of treated seed; cleaning, calibrating, and repairing equipment; operating a forklift; and planting treated seed. The Agency was able to estimate exposures for a subset of these activities. Individual workers may perform one or more of these tasks during the course of the workday. On-farm seed treatment represents a relatively small proportion of the total treated seed in the U.S. Workers are more likely to perform multiple seed treatment tasks when seed is treated on the farm or at smaller commercial facilities.

Table 9 provides short- and intermediate-term risk estimates for seed treatment handlers engaged in selected activities, wearing baseline attire of long pants, long sleeved shirts, gloves, and no respirator and using open systems. All registered seed uses of PCNB were assessed, but only those seed types with MOEs below 100 are shown below. The target MOE is 100, so MOEs of less than 100 represent risks of concern. These values are in bold. For the "on-farm" treatment activity, seed is treated in and planted directly from the planter box.

Table 9. Seed Handler Short and Intermediate-Term MOEs by Treatment Activity

Crop	Loader/applicator		Bagger		Multiple activities		On-Farm		Planters	
	D*	I	D	I	D	I	D	I	D	I
Barley	1000	200	2500	500	550	**50**	300	9000	3600	900
Pea	1500	350	4000	730	800	**75**	250	9000	13000	3000
Rice	900	200	2300	400	500	**50**	150	5300	2000	500
Soybean	1500	350	3900	700	800	**75**	3300	120000	7000	1600

* D = dermal MOE, I = inhalation MOE

Most of the seed-handler exposure scenarios assessed by the Agency do not pose risks of concern for seed handlers who use open systems for loading and applying PCNB formulations, and who wear long pants, long sleeved shirts, and gloves, but no respirators. For workers

engaging in multiple seed treatment tasks with barley, pea, rice, and soybean, MOEs are less than the target of 100 and are potentially of concern. Since these risks result from inhalation exposures, they can be addressed with the use of respirators. The Agency believes different respirators are appropriate for different tasks (e.g., applying PCNB to seed vs. operating a forklift to move bags of treated seed). Specific respirator requirements for seed handlers are detailed in Section V of this RED.

(2) Handler Risks for Soil and Foliar Uses of PCNB

The Agency assessed over 100 scenarios for risks to occupational handlers associated with the non-seed treatment uses of PCNB. These handlers may be exposed while mixing, loading, or applying PCNB products (or a combination of these activities), and during flagging for aerial applications.

The risks associated with these scenarios have been assessed at increasing levels of protection from addition of personal protective equipment, or PPE and engineering controls. All workers are assumed to be wearing baseline attire (long-sleeved shirts, long pants, socks and shoes or boots, no gloves, and no respirator). Additional PPE or engineering controls added to the baseline for the different levels of protection, from least to greatest protection, are:

- PPE1 = baseline attire plus chemical resistant gloves and no respirator (with open mixing techniques and open cab tractors).

- PPE2 = baseline attire plus chemical resistant gloves and a dust/mist (5-fold Protection Factor, or PF) respirator (with open mixing techniques and open cab tractors).

- PPE3 = baseline attire plus chemical resistant gloves and an air purifying (10-fold PF) respirator (with open mixing techniques and open cab tractors).

- PPE4 = coveralls over baseline attire plus chemical resistant gloves and no respirator (with open mixing techniques and open cab tractors).

- PPE5 = coveralls over baseline attire plus chemical resistant gloves and a dust/mist (5-fold PF) respirator (with open mixing techniques and open cab tractors).

- PPE6 = coveralls over baseline attire plus chemical resistant gloves and an air-purifying (10-fold PF) respirator (with open mixing techniques and open cab tractors).

- Engineering Controls = baseline attire plus chemical resistant gloves and no respirator with closed mixing techniques and enclosed cab tractors or cockpits.

Additional assumptions, descriptions of scenarios, and data sources for assessment of occupational risk may be found in Table D1 of the November 15, 2004 document "Revised Occupational and Residential Exposure Assessment for the [PCNB] Reregistration Eligibility Decision Document," which has been posted to http://www.regulations.gov/ in Docket Number

Tables 10-14 show short- and intermediate-term risk estimates for non-seed treatment occupational handlers, based on the uses of PCNB as currently registered, for scenarios associated with risks of concern at any level of protection. (The full complement of scenarios and associated MOEs may be found in Table 10 of the November 15, 2004 document).

MOEs below 100 represent risks of concern; these risks, at the highest level of protection available or feasible, are shown in bold. Scenarios are defined by handler and formulation type, method of application and application equipment, and use site. For scenarios with hand-held equipment, engineering controls are not feasible and are marked N/A. Scenario numbers are provided for ease of reference to the November 15 document.

Table 10. Short and Intermediate-Term Risk for Mixer/Loaders and Loaders

Exposure Scenario (#)	Use Site	Dermal MOE				Inhalation MOE			
		Baseline	PPE1 PPE2 PPE3	PPE4 PPE5 PPE6	Engineering Controls	Baseline PPE1 PPE4	PPE2 PPE5	PPE3 PPE6	Engineering Controls
Mixer/Loader, or for Granular Formulations, Loader									
Dry Flowables; Chemigation (6)	Sod farms	28	28	**39**	N/A	8	41	**80**	N/A
Dry Flowables; Groundboom (9)	Soil band treatment (cole crops)	130	130	190	N/A	38	190	380	N/A
Dry Flowables; Groundboom (11)	Peanuts	340	340	480	N/A	98	500	980	N/A
Liquids; Groundboom (12)	Band treatment (dried beans, succulent beans, lima)	45	5700	7700	15000	360	1800	3600	5300
Liquids; Groundboom (13)	Band treatment, soil treatment (garlic)	4.5	570	770	1500	36	180	360	530
Liquids; Chemigation (14)	Ornamental lawn and turf	44	5600	7600	15000	360	1800	3600	5200
Liquids; Chemigation (15)	Commercial/ industrial lawns	22	2800	3800	7500	180	890	1800	2600
Liquids; Chemigation (16)	Sod farms	0.63	80	110	210	5.1	26	51	**74**
Liquids; Groundboom (16a)	Sod farms	2.8	350	470	930	22	110	220	320

Exposure Scenario (#)	Use Site	Dermal MOE				Inhalation MOE			
		Baseline	**PPE1 PPE2 PPE3**	**PPE4 PPE5 PPE6**	**Engineering Controls**	**Baseline PPE1 PPE4**	**PPE2 PPE5**	**PPE3 PPE6**	**Engineering Controls**
Mixer/Loader, or for Granular Formulations, Loader									
Liquids; Chemigation (17)	Golf course turf	22	2800	3800	7500	180	890	1800	2600
Liquids; Chemigation (18)	Golf course fairways	5.5	700	950	1900	45	220	450	650
Liquids; High-Pressure HandWand (19)	Commercial/ industrial lawn	48	6100	8200	16000	390	1900	3900	5600
Liquids; Groundboom (20)	Cotton	18	2300	3100	6100	150	730	1500	2100
Liquids; Groundboom (21)	Garlic	4.5	570	770	1500	36	180	360	530
Liquids; Groundboom (22)	Peanuts	9.1	1100	1500	3100	73	360	730	1100
Liquids; Groundboom (23)	Potato	3.6	460	620	1200	29	150	290	420
Liquids; Chemigation (24)	Potato	0.83	100	140	280	6.7	33	67	**96**
Liquids; Aerial (25)	Potato	0.83	100	140	280	6.7	33	67	**96**
Liquids; Groundboom (26)	Soil band treatment (cole crops)	3	380	510	1000	24	120	240	350
Liquids; Airblast (28)	Foliar spray (magnolia tree)	60	7600	10000	20000	490	2400	4900	7000
Liquids; Groundboom (29)	Tomato, pepper	12	1500	2100	4100	97	490	970	1400
Liquids; Groundboom (30)	Southern pine (seed orchard)	17	2100	2900	5700	140	690	1400	2000
Granulars; Tractor-Drawn Spreaders (33)	Soil band treatment (cole crops)	1000	1300	2600	51000	17	86	170	860
Granulars; Tractor-Drawn Spreaders (34)	Golf course turf (tees, greens)	5700	7000	14000	280000	95	470	950	4700
Granulars; Tractor-Drawn Spreaders (35)	Golf course turf (fairways)	1400	1700	3500	71000	24	120	240	1200

Exposure Scenario (#)	Use Site	Dermal MOE				Inhalation MOE			
		Baseline	PPE1 PPE2 PPE3	PPE4 PPE5 PPE6	Engineering Controls	Baseline PPE1 PPE4	PPE2 PPE5	PPE3 PPE6	Engineering Controls
Mixer/Loader, or for Granular Formulations, Loader									
Granulars; Tractor-Drawn Spreaders (36)	Sod farms	720	870	1800	35000	12	59	120	590
Granulars; Tractor-Drawn Spreaders (39)	Potato	1300	1500	3100	62000	21	100	210	1000
Wettable Powders; Groundboom (40)	beans (lima, snap, dried)	47	1000	1300	18000	14	68	140	2400
Wettable Powders; Chemigation (41)	beans(lima, snap, dried)	11	240	310	4100	3.1	16	31	560
Wettable Powders; Chemigation (42)	soil band treatment (cole crops)	0.54	12	15	200	0.16	0.78	1.6	**28**
Wettable Powders; Groundboom (43)	soil band treatment (cole crops)	2.4	51	67	890	0.68	3.4	6.8	120
Wettable Powders; Chemigation (44)	commercial/ industrial lawns	14	300	400	5300	4	20	40	710
Wettable Powders; High-Pressure HandWand (45)	commercial/ industrial lawns	11	250	320	4300	3.3	16	33	580
Wettable Powders; Groundboom (46)	cotton	14	310	400	5400	4.1	20	41	730
Wettable Powders; Chemigation (47)	cotton	8.1	180	230	3100	2.3	12	23	420
Wettable Powders; Chemigation (48)	golf course tees, greens	14	300	400	5300	4	20	40	710
Wettable Powders; Chemigation (49)	golf course fairways	3.5	76	99	1300	0.100	5	1.00	180
Wettable Powders; Chemigation (50)	sod farms	0.4	8.7	11	150	0.11	0.57	1.1	**20**
Wettable Powders; Groundboom (51)	sod farms	1.7	38	49	660	0.50	2.5	5	**89**
Wettable Powders; Groundboom (52)	peanuts	35	770	1000	13000	10	51	100	1800
Wettable Powders; Chemigation (53)	peanuts	8.1	180	230	3100	2.3	12	23	420

Exposure Scenario (#)	Use Site	Dermal MOE				Inhalation MOE			
		Baseline	PPE1 PPE2 PPE3	PPE4 PPE5 PPE6	Engineering Controls	Baseline PPE1 PPE4	PPE2 PPE5	PPE3 PPE6	Engineering Controls
Mixer/Loader, or for Granular Formulations, Loader									
Wettable Powders; Groundboom (54)	pepper, tomato	9.5	210	270	3600	2.7	14	27	490
Wettable Powders; Groundboom (55)	pine (seed orchard)	15	330	430	5700	4.3	22	43	780

*****N/A = data not available

Table 11. Short and Intermediate-Term Risk for PCNB for Applicators

Exposure Scenario (#)	Use Site	Dermal MOE				Inhalation MOE			
		Base-line	PPE1 PPE2 PPE3	PPE4 PPE5 PPE6	Engineering Controls	Baseline PPE1 PPE4	PPE2 PPE5	PPE3 PPE6	Eng. Controls
Applicator									
Dry Flowables; Sprays; High-Pressure HandWand (57)	commercial/ industrial, residential lawns	310	880	1600	N/A	24	120	240	N/A
Dry Flowables; Sprays; High-Pressure HandWand (58)	ornamentals (foliar application only)	7.8	22	**39**	N/A	0.59	2.9	**5.9**	N/A
Dry Flowables; Sprays; Groundboom (60)	Soil band treatment (cole crops)	630	630	800	1800	39	190	390	680
Emulsifiable Concentrates; Sprays; Groundboom (64)	Band treatment, (garlic)	940	940	1200	2600	59	290	590	1000
Emulsifiable Concentrates; Sprays; High-Pressure HandWand (65)	Commercial/ industrial lawn	78	220	390	N/A	5.9	29	**59**	N/A
Emulsifiable Concentrates ;Sprays; Groundboom (67)	Garlic	940	940	1200	2600	59	290	590	1000
Emulsifiable Concentrates; Sprays; Groundboom (69)	Potato	750	750	950	2100	47	230	470	810
Emulsifiable Concentrates;Sprays; Groundboom (71)	Soil band treatment (cole crops)	630	630	800	1800	39	190	390	680
Emulsifiable Concentrates; Sprays; High-Pressure HandWand (72)	container stock (cole crops)	780	2200	3900	N/A	59	290	590	N/A

Exposure Scenario (#)	Use Site	Dermal MOE				Inhalation MOE			
		Base-line	PPE1 PPE2 PPE3	PPE4 PPE5 PPE6	Engineering Controls	Baseline PPE1 PPE4	PPE2 PPE5	PPE3 PPE6	Eng. Controls
Applicator									
Granulars; Tractor-Drawn Spreaders (77)	Soil band treatment (cole crops)	880	1200	2100	4200	24	120	240	130
Granulars; Tractor-Drawn Spreaders (79)	Golf course turf (fairways)	1200	1700	2900	5700	33	170	330	180
Granulars; Tractor-Drawn Spreaders (80)	Sod farms	610	840	1400	2900	17	84	170	91
Granulars; Tractor-Drawn Spreaders (84)	Potato	1100	1500	2500	5000	29	150	290	160
Wettable Powders; Sprays; Groundboom (86)	Soil band treatment (cole crops)	630	630	800	1800	39	190	390	680
Wettable Powders; Sprays; High-Pressure HandWand (87)	commercial/ industrial lawns	23	66	120	N/A	1.8	8.8	**18**	N/A
Wettable Powders; Sprays; Groundboom (89)	Sod farms	460	460	580	1300	29	140	290	500
Wettable Powders; Sprays; Groundboom (89a)	Sod farms	570	570	730	1600	36	180	360	620

Table 12. Short and Intermediate-Term Risk for PCNB for Flaggers

Exposure Scenario (#)	Use Site	Dermal MOE				Inhalation MOE			
		Baseline	PPE1 PPE2 PPE3	PPE4 PPE5 PPE6	Engineering Controls	Baseline PPE1 PPE4	PPE2 PPE5	PPE3 PPE6	Engineering Controls
Flagger									
Aerial Spray s (93)	Potato	220	240	240	11000	23	110	230	1100

Table 13. Short and Intermediate-Term Risk for PCNB for Mixer/Loader/Applicators or Loader/Applicators

Exposure Scenario (#)	Use Site	Dermal MOE				Inhalation MOE			
		Baseline	PPE1 PPE2 PPE3	PPE4 PPE5 PPE6	Engineering Controls	Baseline PPE1 PPE4	PPE2 PPE5	PPE3 PPE6	Engineering Controls
Mixer/Loader/Applicator, or; Granulars, Loader/Applicator									

Exposure Scenario (#)	Use Site	Dermal MOE				Inhalation MOE			
		Baseline	**PPE1 PPE2 PPE3**	**PPE4 PPE5 PPE6**	**Engineering Controls**	**Baseline PPE1 PPE4**	**PPE2 PPE5**	**PPE3 PPE6**	**Engineering Controls**
Liquids; Handgun Sprayer (94)	Ornamental herbaceous plants, woody shrubs, vines	Data not available		**77**	N/A	**36**	Data not available		N/A
Granulars; Push-type spreader (96)	Commercial/ industrial lawns	280	440	880	N/A	**44**	Data not available		N/A
Granulars; Belly Grinder (97)	Ornamental lawns and turf	96	100	No data	N/A	52	270	520	N/A
Granulars; Belly Grinder (98)	Ornamental shade trees, herbaceous, woody shrubs, vines	19	**21**	No data	N/A	10	54	100	N/A
Granulars; Push-type spreader (99)	Ornamental shade trees, herbaceous, woody shrubs, vines	550	880	1800	N/A	**88**	Data not available		N/A
Wettable Powders; Low Pressure Handwand (100)	Ornamental woody shrubs, vines, herbaceous plants	2.2	2.2	**3.1**	N/A	0.058	0.29	**0.58**	N/A
Wettable Powders; Low Pressure Handwand (101)	Ornamental shade trees	13	13	**18**	N/A	0.34	1.7	**3.4**	N/A

For many scenarios with risks of concern at lower levels of protection, the addition of PPE or engineering controls can increase MOEs above 100. For applications with hand-held equipment, the use of engineering controls is not feasible. For some scenarios, there are no feasible protective measures that will increase MOEs above 100. MOEs less than 100 at the highest level of protection assessed or feasible are in bold.

e) Occupational Post-application Risks

In general, there is a low potential for occupational post-application exposure when a pre-plant or at-plant fungicide is used. Significant exposure during harvesting or other late season activities is not likely for a pesticide applied at this time. The Agency has not assessed post-application risk for seed treatments or at-plant uses of PCNB. Applications of PCNB may be

made to turf at any time during the growing season, and into winter in some areas. There are potential post-application exposures for workers re-entering PCNB-treated turf for mowing and other maintenance activities. The Agency believes that these scenarios represent the highest potential occupational post-application exposures for PCNB. The Agency typically estimates risk to workers on the day of treatment (day 0), and if MOEs are below 100, will estimate risk for subsequent days until the MOEs exceed 100. In the case of PCNB, the assessment yields MOEs above the threshold on day 0. MOEs were estimated for two application rates. These estimates are shown in Table 14.

Chemical specific post-application exposure data have not been submitted in support of the reregistration of PCNB. Details on the studies used as the basis for estimating post-application risk associated with PCNB and the approach the Agency took to assess those risks may be found in the document "Revised Occupational and Residential Exposure Assessment for the [PCNB] Reregistration Eligibility Decision Document, November 15, 2004."

Table 14. Occupational Post-application Risks at Day Zero

Use Site	Application Rate (lb ai/acre)	Activities	MOE
Golf Course Turf	32.67-43.56	Mow, seed, weed (mechanically), aerate, fertilize, prune	2100-1580
Sod Farms	32.67-43.56	Mow, scout, weed (mechanically), irrigate	1120-790

At day zero, all MOEs are above the target of 100. The Agency believes that other post-application occupational scenarios are also likely to yield MOEs greater than 100.

7. Human Incident Data

According to the *Recognition and Management of Pesticide Poisoning,* 5th Edition, symptoms of prolonged exposure to PCNB can include skin sensitization and irritation, and following eye contact, conjunctivitis and keratitis. Systemic poisoning has not been reported. Clearance is chiefly via the liver and biliary excretion.

According to the American Association of Poison Control Centers, between 1993 and 1998, 41 cases of PCNB exposure were reported. There were 21 symptomatic cases, including six ranked moderate. Fifteen of the individuals reported in the 41 cases were seen in a health care facility, and one was hospitalized.

The California Pesticide Illness Surveillance Program reported 30 PCNB incidents from 1982-1997, most involving PCNB in mixtures with other pesticides. Of the seven case reports for PCNB alone, most were older cases related to eye contamination.

Between 1984 and 1991, the National Pesticides Telecommunications Network reported 16 human incidents and five animal incidents associated with PCNB.

These numbers are relatively small compared to other pesticides for which incidents have been reported and are consistent with the low acute toxicity of PCNB.

B. Environmental Risk Assessment

The basis for this summary of the environmental risk assessment for PCNB is the document entitled "Environmental Fate and Ecological Risk Assessment for the Re-registration of Pentachloronitrobenzene," February 12, 2005. The complete assessment has been posted to http://www.regulations.gov/ in Docket Number OPP-2004-0202.

1. Fate and Transport

Based on the submitted environmental fate data, physical-chemical properties, use patterns, and information found in the published literature, PCNB is, in general, expected to be a persistent, moderately volatile compound that will be immobile in most soils, but may have slight or even moderate mobility in coarser (sandy) soils, particularly those that are low in organic matter. Table 15 summarizes the physical-chemical properties of PCNB, a relatively high molecular weight compound with low water solubility.

Table 15. Fate and Physical-Chemical Properties of PCNB

Parameter	Value
Molecular Weight	295.3g
Solubility (25 ^{o}C)	0.44 mg/L (440 ppb)
Vapor Pressure (25 ^{o}C)	1.13 x 10^{-4} mmHg
Hydrolysis Half-life (pH 5, 7, 9; 25 ^{o}C)	stable
Aqueous Photolysis Half-lives (pH 5)	2.5 days 26.8 hours
Soil Photolysis Half-life	stable
Aerobic Soil Metabolism Half-lives	77, 189 days (measured, parent only); Calculated values: 489, 1012 days (parent plus PCA) 983, 1052 days (total residues)
Anaerobic Soil Metabolism Half-lives	9 days, <30 days (DT_{50}; parent only); 410 days (parent plus PCA) 334 days (total residues)
Organic Carbon Partition Coefficients (K_{oc})	1588-17508

Parameter	Value
Soil Partition Coefficients (K_d, mL/g)	7.3, 15.5, 19.1, 210
Bioconcentration Factors (BCF) in fish (bluegill sunfish)	370-400 edible tissue 1800 viscera 960-1100 whole fish tissue

a) Metabolites

PCNB has over 80 metabolites, or degradates. The major degradates of PCNB in the environment are PCA, PCTA, and pentachlorobenzene (also present as an impurity); minor degradates are pentachlorothioanisole sulfoxide (PCTASO), and pentachlorothioanisole sulfone ($PCTASO_2$). PCNB also contains the manufacturing contaminant hexachlorobenzene (HCB), which also has been reported as a degradate in registrant-submitted field dissipation and anaerobic aquatic metabolism studies. Pentachlorophenol, which is also a pesticide active ingredient and a probable carcinogen, also was detected as a metabolite of PCNB in several registrant-submitted studies but the conditions which favor its formation have not been identified. Structures of the parent compound and its degradates are presented in APPENDIX C of the "Environmental Fate and Ecological Risk Assessment for the Re-registration of Pentachloronitrobenzene, February 12, 2005."

For the drinking water and ecological risk assessments, degradation half-lives in water were calculated using parent data plus data for degradates in soil. To determine the half-lives, the concentrations of the parent and appropriate degradate(s) were summed, and half-lives were calculated using first-order linear regression; degradation kinetics for the parent and the various degradates were not determined separately and then combined. This approach is conservative, but should not overestimate the half-lives relative to such estimates determined using individual kinetic rates for each compound. Volatiles were included when half-lives were recalculated

For use in the drinking water assessment, half-lives were recalculated for the parent compound plus the degradate PCA. Half-lives were recalculated for total residues (represented by PCNB, PCA, PCTA, pentachlorobenzene, pentachlorophenol, PCTASO, $PCTASO_2$ and HCB) for use in the environmental assessment.

b) Field Dissipation

In terrestrial field dissipation studies, PCNB dissipated more rapidly when the pesticide was not incorporated. Major degradates in these studies included PCA, PCTA and pentachlorobenzene. Although pentachlorobenzene is present as a manufacturing impurity in PCNB, increases in its concentration over time confirmed that it was formed as a degradate of PCNB in the field. In a study of field soils cropped with potatoes and to which PCNB had been applied over the previous five to 11 years, field half-lives were as long as 1059 days.

c) Volatility

PCNB and many of its metabolites are moderately volatile. Volatilization is likely a significant route of dissipation when the pesticide is not incorporated, as when it is applied as a foliar spray (e.g., to turf) or through overhead sprinkler irrigation; e.g., chemigation on potatoes). PCNB may volatilize more from moist or saturated soils than dry soils because it adsorbs less to wetter soils. One study reports that most of the PCNB that was lost from soil during 10 months of incubation was due to volatilization.

d) Photodegradation

The primary degradation pathway for PCNB in clear and shallow surface water is through photodegradation, when the compound is present in an unsorbed state. Photodegradation of PCNB in surface water is moderately rapid, with half-lives on the order of a few days or less. Photodegradation of PCNB in turbid or deeper waters may be limited by the attenuation of sunlight and adsorption of the compound to suspended particles in the water column. PCNB is stable to hydrolysis, and stable to photodegradation on soil.

e) Aerobic and Anaerobic Metabolism

As seen in Table 15, PCNB biodegrades slowly in aerobic soils and more rapidly in anaerobic soils. The persistence of PCNB in aerobic soils is supported by data in the published literature, with half-lives of almost 10 months reported in one citation. Guideline aquatic metabolism data for PCNB have not been submitted.

f) Mobility

PCNB is immobile in most soils, but may have slight or even moderate mobility in soils low in organic matter. PCNB has a low potential for leaching to groundwater. PCA and PCTA are expected to be immobile in soil. Pentachlorobenzene is slightly mobile to immobile in soil. In terrestrial field dissipation studies, PCNB generally did not leach below the 6- to 12-inch soil depth, and PCA, PCTA and pentachlorobenzene generally remained in the 0- to 6-inch soil depth.

g) Drift and Surface Water

PCNB may reach surface water through drift when applied as a spray and particularly with foliar applications (such as to turf). PCNB and its major degradates are all generally persistent under field conditions and may reach surface water bodies. The slow biodegradation of PCNB in most soils will increase opportunities for surface water contamination.

h) Bioconcentration

PCNB has a very high potential to bioaccumulate in fish. Fish will metabolize PCNB, but the impact of depuration is limited by the persistence of PCNB and its metabolites in the aquatic environment, which create a regular source of exposure. Bioconcentration factors (BCFs) are reported in other fish species at levels consistent with those reported for bluegill sunfish, i.e., up to 1100X in whole fish. Higher BCF values have been reported for aquatic plants, at up to 3100X for algae.

2. Impact of Fate Characteristics on Risk

The Agency is particularly concerned about PCNB's environmental persistence, bioaccumulative potential, and potential for long-range transport. These fate characteristics increase the extent and scope of the risks PCNB and its metabolites pose to nontarget organisms, but their effect cannot be quantified.

The relationship between PCNB's fate characteristics and ecological risk is detailed in the document "Synopsis of Pentachloronitrobenzene Environmental Loading and Ecological Risk," April 26, 2006, which is accessible through http://www.regulations.gov/ , Docket Number OPP-2004-0202. To summarize this relationship:

The persistence of PCNB and its metabolites in the environment:

- increases opportunities for exposure because organisms are exposed to residues for a long time after application of the pesticide (or may be continuously exposed between applications)
- limits the extent of depuration because organisms remain in contact with or may ingest food items contaminated with residues
- increases opportunities for bioaccumulation through the food chain

The evidence that PCNB and is metabolites are subject to long-range transport is limited but compelling, and:

- field data show significant quantities of PCNB can volatilize from the field
- exposure models do not account for long-range transport and underestimate exposure;
- PCNB is not expected to degrade appreciably in the atmosphere
- atmospheric transport increases opportunities for exposure and increases the extent of risk (exposure occurs outside areas where PCNB is applied and to species which otherwise would not be exposed)

PCNB and its metabolites partition to organic matter and sediment, and:

- effects on benthic organisms are uncertain and unaccounted for in the risk assessment
- this partitioning likely contributes to bioaccumulation and amplification of residues in the food chain

The fate characteristics of PCNB and its metabolites (including persistence and partitioning to lipids and organic matter) indicate the potential to bioaccumulate up the food chain. While bioconcentration data are limited:

- application of the Gobas food web bioaccumulation model developed by EPA's Office of Water (http://www.epa.gov/glnpo/lmmb/foodweb.html) suggests that the aquatic food chain can serve as a mechanism for significant bioaccumulation
- the risk quotients cited in this RED do not account for exposures related to bioaccumulation, so they understate ecological risks

In addition, the metabolites of PCNB are not only likely to be persistent and have the potential to bioaccumulate:

- they are assumed to be toxicologically equivalent to PCNB
- and are accounted for in modeling the aquatic exposures cited in this RED, but not in the terrestrial exposures, resulting in underestimates of risk

3. Environmental Loading

The combined effect of the fate characteristics on the amount of the pesticide and its metabolites entering and remaining in the environment is referred to in this document as "environmental loading." Environmental loading varies with the different use sites for a pesticide, and is a function of how much of the pesticide is introduced into the environment, as measured by usage (pounds applied for a use site on an annual basis), percent crop treated (what proportion of a given use site is treated in a year), application rates, and application methods (for a volatile pesticide like PCNB, a foliar application may result in more volatilization and a greater potential for long-range transport).

PCNB is a widely used pesticide with many different use sites. These use sites differ in usage, percent crop treated, application rate, and application method. The fate characteristics of PCNB and its metabolites tend to increase the amount of these compounds that remain biologically available in the environment, for long periods after application. There is a great deal of evidence to indicate that toxic residues of PCNB will persist in the environment and that the aquatic community is particularly vulnerable to this chemical. Based on the screening level assessment summarized in this RED, estimated environmental concentrations are sufficient to result in both acute and chronic effects on aquatic animals. It likely that if the full effect of the persistence, bioconcentration, and long-range transport characteristics of PCNB and its metabolites associated with environmental loading could be quantified, aquatic organisms could be exposed to PCNB residues that exceed acute and chronic effect thresholds by several orders of magnitude. The fate and toxicological characteristics of PCNB and its metabolites are not fully quantified in this RED and contribute to an underestimation of risk.

4. International and Domestic Standards for Persistence, Bioaccumlation, and Long-range Transport

The persistence, bioaccumulative potential, potential for long-range transport , and ecotoxicity of PCNB and its metabolites, when examined relative to national and international standards, suggest that PCNB has much in common with substances that have been officially identified as "persistent organic pollutants" (POPs)" and "persistent bioaccumulative toxic substances" (PBTs).

The 2001 Stockholm Convention establishes global controls on substances listed as POPs, defining them as organic substances that are persistent and bioaccumulate, have potential for long-range transport, and are likely to cause significant adverse human health or environmental effects. PCNB is not one of the 12 POPs listed for elimination or restriction, nor is the Agency proposing

that PCNB be listed as a POP, but the Agency believes that PCNB shares some characteristics with substances which may be proposed for listing.

Screening criteria have been established to identify compounds which may be added to the original POPs list. The screening criteria are described in Annex D of the Convention, which can be found at http://www.pops.int/documents/convtext/convtext_en.pdf. The screening criteria and how PCNB relates to these criteria are described below.

a) Persistence

The POPs criterion for persistence is a half-life in water greater than two months, soil and sediment half-lives greater than six months or, alternatively, evidence that the substance is otherwise sufficiently persistent to be of concern.

No data are available for PCNB half-lives in water. The half-life of PCNB alone in aerobic soil has been measured as 189 days; for the parent plus PCA half-lives are 489 and 1012 days (two studies, results supported by the open literature). The anaerobic soil half-life for PCNB plus PCA is 410 days. Residues of PCNB and its metabolites remain in soil and may be taken up by plants in measurable quantities several years after PCNB was last applied. PCNB clearly meets the persistence criterion.

b) Bioaccumulation

The POPs criterion for bioaccumulation is a bioaccumulation or bioconcentration factor greater than 5,000 in aquatic species; a log octanol-water coefficient (Kow) greater than 5; evidence that a chemical presents other reasons for concern, such as high bioaccumulation in other species, high toxicity or ecotoxicity; or monitoring data indicating the bioaccumulation potential of the chemical is sufficient to warrant its consideration.

Bioaccumulation is the net uptake of a chemical from the environment by all possible routes (respiration, diet, dermal) from any source (water, dissolved, colloidal or particular organic carbon, sediment and other organisms) (Spacie et al. 1995). Bioconcentration is a measure of the relative amounts of residues in tissue to concentrations in water.

PCNB has a tendency to bioconcentrate in aquatic organisms. Bioconcentration factors (BCFs) of 1100 and 1800X have been reported for whole fish and visceral tissue respectively. BCFs as high as 3100X have been observed for PCNB in aquatic plants. The log Kow for PCNB is reported as 4.22 (Hansch et al., 1995). PCNB does not meet the bioconcentration criterion on the basis of either BCFs or log Kow.

Empirical information on bioaccumulation for PCNB is lacking, but its fate characteristics, and the fate characteristics of its metabolites, suggest a tendency to bioaccumulate up the food chain, based on their tendency to concentrate in organic matter, sediment, and lipids. In addition, the ecotoxicity and fate characteristics of PCNB contribute to opportunities for non-target exposures, and potential risks of concern, in a broad range of species and both within and outside

areas where PCNB is applied. Although it is not clear that PCNB meets the POPs numerical criteria for bioaccumulation, its ecotoxicity and fate characteristics suggest other reasons for concern about its bioaccumulative potential.

c) Long-range Transport

The POPs criterion for long-range environmental transport is detection of the chemical in locations distant from the source; monitoring data showing that long-range transport may occur via air, water or migratory species; environmental fate properties demonstrating potential for long-range transport; and, for a chemical that migrates through air, a half-life in air of greater than two days

Residues of PCNB have been detected in locations, e.g., Saskatchewan, Canada, where it is not used. Based on its vapor pressure, PCNB will exist almost exclusively in the vapor phase in the atmosphere. The estimated photo-oxidation half-life for PCNB in the vapor phase is estimated to be 2,200 days. Given that the compound is also hydrolytically stable, degradation in the atmosphere is expected to be negligible. PCNB meets the long-range transport criterion.

d) Adverse Effects

The POPs criterion for adverse effects is toxicity or ecotoxicity data that indicate the potential for damage to human health or to the environment.

PCNB is toxic in many test species, including those representing wildlife. PCNB is highly toxic to freshwater fish and invertebrates (LC_{50}s between 0.1 and 1.0 mg/L) and very highly toxic to estuarine/marine fish and invertebrates (LC_{50} less than 0.1 mg/L) on an acute exposure basis. PCNB is toxic on chronic basis to aquatic and terrestrial animals. PCNB meets the adverse effects criterion established by the Stockholm Convention.

A contaminant and metabolite of PCNB, pentachlorobenzene, has been nominated for addition to the Convention on Long-range Transboundary Air Pollution (LRTAP), a regional agreement on air pollutants similar to the global POPs Convention.

e) PBT Criteria and the Resource Conservation Challeng

The Agency has also established criteria for identifying Persistent Bioaccumulative Toxic substances (PBTs). Criteria are defined at two levels, the more restrictive of which calls for a ban on production while additional data are developed. The criteria can be found at: http://www.epa.gov/fedrgstr/EPA-TOX/1999/November/Day-04/t28888.htm.

The more restrictive criterion for persistence is a half-life in soil of 60 days or more. PCNB alone and PCNB plus its predominant metabolite, PCA, exceed this criterion. PCNB exceeds the less restrictive bioconcentration criterion of a BCF greater than 1000. According to PBT criteria, determinations of toxicity are based on best professional judgment on existing data. As noted above, PCNB is very toxic to a wide range of fauna.

The PBT criteria, which are the basis for regulatory action relating to pre-manufacture notices for toxic substances, excluding pesticides, have also been used by the Agency to identify priority chemicals for the Resource Conservation Challenge (RCC). Under the RCC, PCNB has been identified as one of 31 priority chemicals for which a strategy is being developed for voluntary reduction in waste streams, through a variety of programs including pollution prevention, substitution, minimization, and cradle-to-grave chemical management. Documentation may be found at http://www.epa.gov/epaoswer/hazwaste/minimize/chemlist.htm and http://www.epa.gov/epaoswer/osw/conserve/strat plan/strat plan.htm#chemreduc.

5. Monitoring Data

There are no surface water monitoring data available for PCNB or PCA in the US Geological Survey's National Water Quality (NAWQA) database (neither of the compounds is an analyte). According to EPA's *Pesticides in Ground Water Database, A Compilation of Monitoring Studies: 1971-1991, National Summary*, PCNB is not found in groundwater at significant levels or frequencies. In sampling of 1708 wells, only three detections of PCNB occurred, at a range of 0.008 to 0.275 µg/L. No information is available on whether the monitoring sites corresponded with PCNB use sites or times of usage.

In a groundwater monitoring study of 18 wells in three counties in California (July 1994–1995), PCNB was not detected (California EPA, 1995). In a review of multiple studies in which sampling was conducted in surface water and/or groundwater at golf courses, PCNB was monitored in surface water for an unspecified number of studies, but was not detected (Cohen *et al.*, 1999).

A literature search was conducted to obtain published information (generally post-1990) on the occurrence of PCNB and its degradates in the aquatic and terrestrial environments. PCNB, PCA, and PCTA have not been detected frequently in North American waters. Detections of pentachlorophenol in the environment cannot necessarily be attributed to the degradation of PCNB, as pentachlorophenol itself is extensively used as a wood preservative. Similarly, detections of pentachlorobenzene are probably most commonly the result of its formation as a byproduct in the manufacture of other compounds or as a degradate of hexachlorobenzene (HCB), and industrial uses.

The compounds PCA, pentachlorobenzene, and PCP were monitored in studies of the Mississippi River and tributaries (Illinois, Missouri, Ohio, Arkansas, White, and Yazoo Rivers; Rostad *et al.*, 1993). PCA was detected in the surface waters at multiple locations, at concentrations of 0.018 to 0.055 ng/L. Pentachlorobenzene was detected in the Mississippi River and two of its main tributaries, but was not likely a result of PCNB use. Its presence was attributed to degradation of HCB, as suggested by the concentration profiles of the two compounds. PCP was not found in any of the surface water samples.

The Agency has concluded that monitoring data on PCNB are limited and/or incomplete information is available. As such, the data are not substantial enough to quantitatively incorporate

into the water assessments. Additionally, it is not clear in most cases whether the water bodies and wells sampled correspond with, or were targeted to correspond with, PCNB usage in terms of location or time. Subsequently, when the registrants submitted study-specific information from a number of monitoring studies previously submitted in summary form, the Agency concluded that the data do not support the registrants' contention that a weight-of-evidence approach incorporating the newly-submitted monitoring data would indicate that modeled values were too high. This later review, in its entirety, may be viewed the "Review of Surface Water Monitoring Data (Summary Report and Original Monitoring Reports) Submitted to Support PCNB Reregistration, July 19, 2005," which has been posted to the PCNB docket.

6. Estimated Concentrations of PCNB and Metabolites in Water Resources

a) Estimated Environmental Concentrations (EECs) for the Ecological Risk Assessment

Environmental fate parameters and use characteristics were input to PRZM/EXAMS modeling to yield estimates of environmental concentrations for use in the PCNB ecological risk assessment. The use parameters used in the model are those associated with PCNB as currently registered. Table 16 shows input values for the five scenarios modeled in this manner. The EECs are based on data for residues of the parent, PCA, PCTA, pentachlorobenzene, pentachlorophenol, PCTASO, $PCTASO_2$ and HCB, including volatiles.

Table 16. Selected input parameters for EECs of PCNB plus metabolites

Parameter	Value	Source and/or Comments
Application Rate: lb ai/A/application (turf: 2 applications/year, 21-day interval; others: 1 application/year)	turf: 32.67 peanuts: 10 cabbage (cole crop): 30 potatoes: 25 cotton: 2	product labels
Date of First Application	turf: November 15 peanuts: April 15 cabbage: August 15 potatoes: May 20 cotton: April 20	USDA Crop Profiles: http://www.ipmcenters.org/CropProfiles/
Application Type; Depth of Incorporation	turf, foliar/ground spray; 0 cm peanuts, band/ground spray; 0 cm cabbage, broadcast spray; 10 cm potatoes, granular; 10 cm cotton, in-furrow spray; 0 cm	product labels
Soil Partition Coefficient (K_d; in mL/g)	15.5 (lowest non-sand value)	MRID 416482-01
Aerobic Soil Metabolism Half-life	$t_{1/2}$ = 1124 days (total residues; 90th percentile of upper confidence bound on mean of two values)	MRID #s 429119-02, 413845-01, 417132-02, 421128-01
Spray Drift Fraction (ground spray)	0.01	input parameter guidance
Application Efficiency	0.99	
Molecular Weight	295.3 g/mole	product chemistry data
Vapor Pressure	1.13 x 10^{-4} Torr	
Henry's Law Constant	4.42 x 10^{-5} atm-m^3-mol	
Solubility in Water at 25^{o}C	4.4 ppm	10X solubility limit of 0.44 ppm, per input parameter guidance
Aerobic Aquatic Metabolism Half-life	$t_{1/2}$ = 2248 days (total residues)*	2X aerobic soil metabolism $t_{1/2}$ per input parameter guidance

Parameter	Value	Source and/or Comments
Anaerobic Aquatic Metabolism Half-life	$t_{1/2}$ = 2004 days (total residues)*	2X anaerobic soil metabolism $t_{1/2}$ per input parameter guidance; data from MRID 413843-01
Hydrolysis Half-life @ pH 7	stable	MRID #s 408653-01, 409726-01
Aquatic Photolysis Half-life	1.83 days @ pH 5	MRID #s 426062-01 and -02, 423362-01

* empirical data lacking; values derived from soil metabolism data as described in risk assessment

Results of the PRZM/EXAMS modeling for PCNB and metabolites, for selected uses as currently labeled, are found in Table 17. Peak concentrations are used to calculate acute RQs and the 1-in-10-year concentrations are used to calculate chronic RQs. A 1-in-10 year value is a value that would be equaled or exceeded once every ten years, on average. One-in-ten-year means are estimated from running averages of 21 and 60 days.

Table 17. Surface Water Concentrations for Use in the Ecological Risk Assessment

Use Site (Rate/Year)	Peak (Acute Assessment)	1-in-10-Year 21-day (Fish Chronic Assessment)	1-in-10-Year 60-day (Invertebrate Chronic)
Cabbage (30 lb ai/A)	84 ppb	56 ppb	36 ppb
Cotton (2 lb ai/A)	28 ppb	20 ppb	14 ppb
Peanuts (10 lb ai/A)	97 ppb	46 ppb	25 ppb
Potato (25 lb ai/A)	22 ppb	11 ppb	5 ppb
Turf (32.67 lb ai/A, 2X)	259 ppb	187 ppb	139 ppb

Detailed information on the modeling and complete results are presented in Appendix D6 of the "Environmental Fate and Ecological Risk Assessment for the Re-registration of Pentachloronitrobenzene, February 15, 2005." Water concentrations used for the ecological RQs have been recalculated to reflect proposed mitigation. The revised EECs are discussed in Section IV.

b) Drinking Water Concentrations

The water concentration used to estimate dietary risk is shown in Table 5 above. The value was derived from PRZM/EXAMS modeling of physical-chemical properties of PCNB and PCA and the high-end application parameters for PCNB use on turf. Even though concentrations of PCNB in groundwater from use of PCNB on ornamental bulbs are estimated to be higher, the drinking water assessment relies on the surface water/turf values because of the extent of turf use and the predominance of surface water as the source of drinking water. Water concentrations for the drinking water assessment have been recalculated to reflect proposed mitigation, as discussed in Section IV.

7. Estimates of Ecological Risk

The Agency typically estimates ecological risk by calculating the ratio of EECs to ecotoxicity values. These risk quotients (RQs) are then compared to LOCs used by the Agency to indicate potential risk to nontarget organisms and the need to consider regulatory action. As noted above, the fate characteristics of PCNB and its metabolites cannot be fully accounted for in developing the RQs, and so contribute to the underestimation of risks. When they are available and of good quality, the results of field studies and incident data may add to the weight-of-evidence. LOCs are established for duration of exposure (acute and chronic), wildlife type (e.g., mammals and birds, fish and aquatic invertebrates), and endangered species. The standard LOCs and the corresponding risk presumptions are presented in Table 18.

Table 18. LOCs and Risk Presumptions

IF...	**THEN the Agency presumes...**
Mammals and Birds	
The acute RQ > LOC of 0.5	Acute risk
The acute RQ > LOC of 0.1	Acute effects may occur in Endangered Species
The chronic RQ > LOC of 1	Chronic risk *and* Chronic effects may occur in Endangered Species
Fish and Aquatic Invertebrates	
The acute RQ > LOC of 0.5	Acute risk
The acute RQ >LOC of 0.05	Acute effects may occur in Endangered Species
The chronic RQ > LOC of 1	Chronic risk *and* Chronic effects may occur in Endangered Species
Terrestrial and Aquatic Plants	
The acute RQ > LOC of 1	Acute effects may occur in Endangered Species

The combination of uses and application methods for PCNB, and the particular fate characterstics of PCNB and its metabolites, result in many potential routes of exposure to non-target terrestrial and aquatic organisms. For the terrestrial exposure assessment (birds and mammals), food item exposures resulting from seed treatment and foliar applications are the major, quantifiable routes of exposure; for aquatic exposures, residues in water from soil and foliar applications are quantified.

RQs for ecological risk have been reassessed based on proposed mitigation and the use of a more refined model for terrestrial risk. These risk assessments are discussed in more detail in Section V of this RED.

a) Risk to Birds

(1) Avian Toxicity

Table 19 summarizes the avian toxicity endpoints associated with PCNB.

Table 19. PCNB Toxicity Data for Avian Species

Species	5-day LC_{50} (ppm)	Subacute Dietary Toxicity	NOEC/LOEC (ppm)	Affected Endpoints
Northern bobwhite quail	>54,000	practically non-toxic	600/1200	Reproduction
Mallard duck	>54,000	practically non-toxic	600/1200	Growth

For both test species, there was no mortality even at the highest dose tested. The Agency believes that PCNB is practically non-toxic to birds on both an acute and subacute dietary basis The Agency considers measures of toxicity to birds to serve as surrogates for toxicity to reptiles and terrestrial-phase amphibians, so PCNB is considered to be highly toxic to these taxa as well.

(2) Avian Exposures

Birds may ingest seed treated with PCNB, or they may be exposed when consuming other food items (plant parts and insects) contaminated via spray or chemigation applications of PCNB. In addition to these exposures, which have been quantified for the avian risk assessment, exposure may result from incidental ingestion of contaminated soil, dermal contact with treated surfaces, preening activities, inhalation of pesticide vapor, and ingestion of contaminated drinking water.

(a) Avian Exposures from Treated Seed

Acute RQs were calculated in two ways for assessing risk from PCNB-treated seeds. The first method assumes that a bird eats (treated) seed only, and compares exposure from ingestion of treated seed to the acute oral toxicity endpoint (LD_{50}). The second method compares the LD_{50} to the amount of pesticide available to birds in a square foot of planted area. For chronic risks from treated seed, exposure is based on peak concentration on the seed. Exposures are shown in Table 21 below, along with corresponding RQs.

(i) Seed as Sole Food Source (Method 1)

The first method of assessing acute risks from treated seeds is based on the exposures to the smallest seed-eating birds, generally weighing about 20 g; small birds tend to eat more per unit body weight than larger birds. Exposure is estimated from the concentration of PCNB on treated seed, using daily food intake as estimated by Nagy (1987). Seeding rates were obtained from crop profiles (found at http://pestdata.ncsu.edu/cropprofiles/cplist.cfm?org=crop) or through discussions with registrants. LD_{50}s were adjusted to account for the difference in body weights between the smallest seed-eating birds and the ecotoxicity test species based on the formula recommended by Mineau et al. 1996.

(ii) PCNB Per Square Foot (Method 2)

For the second method of assessing acute risk to birds from treated seed, it is assumed that 100% of the seed is available for consumption. The Agency believes this is a reasonable assumption because the seed is small and is generally not planted deeply (<2 inches). Seed can be planted by drill or by broadcast followed by a drag chain; either method will place the seed near the surface. The amount of PCNB available for ingestion by birds is the amount present on the treated seed, expressed on a per square foot basis. The LD_{50} (adjusted for different body weights) is then multiplied by the weight of the bird to yield the lethal dose of PCNB. The RQ is calculated as the ratio of the amount present on the treated seed (on a per square foot basis) to the lethal dose.

(b) Terrestrial Exposures, Sprays and Chemigation

The avian and mammalian risk assessments for spray and chemigation applications presented in this Section rely on EECs generated from a spreadsheet-based model (ELL-FATE) that calculates the decay of a chemical applied to foliar surfaces for single or multiple applications. The exposure assessment also uses the methods of Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994), which are based on a large set of actual field residue measurements (including information over a hundred plant species and pesticides). Further explanation of the models used to estimate exposures presented in this Section is found in Appendix F of the "Environmental Fate and Ecological Risk Assessment for the Re-registration of Pentachloronitrobenzene, February 12, 2005." More recently, the Agency has moved to an improved model for assessing terrestrial wildlife exposures and risks, called TREX, which accounts for different diets and food source preferences for different kinds of birds and mammals. Risk quotients derived from the TREX model, and taking into account risk mitigation measures proposed by the registrants, are presented in Section IV of this RED.

Terrestrial EECs for nongranular formulations were calculated for cole crops, cotton, peanuts, and turf, using labeled application parameters. EECs were calculated for four categories of food items potentially contaminated with residues as a result of the PCNB applications: short grass; tall grass; broadleaf plants and small insects; and fruits, pods, seeds, and large insects. EECs for PCNB are always highest on short grass and for smaller birds, and lowest on fruits, pods, seeds, and large insects and for larger birds, with concentrations on the short grass more than an order of magnitude higher. A summary of environmental exposures estimated in this way is found in Table 20.

Uncertainties in the terrestrial EECs are primarily associated with a lack of data on interception and subsequent dissipation from foliar surfaces. When such data are lacking, as in this case, EFED assumes a 35-day foliar dissipation half life, based on the work of Willis and McDowell (1987*)*. The assumption is a conservative one for foliar surfaces, because even a persistent chemical like PCNB will be washed off leaves by rain or dew. Given that PCNB residues have been shown to remain in agricultural fields for several years after the last application, residues may remain in grit well beyond the 35-day half-life.

Table 20. EECs on Bird/Mammal Food Items from Spray and Chemigation Applications

Use site	Application rate modeled (#applications/ interval, if relevant)	Maximum EECs (ppm), for acute assessment	Mean EECs (ppm) for chronic assessment
Cole crops (Cabbage)	22.5 lbs ai/A* (1 application)	338 to 5400	158 to 1913
Peanuts	10 lbs ai/A (1 application)	150 to 2400	70 to 850
	5 lbs ai/A (2 applications/30 days)	116 to 1862	54 to 660
	3.2 lbs ai/A (3 applications/7 days)	128 to 2049	60 to 726
Potato	5.0 lbs ai/A (4 applications/7 days)	247 to 3946	115 to 1397
Turf	43.56 lbs ai/A (2 applications/7 days)	1222 to 19555	570 to 6926

* not the highest rate on current labels for this use

(3) Avian Risk Quotients

(a) From Ingestion of PCNB-Treated Seed

Acute and Chronic RQs associated with treated seed are shown in Table 21.

Table 21. Avian Acute and Chronic Risk Quotients for PCNB-treated Seed

Crop	EEC mg ai/day	Acute RQ Method 1[a]	EEC mg ai/ft^2	Acute RQ Method 2[b]	EEC mg/kg seed	Chronic RQ[c]
Barley	296	<0.19	1.22	<0.04	1171	2.0[d]
Bean	119	<0.07	0.78	<0.02	469	0.78
Corn	119	<0.07	0.12	<0.01	469	0.78
Cotton	573	<0.36	0.43	<0.01	2265	3.8[d]
Oats	435	<0.27	2.29	<0.07	1718	2.9[d]
Peas	237	<0.15	1.76	<0.06	937	1.6[d]
Peanuts	138	<0.09	0.77	<0.02	547	0.91
Rice	352	<0.22	2.32	<0.07	1390	2.3[d]
Sorghum	69	<0.04	0.02	<0.01	273	0.46
Soybeans	237	<0.15	0.98	<0.03	937	1.6[d]
Sugar Beets	425	<0.27	0.14	<0.01	1679	2.8[d]

[a] Acute RQ Method 1 = mg kg^{-1} day^{-1} / LD_{50}
[b] Acute RQ Method 2 = mg ft^2 / LD_{50}
[c] Chronic RQ = mg kg^{-1} seed / NOAEC
[d] Exceeds chronic risk level of concern, RQ > 1.0

PCNB is practically nontoxic to birds on an acute exposure basis (no mortality was observed at the highest dose tested in birds). The Agency's concern for birds is primarily with chronic exposures. Chronic RQs exceed levels of concern for seven of the 11 seed types that were assessed.

(b) From Spray and Chemigation Applications

Acute and chronic RQs associated with selected non-seed treatment uses of PCNB (as currently labeled), for a range of food items and sizes of bird, are summarized in Table 22. The use parameters used to generate these RQs are shown in Table 20.

Table 22. Avian Risk Quotients from Spray and Chemigation Applications

Use site	Range of acute RQs	Range of chronic RQs
Cole crops (Cabbage)	<0.01 to<0.10	0.56 to 9.0[1]
Peanuts	<0.01 to<0.04	0.19 to 4.0[1]
Potato	<0.01 to<0.07	0.41 to 6.6[1]
Turf	<0.02 to <0.36	2.0[1] to 33[1]

[1] exceeds chronic risk level of concern

PCNB is practically nontoxic to birds on an acute exposure basis (no mortality was observed at the highest dose tested in birds). The Agency's concern for birds is primarily with chronic exposures. For the modeled uses, as currently labeled, chronic RQs exceed LOCs (RQ > 1) in many instances. When the impact of environmental loading is factored in, risks would be higher than those represented by risk quotients alone. Risk Quotients for birds and spray and chemigation applications of PCNB have been reassessed with the improved model TREX and based on the registrant risk mitigation proposal. This reassessment is discussed in Section IV of this RED.

b) Risk to Mammals

(1) Mammalian Toxicity

Table 23 summarizes mammalian toxicity endpoints for PCNB.

Table 23. PCNB Toxicity Data for a Representative Mammalian Species

Species	LD_{50} in ppm	Acute oral toxicity (MRID#)	NOAEC in ppm (MRID#)	Chronic Endpoints
Laboratory rat *Rattus norvegicus*	>5050	practically non-toxic (414431-01)	200 (434693-03)	liver, thyroid hypertrophy; thyroid follicular cell hyperplasia

In the rat acute oral study, no mortality was seen even at the highest dose tested. The Agency believes that PCNB is practically nontoxic to mammals on an acute oral exposure basis. Chronic RQs are based on the NOAEC from a two-generation rat reproduction study. The relationship of the endpoints in this study (liver and thyroid effects) to more typical ecological assessment endpoints (e.g., impaired reproduction, growth and survival) is not clear.

(2) Mammalian EECs

Mammalian exposures from treated seed were calculated in the same manner as that described above for birds. Exposures are shown in Table 24 below.

Potential exposures resulting from spray and chemigation applications of PCNB were calculated for mammals in the same way as for birds, with the same use sites and application parameters. The range of potential exposures for mammals can be found in Table 20 above.

(3) Mammalian Risk Quotients

(a) From Ingestion of PCNB-Treated Seed

Table 24 shows the EECs and RQs for acute and the chronic mammalian exposures from ingestion of treated seed.

Table 24. Mammalian Risk Quotients for Ingestion of Treated Seed

Crop	EEC mg ai/day	Acute RQ Method 1[a]	EEC mg ai/ft^2	Acute RQ Method 2[b]	EEC mg/kg seed	Chronic RQ[c]
Barley	172	<0.02	1.22	<0.01	1171	5.9[d]
Bean	69	<0.01	0.78	<0.01	469	2.3[d]
Corn	69	<0.01	0.12	<0.01	469	2.3[d]
Cotton	332	<0.04	0.43	<0.01	2265	11[d]
Oats	252	<0.03	2.29	<0.02	1718	8.6[d]
Peas	137	<0.02	1.76	<0.01	937	4.7[d]
Peanuts	80	<0.01	0.77	<0.01	547	2.7[d]
Rice	204	<0.02	2.32	<0.01	1390	7.0[d]
Sorghum	40	<0.01	0.02	<0.01	273	1.4[d]
Soybeans	137	<0.02	0.98	<0.01	937	4.7[d]
Sugar Beets	246	<0.03	0.14	<0.01	1679	8.4[d]
Wheat	69	<0.01	0.66	<0.01	469	2.3[d]

[a] Acute RQ Method 1 = mg kg^{-1} day^{-1} / LD_{50}
[b] Acute RQ Method 2 = mg ft^2 / LD_{50}
[c] Chronic RQ = mg kg^{-1} seed / NOAEC
[d] Exceeds chronic risk level of concern (RQ > 1)

PCNB is practically nontoxic to mammals on an acute oral exposure basis. The Agency considers the likelihood of acute mortality to mammals to be low for the modeled uses. Chronic risk LOC (RQ > 1) is exceeded for every type of treated seed.

(b) From Spray and Chemigation Applications

RQs were calculated for mammals of three sizes. RQs are shown in Table 25; use parameters used to generate these RQs are as in Table 20.

Table 25. Acute RQs for Mammals

Use site	Range of Acute Mammalian RQs (by animal weight)		
	15 g	35 g	1000 g
Cole crops (Cabbage)	<0.01 to <1.0	<0.01 to <0.71	<0.01 to <0.16
Peanuts	<0.01 to <0.45	<0.01 to <0.31	<0.01 to <0.07
Potato	<0.01 to <0.74	<0.01 to <0.52	<0.01 to <0.12
Turf	<0.05 to <3.7	<0.04 to <2.6	<0.01 to <0.58

PCNB is practically nontoxic to mammals on an acute basis. The Agency considers the likelihood of mammalian acute mortality to be low for all of the modeled uses.

Chronic risk quotients from spray and chemigation applications for mammals are based on a NOAEC of 200 ppm, but the relevance of the thyroid and liver effects from this study of laboratory rats to more relevant ecological assessment endpoints of impaired reproduction, growth and survival in wildlife is not clear. Chronic RQs were calculated for different food sources and mammals in a range of three sizes. RQs are shown in Table 26; use parameters are those shown in Table 20.

Table 26. Chronic mammalian risk quotients for selected uses of nongranular products

Use Site	Range of Chronic Mammalian RQs (by animal wt.)		
	15 g	35 g	1000 g
Cole crops (Cabbage)	7[1] to 513[1]	5[1] to 356[1]	1[1] to 81[1]
Peanuts	2[1] to 228[1]	2[1] to 158[1]	0.35 to 36[1]
Potato	5[1] to 375[1]	4[1] to 260[1]	0.74 to 59[1]
Turf	26[1] to 1858[1]	18[1] to 1291[1]	4[1] to 293[1]

[1] exceeds chronic risk of concern

For the majority of the selected uses sites, as currently labeled, the chronic mammalian chronic risk LOC (RQ > 1) is exceeded for all sizes of animal and food items evaluated. When the impact of environmental loading is factored in, risks would be higher than those represented by risk quotients alone. Risk Quotients for mammals and spray and chemigation applications of PCNB have been reassessed with the improved model TREX and based on the registrant risk mitigation proposal. This reassessment is discussed in Section IV of this RED.

c) Risk to Fish and Aquatic Invertebrates

Tables 27 and 28 summarize the toxicity endpoints used in the hazard assessment of aquatic species for PCNB.

(1) Toxicity to Freshwater Species

Table 27. Acute and chronic toxicity data for freshwater species

Species	Acute Toxicity		Chronic Toxicity	
	96-hr LC_{50} (mg/L)	**Acute Toxicity**	**NOEC/LOEC (mg/L)**	**Endpoints**
Freshwater fish				
Rainbow trout *Oncorhynchus mykiss*	0.32	highly toxic	0.013/0.032	reduced growth and reproduction
Bluegill sunfish *Lepomis macrochirus*	0.10	highly toxic	--	--
Rainbow trout *Oncorhynchus mykiss* (formulated product)	0.31	highly toxic	--	--
Bluegill sunfish *Lepomis macrochirus* (formulated product)	0.24	highly toxic	--	--
Freshwater invertebrate				
Water flea *Daphnia magna*	0.77 (48h LC_{50})	highly toxic	0.018/0.030	reduced growth and reproduction

PCNB is highly toxic to freshwater fish and invertebrates on an acute exposure basis. The Agency considers measures of toxicity to freshwater fish to serve as surrogates for toxicity to aquatic-phase amphibians, so PCNB is considered to be highly toxic to aquatic-phase amphibians as well.

(2) Toxicity to Estuarine/Marine Species

Table 28. Acute Toxicity Data for Estuarine/Marine Species

Species	96-hr LC_{50} (in mg/L)	Acute Toxicity
Estuarine/Marine Fish		
Sheepshead minnow *(Cyprinodon variegatus)*	7.9	moderately toxic
Estuarine/Marine Invertebrates		
Eastern oyster (*Crassostrea virginica)*	0.023	very highly toxic
Mysid shrimp *(Mysidopsis bahia*)	0.012	very highly toxic

PCNB is moderately toxic to estuarine/marine fish and very highly toxic to estuarine/marine invertebrates on an acute exposure basis. Chronic data are lacking for estuarine/marine species. Since estuarine/marine invertebrates are more sensitive to PCNB on an acute basis than their freshwater counterparts, it is reasonable to assume that they may be more sensitive on a chronic exposure basis as well.

(3) Exposure for Aquatic Species

Surface water concentrations resulting from PCNB application to five selected crops, as currently labeled, were estimated with the Tier II model PRZM-EXAMS. The results of this modeling are summarized in Table 17 above.

(4) Risk Quotients for Aquatic Species

Peak EECs as derived from the PRZM-EXAMS model were compared to acute toxicity endpoints for aquatic species to derive acute risk quotients. There are no chronic toxicity data for PCNB in estuarine/marine animals, so chronic risk quotients could not be generated for these species. The results of these assessments are summarized in Tables 29 (freshwater animals) and 30 (estuarine/marine animals).

Table 29. Acute and chronic risk quotients for freshwater animals exposed to PCNB

Use site (application parameters as in Table 16)	Acute RQs		Chronic RQs	
	Freshwater Fish	Freshwater Invertebrates	Freshwater Fish	Freshwater Invertebrates
Cole crops	0.84[1]	0.11[2]	4.3[3]	3.1[3]
Cotton	0.28[2]	0.04	1.5[3]	1.1[3]
Peanuts	0.97[1]	0.13[2]	3.5[3]	2.6[3]
Potatoes	0.22[2]	0.03	0.8	0.6
Turf	2.6[1]	0.34[2]	8.2[3]	5.9[3]

[1] exceeds acute risk to nonlisted species (RQ > 0.5) and endangered species (RQ > 0.05) LOCs
[2] exceeds acute risk to endangered species LOC (RQ > 0.05)
[3] exceeds chronic risk LOC (RQ > 1)

Table 30. Acute risk quotients for estuarine/marine animals exposed to PCNB

Crop (application parameters as in Table 16)	Acute RQs	
	Estuarine/Marine Fish	Estuarine/Marine Invertebrates
Cole crops	0.01	7.0[1]
Cotton	<0.01	2.3[1]
Peanuts	0.01	8.1[1]
Potatoes	<0.01	1.8[1]
Turf	0.03	22[1]

[1] exceeds acute risk to nonlisted species (RQ > 0.5) and endangered species (RQ > 0.05) LOCs

For these uses as currently labeled, acute risk LOCs for nonlisted species are exceeded for freshwater fish following application to cole crops, peanuts, and turf; acute risk endangered species LOCs are exceeded for all sites. The chronic risk LOC is exceeded for freshwater fish and invertebrates on all sites but potatoes.

While no acute risk LOCs for estuarine/marine fish are exceeded for any of the crops, the likelihood of adverse chronic effects is uncertain since no data are available to assess the chronic toxicity of PCNB in these species. Estuarine/marine invertebrates appear to be much more sensitive to PCNB than their freshwater counterparts on an acute exposure basis; based on the chronic RQs for invertebrates in Table 29, it is reasonable to assume that the chronic risk LOC may be exceeded for estuarine/marine invertebrates. Based on this uncertainty, the Agency presumes chronic risk to estuarine/marine animals.

Risk quotients for aquatic species have been reassessed based on the risk mitigation proposal submitted by the registrants, as discussed in Section IV of this RED.

d) Risks to Insects

PCNB is practically nontoxic to bees on an acute exposure basis (LD_{50}>0.1 µg/bee). The Agency did not conduct a risk assessment for nontarget insects.

e) Risks to Terrestrial and Aquatic Plants

No data are available on the toxicity of PCNB to terrestrial or aquatic plants. The Assessment Tools for the Evaluation of Risk (ASTER) model, which relies on structure-activity relationships, suggests that the toxicity of chlorinated benzenes like PCNB increases with the number of chlorine atoms. Further discussion of the ASTER model and its implications for PCNB can be found in the "Environmental Fate and Ecological Risk Assessment for the Re-registration of Pentachloronitrobenzene," February 15, 2005.

8. Risk to Endangered Species

The risk assessment for PCNB indicates a potential for acute and chronic risks to listed species associated with the modeled use sites. These risks have been reassessed pursuant to mitigation measures proposed by the registrants, as detailed in Section IV. A full accounting of risks to listed species is made in that Section.

The Agency can not preclude the potential for indirect effects to listed species that may be dependent upon taxa that experience direct effects from the use of PCNB. These findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act (ESA) for any listed species.

To address concerns about risks to Federally-listed endangered and threatened species from pesticide use, the Agency has developed the Endangered Species Protection Program (ESPP). The assessments of risk for aquatic and terrestrial wildlife described in this RED serve as a screening tool to determine the need for any species-specific assessments for PCNB and listed species. In accordance with the ESPP, EPA will consider ecological parameters, use information, and geographic relationships, as well as biological requirements and behavioral aspects of a particular species to develop a species-specific assessment for listed species. The Agency's species-specific analysis also will take into consideration any risk mitigation measures implemented as part of the RED decision for PCNB.

Following this future species-specific analysis, a determination whether there is a likelihood of potential effects to a listed species may result in additional limitations on the use of PCNB, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries as appropriate. If the Agency's species-specific assessments result in the need to modify the use of the pesticide in specific geographic

areas, those changes will be undertaken through the process described in the Agency Federal Register Notice (54 FR 27984) on implementation of the Endangered Species Protection Program.

Until a species-specific analysis is completed, the ecological risk mitigation measures being implemented through the RED will reduce the likelihood that endangered and threatened species may be exposed to PCNB. Information about the Agency's assessment process for threatened and endangered species is posted at www.epa.gov/espp.

9. Ecological Incident Reports

One incident has been recorded for PCNB in the Ecological Incident Information System (EIIS), for cotton seed which failed to germinate following an unincorporated granular application.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing PCNB as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to formulate the reregistration eligibility decision for products containing PCNB.

The Agency has completed its assessment of the dietary, occupational, residential, environmental, and ecological risks, and the benefits associated with the use of pesticide products containing the active ingredient PCNB. Based on the assessments and on public comments on the assessments, the Agency is announcing decisions about the human health and ecological effects associated with PCNB, including tolerance reassessment decisions under FFDCA and reregistration decisions under FIFRA as amended by FQPA. The Agency has determined that PCNB-containing products for some uses are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect those mitigation measures. Label changes are described in Section V. Those uses of PCNB eligible for reregistration are:

- Cole crops (products labeled for control of clubroot only)[2]
- Seed treatments
- Flowering bulbs in commercial production

[2] The only products for use on cole crops which are eligible for reregistration are those which are limited to the cole crop/clubroot combination, and no other diseases may be added to the label of a registered product either by amendment or through the notification process (PR Notice 98-10).

The Agency has determined that the uses of PCNB on turf, residential ornamentals, green beans, cotton, potatoes, dry beans and peas, garlic, peanuts, tomatoes, peppers, and ornamentals in commercial production (except for flowering bulbs) are not eligible for reregistration and must be deleted from product labels. Products labeled exclusively for one or more of these ineligible uses will not be eligible for reregistration.

Based on its evaluation, the Agency has determined that PCNB products, unless labeled solely for use on sites listed as eligible for reregistration and otherwise as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the relevant risks. If all changes outlined in this document are incorporated into the product labels and/or effected via product cancellation, then the risks associated with the use of PCNB will be adequately mitigated for the purposes of this determination.

B. Public Comments and Responses

Following the release of the Agency's revised risk assessments and the solicitation of risk management options for PCNB, public comment came primarily from the registrants. These comments were mostly technical in nature and the Agency examined each comment to determine if the risk assessments should be revised to reflect the criticisms, alternative methodologies, and additional information they provided. Public comments on benefits were submitted by the Golf Course Superintendents Association of America. These comments were also examined and considered in development of the Agency's benefits assessment for PCNB. The public comments, responses from the Agency, revised risk assessments, and the PCNB benefits assessment can all be accessed through the Federal government-wide electronic docket management and comment system at http://www.regulations.gov/, in Docket Number OPP-2004-0202.

After the comment period on the risk assessments closed, the registrants raised questions about an adsorption coefficient used in the drinking water assessment for turf. These questions led to a minor modification of the water assessment. The registrants also have proposed a number of risk mitigation measures for PCNB. The Agency assessed risks as they would be if these measures were adopted, and has based its reregistration decision for PCNB on the impact of these measures on risk: where risks would be mitigated adequately by the mitigation measures, and where they would not, and what additional measures would be needed to reduce all risks below levels of concern.

C. Regulatory Position

1. Food Quality Protection Act Findings

a) "Risk Cup" Determination

Based on available data, EPA has reassessed the tolerances associated with this pesticide. EPA has determined that risk from dietary (food sources only) exposure to PCNB is within its own "risk cup," if the risk mitigation measures proposed by the registrants are considered. Based on the risk mitigation proposal, the chronic dietary risk associated with PCNB for food only is less than 100% of the cPAD.

An aggregate assessment was conducted for exposures through food, drinking water, and residential use, incorporating the adjustments to the drinking water assessment that would be appropriate if the registrants' risk mitigation proposal were implemented. Under these conditions, the dietary risk from food and water combined is less than 100% of the cPAD. The Agency has determined that the aggregate human health risks from exposures to PCNB are within the risk cup (still less than 100% of the cPAD) only when the exposures associated with residential uses of PCNB are eliminated. Amvac and Chemtura have proposed to terminate the residential turf uses of PCNB. The Agency believes that the use of PCNB on residential ornamentals also contributes to potential residential risks of concern, similar to those from use on turf. Thus, this use is ineligible for reregistration. Based on the aggregate assessment, and if all residential uses of PCNB are terminated, EPA has concluded that the tolerances for PCNB meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food, water, and residential uses.

b) Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for PCNB, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of PCNB. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices, exposure scenarios, and environmental behavior of PCNB.

c) Determination of Safety to Infants and Children

EPA has determined that the established tolerances for PCNB, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of PCNB residues in this population subgroup.

FQPA directs EPA, in setting pesticide tolerances, to use an additional tenfold margin of safety to protect infants and children, taking into account the potential for pre- and postnatal toxicity and the completeness of the toxicology and exposure databases. The statute authorizes EPA to replace this tenfold FQPA safety factor with a different FQPA factor only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children. For

PCNB, the Agency has determined that an uncertainty factor of 10X must be retained for the dietary (chronic), residential exposure (incidental oral, dermal and inhalation), and aggregate risk scenarios for PCNB.

No findings of significant toxicological concern were identified in the submitted developmental or reproductive toxicity data, and no neurobehavioral alterations or evidence of neuropathological effects were observed in the available data. The Agency's retention of the 10X factor relates to potential effects on thyroid function after *in utero* exposure and in children that would not have been detected in studies already undertaken. There are additional uncertainties associated with the potential effects of bioaccumulation of PCNB and metabolites in human systems. The Agency's uncertainty about potential thyroid effects after *in utero* exposure and in children is discussed in Section III of this RED.

d) Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." When the appropriate screening and/or testing protocols being considered under the Endocrine Disruptor Screening Program have been developed, PCNB may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

e) Cumulative Risks

The Food Quality Protection Act (FQPA) requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals.

PCNB is an organochlorine member of the substituted aromatics class of pesticides (George W. Ware, The Pesticide Book, Fourth ed., 1994). A cumulative risk assessment has not been conducted for members of this class of pesticides as part of this human health risk assessment. Exposure of test animals with PCNB does not appear to result in endpoints the same as those resulting in test animals exposed to the organochlorine pesticides chlorothalonil or pentachlorophenol. The endpoints used to assess human health risks for PCNB are primarily thyroid hypertrophy and hepatocellular hypertrophy and hyperplasia. The endpoints for chlorothalonil have been identified as various kidney and forestomach effects, and the endpoints identified for pentachlorophenol are carcinogenicity (hemangiosarcomas, hepatocellular tumors, and adrenal tumors) and developmental effects (increased resorptions of fetuses, reduced fetal weight, skeletal malformations of fetuses). The Agency has not undertaken a comprehensive assessment of organochlorine pesticides with respect to common mechanism. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and

to evaluate the cumulative effects of such chemicals, see the policy statements by the EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://epa.gov/pesticides/cumulative/ .

2. Tolerance Summary

The Agency has reassessed all current tolerances for PCNB. The Agency has also determined the eligibility of reregistration for all uses of PCNB; the rationale for these determinations is described later in this Section. The Agency will give consideration to overseas use of PCNB and international trade in determining whether to propose revocation of tolerances associated with uses of PCNB that are not eligible for reregistration. In proposing a schedule for revocation, the Agency also will take into account the last legal use date, movement through the market of commodities with residues resulting from legal use, and the persistence of PCNB and its metabolites.

The Agency has also evaluated residue data associated with uses of PCNB for which tolerances have not yet been established. Some of these uses are not eligible for reregistration, and the Agency will not establish tolerances for the associated commodities.

The Agency believes that the correct tolerance expression for residues of PCNB and its metabolites is residues of PCNB, PCA, and PCTA. The current tolerance expressions for "pentachloronitrobenzene" or "pentachloronitrobenzene (PCNB) and its metabolites pentachloroaniline (PCA) and methyl pentachlorophenyl sulfide (MPCPS)" should be changed to "pentachloronitrobenzene (PCNB) and its metabolites pentachloroaniline (PCA) and pentachlorothioanisole (PCTA)." PCTA and MPCPS are two different names for the same compound.

a) Tolerances Currently Listed Under 40 CFR §180.291(a)

The tolerance expression in 40 CFR §180.291(a) for pentachloronitrobenzene will be changed to pentachloronitrobenzene (PCNB) and its metabolites pentachloroaniline (PCA) and pentachlorothioanisole (PCTA).

Table 31. PCNB Tolerances Listed Under 40 CFR §180.291(a)

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
Cottonseed	0.1	TBD*	Confirmatory residue data for seed treatment use are currently in review. Conservative assumptions have been applied to ensure that dietary risks are not underestimated.

* TBD = To be determined

b) Tolerances Currently Listed Under 40 CFR §180.291(b)

Tolerances listed at 40 CFR §180.291 (b) will be moved to 40 CFR §180.291 (c) to conform to the Agency standard for citing regional tolerances. 40 CFR §180.291 (b) will be reserved for tolerances associated with Section 18 uses. The tolerance expression in 40 CFR §180.291(c) will be changed to pentachloronitrobenzene (PCNB) and its metabolites pentachloroaniline (PCA) and pentachlorothioanisole (PCTA).

Table 32. Tolerances Listed Under 40 CFR §180.291(b)

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments
Collards	0.2	0.2	Residue data from IR-4 support the current tolerance for regional registrations.
Kale	0.2	0.2	
Mustard Greens	0.2	0.2	

c) Interim Tolerances Listed Under 40 CFR §180.319

Tolerances listed under §180.319 will be reassigned to §180.291(a).

Table 33. Interim tolerances Listed Under 40 CFR §180.319

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Beans	0.1	TBD*	Confirmatory residue data for seed treatment use are currently in review.
Broccoli	0.1	0.1	*Head and Stem Brassica Vegetable Crop Subgroup*
Brussels Sprouts			
Cabbage			
Cauliflower			
Garlic	0.1	0.1	
Peanuts	1	TBD*	Confirmatory residue data for seed treatment use are currently in review.
Potatoes	0.1	0.1	
Peppers	0.1	0.1	*Fruiting Vegetables (except Cucurbits) Crop Group*
Tomatoes	0.1		

* TBD = To be determined. Conservative assumptions have been applied to ensure that dietary risks are not underestimated.

40 CFR §180.291(d) will be reserved for tolerances associated with inadvertent residues.

d) Tolerances That Need to Be Proposed Under 40 CFR §180.291(a)

For several uses of PCNB resulting in residues in associated commodities, tolerances have not been proposed previously. For commodities listed in Table 34 with residues from seed treatment use, new data may be required pending approval of the new analytical method.

Table 34. Tolerances That Need To Be Proposed under 40 CFR §180.291(a)

Commodity	Tolerance Assessment (ppm)	Comment
Cotton gin byproducts	TBD*	Confirmatory residue data for seed treatment uses are currently in review.
Barley, grain, hay and straw		
Corn, grain, forage and fodder		
Oat, forage, grain, hay and straw		
Peas		
Rice, grain and straw		
Safflower, seed		
Sorghum forage, grain, and stover		
Soybean, forage, hay and seeds	0.02	
Sugar beet, roots and tops	TBD*	Confirmatory residue data for seed treatment uses are currently in review.
Wheat, forage, grain, hay, and straw		
Milk		
Cattle fat, meat, and meat-byproducts (mbyp)		
Goat fat, meat, and mbyp		
Horse fat, meat, and mbyp		
Sheep fat, meat, and mbyp		
Hog fat, meat, and mbyp		
Eggs		
Poultry, fat		
Poultry, mbyp		

* To be determined. Conservative assumptions have been applied to ensure that dietary risks are not underestimated.

e) Codex Harmonization

There are no established or proposed Codex maximum residue limits (MRLs) for PCNB.

f) Analytical Methods and Residue Data Requirements

The Agency has reassessed the current tolerances for PCNB based on the current analytical methodology. The current analytical method determines just three compounds (parent + PCA + PCTA). The Agency has determined that a new analytical method must be developed to

account for all metabolites of PCNB. The Agency is requiring a new standardized analytical method for PCNB that converts all or most of the 80 plus residues of concern (parent and metabolites) to one or a few common moieties for use in quantifying total residues in field trials. The new method is needed because all PCNB metabolites are of toxicological concern, are fairly stable in the environment, tend to accumulate in treated soil, are found in rotational crops, and occur in varying ratios. It is possible that the tolerance expression for residues associated with the use of PCNB will be revised based on this new method.

The Agency is deferring a decision about what additional data will be needed for magnitude of residues until after a new analytical method is approved. It is possible that additional residue data will be needed at that time, and that those data could result in a determination by the Agency that one or more of the tolerance level recommendations made here should be changed. Decisions about whether a new enforcement method is needed will also be deferred until a new analytical method is approved, so the requirement for developing an enforcement method is reserved. The requirement for submitting analytical reference standards is reserved on the same basis.

3. Regulatory Rationale

The Agency has determined that certain uses of PCNB are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures, as described in this document.

The following is a summary of the rationale for managing risks associated with the use of PCNB. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document. The Agency's decisions on the reregistration of PCNB are based on the Agency's initial assessment of risks, a risk mitigation proposal submitted by the registrants, and whether additional risk mitigation is necessary to justify reregistration. The registrants' risk mitigation plan was proposed in two parts, and the Agency also made some technical refinements and an error correction to its risk assessments during the same interval. A chronology is provided below to facilitate understanding of the risks and potential risk reduction associated with the registrants' proposal and the Agency's changes. The Agency's assessments and supporting documents identified in the chronology are all available through http://www.regulations.gov/ in Docket Number OPP-2004-0202.

a) Chronology of Assessments and Mitigation Proposals

The Agency initially assessed the human health and ecological risks of PCNB as currently registered. The Agency also assessed the benefits associated with the major, currently registered uses of PCNB. The reregistration eligibility decision for PCNB is based on an evaluation of both risks and benefits. The risk assessments went through several iterations based on public comments, proposed mitigation, and the correction of an error in and refinements to the dietary assessment. A chronology of the Agency risk reassessments and registrant responses may be helpful in tracking the risk conclusions discussed in this document.

The Agency released risk assessments revised to address public comments (mostly technical in nature) on March 2, 2005, and determined at that time that the dietary, residential, aggregate, ecological, and some occupational risks associated with the uses of PCNB were of concern. The risks discussed in Section III of the RED reflect the assessments made public in March 2005.

On June 10, 2005, the two registrants of technical grade PCNB, Amvac and Chemtura, proposed a risk mitigation plan focused mainly on reducing dietary and worker risk.

The Agency subsequently determined that the proposal adequately addressed most of the occupational risks, but that dietary, residential, and ecological risks would not be reduced below levels of concern.

Subsequent to the Agency's evaluation of this proposal, the registrants verbally supplemented their original mitigation plan by proposing that all turf uses of PCNB except golf course tees, greens, and fairways be terminated. At the same time, the Agency moved to correct an error in its dietary risk assessment related to how PCNB residues partition in the liquid and fat portions of milk, and to refine the dietary assessment by more accurately reflecting the composition of the diet for lactating cows and its contribution to residues in milk. In addition, the proposal to eliminate all turf uses except specific golf course sites allowed the Agency to incorporate a Golf Course Adjustment Factor (GCAF) into the drinking water and ecological water exposure assessments to represent the smaller portion of golf course area on potentially treated with PCNB. The risks discussed in this Section of the RED primarily reflect the Agency's assessment of the registrants' complete proposal.

The Agency concluded that the registrant's complete proposal, together with the correction to and refinement of the dietary assessment, would decrease estimates of dietary and most of the occupational and residential risks below levels of concern. The dietary risk conclusions are captured in an October 20, 2005 assessment. Residential risk would be eliminated for applications to turf. Residential risks posed by the use of PCNB on ornamentals would not be mitigated by the proposal.

Although the complete proposal would also reduce wildlife risk estimates for PCNB, the Agency did not find it adequate to address ecological risk concerns. The ecological risk quotients associated with the registrants' proposal are captured in the Agency documents dated July 7 and August 9, 2005. In addition to risk quotients that exceed ecological levels of concern for most of the assessed uses, the fate and transport characteristics of PCNB and its metabolites are indicative of a potential for environmental loading that increases risks substantially, although to a degree that cannot be quantified.

The Agency also conducted a complete benefits assessment for the major uses of PCNB. The assessment, captured in a May 16, 2006 document, is described in this Section. The Agency has developed a qualitative analysis of benefits for the minor uses of PCNB. The Agency acknowledges that for these uses, more complete benefits information could result in a different assessment of potential benefits. The Agency is actively soliciting such information in an effort to

gain a better understanding of the relationship between risks and benefits for those uses. The minor uses for which the Agency seeks such information and the particular kinds of information that could be useful in refining the benefits analysis for these uses are detailed in this Section. It is possible that such information, provided during the comment period, could change the Agency's understanding of the risk/benefit relationship for specific uses, and result in amendment of the reregistration eligibility decisions on the subject uses.

All of the assessment documents cited in this RED are available from the docket at http://www.regulations.gov/ in Docket Number OPP-2004-0202.

This RED is based on the Agency's current understanding of the risks and benefits associated with PCNB use. For uses of PCNB which are not eligible for reregistration, the Agency has made a determination that risks outweigh benefits. The rationale for the determinations on the different uses of PCNB is detailed in this Section.

b) Summary of Mitigation Measures Proposed by Registrants

The jointly proposed risk mitigation plan submitted by Amvac and Chemtura on June 10, 2005 focused mainly on reducing dietary and worker risk. Measures proposed by the registrants included:

- Reduction of maximum seasonal application rates
  Peppers (from 20 to16.5 lb ai/A/season)
  Beans (from 2 to 1 lb ai/A/season)
  Peanuts (from 2 to 1 lb ai/A/season)
  Cotton (from 2 to 1.5 lb ai/A/season)
  Cole crops (from 30 to 22.5 lb ai/A/season).
- Termination of garlic use
- Restriction of golf course use to tees, greens, and fairways
- Prohibition of some application methods and formulation types, including all aerial applications and broadcast applications to ornamental bulbs
- Additional PPE for workers

(For peanuts, risk quotients were originally assessed at a rate of 10 lb ai/A/season. The 2 lb rate represents a recent intermediate rate reduction originating with the registrants. For the cole crops, the current labeled maximum application rate of 30 lb ai/A/season was the basis for estimating drinking water concentrations and the environmental concentrations for aquatic organisms in the original assessment. An application rate of 22.5 lb ai/A/season was modeled to calculate risk to terrestrial wildlife in the original assessment.)

The registrants later proposed to terminate all turf uses of PCNB except golf course tees, greens, and fairways. The later proposal would terminate PCNB use on residential lawns; industrial/commercial turf; other ornamental turf including turf in school yards, parks, playing fields, and playgrounds; sod farms; and other golf course areas.

c) Human Health Risk Mitigation

(1) Dietary Risk Mitigation

The Agency assessed the chronic dietary risks from drinking water that would be associated with the registrants' complete mitigation proposal. In this assessment, the Agency used an alternate adsorption coefficient for the turf use than that used in the original assessment, based on a technical comment from the registrants. The proposed rate reductions and termination of most turf uses would not affect estimates of food-only dietary exposure because residues estimated on food were mainly based on field trial data and cannot be reliably adjusted for different application rates, and turf uses do not result in residues on food.

The registrants' complete mitigation proposal would also allow the Agency to incorporate a Golf Course Adjustment Factor (GCAF) into the dietary and ecological water exposure assessments to represent the smaller portion of golf course area on which PCNB could be used. In accordance with Agency policy, as captured in "Golf Course Adjustment Factors for Simulated Aquatic Exposure Concentrations," December 7, 2005, the proportion of golf course turf that is tees, greens, and fairways has been estimated at 34%. The Agency's dietary assessment based on the mitigation proposed by the registrants was also revised to reflect technical refinements needed to more accurately assess the contribution of PCNB residues in animal diets and animal commodities. The use of the GCAF and the technical refinements together resulted in decreased estimates of dietary, residential, and aggregate risk below levels of concern. (The GCAF also contributed to the reduction of estimates of ecological risk associated with the turf use.)

Table 35 shows the modeled surface water drinking water concentrations that would be associated with the proposed mitigation, drawn from the July 7, 2005 memo entitled "Revised/Refined Tier II Aquatic Exposure Values for the Drinking Water and Ecological Exposure Assessments of PCNB for Use During Phase 6 – Risk Mitigation," for potatoes and turf only. The revised values for cole crops, peanuts, and cotton are drawn from the August 9, 2005 memo entitled "Revised Tier II Surface Water Exposure Values and Terrestrial Exposure Values for PCNB Based on Proposed Lower Application Rates (Risk Mitigation Phase)." Both memos are posted to http://www.regulations.gov/ in Docket Number OPP-2004-0202.

Table 35. Estimated Drinking Water Concentrations Based on Proposed Mitigation

Scenario (application rate; # of applications/year)	Source	EDWCs 1-in-10 year concentrations (used to assess chronic risk)
Turf (32.67 lb ai/A; 2)	Surface water	12.2 ppb
Potato (25 lb ai/A; 1)		1.7 ppb
Cabbage (22.5 lb ai/A; 1)		10.3 ppb

Peanuts (1 lb ai/A; 1)		1.7 ppb
Cotton (1.5 lb ai/A; 1)		5.7 ppb

Although the cabbage 1-in-10 year concentration is slightly lower than the turf value, the Agency determined that cabbage concentration was a more reasonable worst-case than the concentration modeled for the use of PCNB on golf courses, because based on the registrants' proposal, PCNB use on golf course would be limited to tees, greens, and fairways. The 1-in-10 year value for cabbage, representing cole crops in general, was selected for use in the revised chronic dietary risk assessment. The values in Table 35 can be compared to the turf value in Table 5, which was used to assess dietary risk from PCNB as currently registered.

Concurrent with the assessment of the risk mitigation proposal, the Agency determined that residues of PCNB and metabolites in animal food items (especially milk) had been overestimated in part because the theoretical diet of lactating cattle contained too high a proportion of potato culls. Lactating cattle are typically fed a higher proportion of grain, rather than potatoes, for more protein. The Agency refined the theoretical diet to more closely approximate the actual diet fed to lactating cows. In addition, the Agency looked more closely at how PCNB and its metabolites are likely to separate into aqueous and fat components of animal tissue and milk, and determined that the metabolites are not likely to appear in milk to the degree which had been assumed for the earlier dietary risk assessments. The Agency corrected this error.

Table 36 shows the revised dietary risk estimates for food alone and food plus water that would be associated with the risk mitigation proposed by the registrants and the revisions to described above. These results are discussed more thoroughly in the memo "Pentachloronitrobenzene (PCNB). Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision (RED)," dated October 20, 2005 and posted to http://www.regulations.gov/ in Docket Number OPP-2004-0202.

Table 36. Chronic Dietary Risk Estimates Based on Proposed Mitigation and Technical Refinement/Correction of the Original Assessment

Population Subgroup	Risk from all crops, no water, % cPAD	Risk from all crops, with water, % cPAD
U.S. Population	12	33.4
All infants (< 1 yr)	8	79
Children 1-2 yrs	34	66
Children 3-5 yrs	25	55
Children 6-12 yrs	16	36

Population Subgroup	Risk from all crops, no water, % cPAD	Risk from all crops, with water, % cPAD
Youth 13-19 yrs	10	26
Adults 20-49 yrs	9	30
Adults 50+ yrs	10	32
Females 13-49 yrs	9	29

For the general population and all subgroups, the dietary risks that would be associated with the proposed mitigation are below 100% of the cPAD. The values in Table 36 can be compared to those in Table 4, which represent the risks based on PCNB as currently labeled, and without the correction and refinement made to the original assessment. The registrants' proposal would be adequate to reduce the dietary risk associated with the use of PCNB below levels of concern. Mitigation required by this RED will reduce overall usage of PCNB and is likely to reduce the occurrence and magnitude of inadvertent residues in crops for which PCNB is not registered.

(2) Residential Risk Mitigation

The registrants proposed to terminate all residential turf uses of PCNB, so residential handler and post-application exposures associated with those uses would be eliminated. The residential risk assessment for PCNB focuses on turf, the predominant residential use site for the fungicide. While PCNB is also used on broadleaf ornamentals, treatment would occur most typically at nurseries and other production facilities, before plants are purchased for placement in lawns and gardens. Residential use on non-turf ornamentals is limited, but based on the very high risks for children on treated turf and the potential for residential ornamental applications to result in similar exposures, the Agency believes that PCNB use on ornamentals in yards and gardens may pose residential post-application risk. The registrants' proposal does not adequately address residential risk. The Agency has determined that the use of PCNB on residential ornamentals is not eligible for reregistration.

(3) Golfer Post-Application Risk Mitigation

Risk to golfers reentering golf course areas treated with PCNB up to nine days previously has been estimated to be above levels of concern. The results of this initial assessment are found in Table 7. Since this initial assessment was made, an ARTF golf course maintenance exposure study has been submitted to the Agency, and the Agency believes it is appropriate to use data from that study to refine the PCNB post-application golfer risk estimates. Review of information (in the form of transfer coefficients and residues on turf) from that study indicates that the golfer reentry risk estimates on the day of treatment are above the target MOE of 1000 (3100-4100), and therefore not of concern. These results are discussed more thoroughly in the memo "PCNB: HED Revision of Golfer Risk Assessment," dated March 6, 2006 and posted to

http://www.regulations.gov/ in Docket Number OPP-2004-0202. No additional risk mitigation is needed to reduce the golfer post-application risk associated with the use of PCNB.

(4) Aggregate Risk Mitigation

Under the registrants' mitigation proposal, the dietary risk estimates associated with PCNB use would fall below levels of concern, and residential risk associated with use on turf would be eliminated. Residential risks of concern, and as a consequence, aggregate risks of concern, would still be associated with the use of PCNB on ornamental plants around the home. The Agency has determined that the aggregate human health risks from exposures to PCNB are within the risk cup (still less than 100% of the cPAD) only when the exposures associated with all residential uses of PCNB are eliminated. The Agency has determined that the full complement of residential PCNB uses, including the use on ornamentals, must be terminated in order for the Agency to make a finding that tolerances associated with the use of PCNB are safe.

(5) Occupational Handler Risk Mitigation

In many cases, occupational risks of concern for PCNB would be adequately reduced by the use of PPE as proposed by the registrants; in other cases, additional PPE is needed. Several scenarios are associated with short- and intermediate–term MOEs below 100 even at the highest applicable levels of protections afforded by PPE and engineering controls. These scenarios are tabulated below. Scenario numbers are provided for ease of reference to the relevant handler risk tables (Tables 10, 11, and 13 above).

Table 37. Risks of Concern for Handlers, with Maximum PPE and Engineering Controls

Exposure Scenario (Number)	Comments
Mixer/Loaders (Non-seed treatment)	
dry flowables/chemigation/sod farms (6)	Even with closed systems, MOEs 20-89
liquids/chemigation/sod farms (16)	
wettable powders/chemigation/soil banding cole crops (42)	
wettable powders/chemigation/sod farms (50)	
wettable powders/groundboom/sod farms (51)	
Non-seed Applicators (Non-seed treatment)	
dry flowables as spray/high-pressure handwand/ornamentals (58)	Engineering controls for applicators (enclosed cab) not feasible for hand-held equipment; even with most protective PPE (coveralls + chemical resistant gloves + air-purifying respirator), MOEs 5.9-59
emulsifiable concentrates /high-pressure handwand/industrial lawn (65)	
wettable powders/high-pressure handwand/industrial lawns (87)	
Mixer/loader/applicators or loader/applicators (Non-seed treatment)	
liquids/handgun sprayer/ornamentals (94)	Enclosed cab not feasible for hand-held equipment; with most protective PPE (coveralls + chemical resistant gloves), dermal MOE is 77

Exposure Scenario (Number)	Comments
granules/belly grinder/ornamentals (98)	Enclosed cab not feasible for hand-held equipment; no data available to assess risk if coveralls worn; with chemical resistant gloves, dermal MOE is 21
granules/push-type spreader/ornamentals (99)	Enclosed cab not feasible for hand-held equipment; no data available to assess risk if respirators worn; with no respirator, inhalation MOE is 88
wettable powders/low-pressure hand-wand/ornamentals (100)	Engineering controls for applicators (enclosed cab, closed systems) not feasible for hand-held equipment; even with most protective PPE (coveralls + chemical resistant gloves + air-purifying respirator), dermal MOEs 3.1-18, inhalation MOEs 0.58-3.4
wettable powders/low-pressure hand-wand/shade trees (101)	

The registrants have proposed mitigation measures would which adequately address the risks for most of the scenarios represented in Table 37. These measures are:

- Terminate turf uses other than tees, greens, fairways (Scenarios 6, 16, 20, 89, 65, 87)
- Prohibit cole crops chemigation (42)
- Prohibit sod farm chemigation (50)
- Prohibit ground boom application of WP formulation to sod farms (51)
- Prohibit foliar and WP applications to ornamentals (58, 94, 100, 101)
- Prohibit granular application by belly-grinder to ornamentals (98)

If these mitigation measures were implemented, occupational risks for all the scenarios shown in Table 37 would be eliminated, except for Scenario #99, applying granules with a push-type spreader to ornamentals. The formulation/application combination for this use poses risks that the Agency addresses in labeling requirements detailed in Table 47 at the end of this Section.

The registrants have not proposed measures to address risks to handlers of treated seed, but respirators are required to address risks of concern for these workers. PPE and other label requirements to address worker risks are detailed in Table 47.

(6) Occupational Post-application Risk Mitigation

Occupational post-application risk mitigation for PCNB use is not necessary because the associated risk estimates fall well below levels of concern even on the day of treatment (Table 14).

d) Ecological Risk Mitigation

The Agency recalculated ecological risk quotients based on the full complement of mitigation measures proposed by the registrants. The revisions based on the mitigation proposal are detailed in the documents "Revised/Refined Tier II Aquatic Exposure Values for the Drinking Water and Ecological Exposure Assessments of PCNB for Use During Phase 6 – Risk

Mitigation," July 07, 2005 (for turf and potatoes) and "Revised Tier II Surface Water Exposure Values and Terrestrial Exposure Values for PCNB Based on Proposed Lower Application Rates (Risk Mitigation Phase)," August 9, 2005 (for cabbage, peanuts, and cotton). Both documents are available at http://www.regulations.gov/ in Docket Number OPP-2004-0202.

Environmental loading is not accounted for in the modeling of RQs for either terrestrial animals or aquatic animals, so ecological risk is underestimated.

Table 38 shows the EECs that would be associated with the proposed mitigation.

Table 38. Surface Water Concentrations Based on Proposed Mitigation

Use Site (Application Parameters)	Peak (Acute Assessment)	1-in-10 Year 21-day (Fish Chronic Assessment)	1-in-10 Year 60-day (Invertebrate Chronic)
Cabbage (22.5 lb ai/A)	36.4 ppb	15.3 ppb	9.5 ppb
Cotton (1.5 lb ai/A)	12.3 ppb	6.4 ppb	4.8 ppb
Peanuts (1 lb ai/A)	8.2 ppb	3.1 ppb	1.9 ppb
Potato (22.5 lb ai/A)	7.7 ppb	2.5 ppb	1.3 ppb
Turf (32.67 lb ai/A, 2 applications)	33.9 ppb	12.1 ppb	7.5 ppb

The values in Table 38 can be compared to the values in Table 17, which were used to estimate RQs for PCNB as currently registered. The values in Table 39 represent what the RQs would be if the proposed mitigation were implemented.

(1) Aquatic Risk Quotients Based on Proposed Mitigaiton

Table 39. Risk Quotients for Aquatic Animals Based on Proposed Mitigation

Use Site (parameters as in Table 38)	Freshwater Acute RQs		Estuarine/Marine Acute RQs		Freshwater Chronic RQs	
	Fish	Invertebrate	Fish	Invertebrate	Fish	Invertebrate
Cabbage	0.36[b]	0.05	<0.01	3.03[a]	0.73	0.85
Cotton	0.12[b]	0.02	<0.01	1.03[a]	0.37	0.36

Use Site (parameters as in Table 38)	Freshwater Acute RQs		Estuarine/Marine Acute RQs		Freshwater Chronic RQs	
	Fish	Invertebrate	Fish	Invertebrate	Fish	Invertebrate
Peanuts	0.08[b]	0.01	<0.01	0.68[a]	0.15	0.17
Potato	0.08 [b]	0.01	<0.01	0.64 [a]	0.1	0.14
Turf	0.34 [b]	0.04	<0.01	2.8 [a]	0.58	0.67

[a] exceeds acute level of concern
[b] exceeds acute endangered species level of concern

RQs from Table 39 may be compared to the RQs in Table 28 and 29, which represent RQs for PCNB as currently registered. Although aquatic concentrations would decrease based on the proposed rate reductions, acute RQs would still exceed the acute high risk or endangered species LOCs for freshwater fish and estauarine/marine invertebrates on all sites. Without chronic toxicity data for estuarine/marine animals, chronic risk quotients for those species cannot be calculated. Since estuarine/marine invertebrates are more sensitive to PCNB on an acute basis than their freshwater counterparts, it is reasonable to assume that they would be more sensitive on a chronic basis (and that corresponding RQs would likely exceed the chronic LOC of 1.0).

(2) Terrestrial Risk Quotients Based on Proposed Mitigation

For cabbage, cotton, and peanuts, RQs for terrestrial wildlife were also recalculated based on the registrant proposal. RQs were not recalculated for potatoes and turf because the registrants did not propose rate reductions for these sites, and the GCAF is not appropriate for application to terrestrial wildlife.

The Agency based its initial assessment of concentrations of PCNB and metabolites on food sources for terrestrial wildlife on the ELL-FATE model. Revisions based on the mitigation proposal (found in the August 9, 2005 document) were estimated with an improved version of that model, called TREX, which accounts for different diets and food source preferences for different kinds of birds and mammals. The TREX results for terrestrial RQs based on the registrant proposal are shown in Tables 40 and 41. Table 40 shows dose-based avian acute RQs, and Table 41 shows dietary-based avian chronic RQs.

Table 40. Avian Acute Dose-based RQs Based on Proposed Mitigation

Use Site	Range of Acute Avian RQs by Body weight		
	20 g	100 g	1000 g
Cabbage	<0.02 to <0.31	<0.05 to <0.88	<0.25 to <3.9
Cotton	<0.01 to <0.02	<0.01 to <0.06	<0.02 to <0.26
Peanuts	<0.01	<0.01 to <0.04	<0.01 to <0.17

Table 41. Avian Chronic Dietary-based RQs Based on Proposed Mitigation

Use Site	Range of Chronic Avian RQs
Cabbage	0.56 to 9.0[a]
Peanuts	0.03 to 0.40
Cotton	0.04 to 0.60

[a] exceeds chronic risk level of concern (RQ ≥1.0)

The terrestrial assessment for PCNB as currently registered relied on ELL-FATE and the assessment based on proposed mitigation relies on TREX, so direct comparisons between RQs are not appropriate. PCNB is practically nontoxic to birds on an acute basis, and the Agency considers the likelihood of avian acute mortality to be low for all of the modeled uses. The proposed mitigation would reduce terrestrial exposures, but some avian chronic RQs would still exceed levels of concern. When the impact of environmental loading is factored in, chronic risks would be higher than those represented by risk quotients alone.

Revised risk quotients for mammalian wildlife also are based on exposures modeled by TREX. Risk quotients are shown in Table 42.

Table 42. RQs for Mammals Based on Proposed Mitigation

Use Site	Range of Acute RQs by Body Wt.			Range of Chronic RQs by Body Wt.		
	15 g	35 g	1000 g	15 g	35	1000 g
Cabbage	<0.01 to 0.46	0.02 to 0.40	0.01 to 0.21	3.3 to 234[a]	2.8 to 200[a]	1.5 to 107[a]
Peanuts	<0.01 to 0.02	<0.01 to 0.02	<0.01 to 0.01	0.14 to 10[a]	0.12 to 8.9[a]	0.07 to 4.8[a]
Cotton	<0.01 to 0.03	<0.01 to 0.03	<0.01 to 0.01	0.22 to 16[a]	0.2 to 13[a]	0.10 to 7.2[a]

[a] exceeds chronic risk level of concern (RQ ≥1.0)

For the modeled chronic mammalian RQs, LOCs are exceeded for all sizes and sites. PCNB is practically nontoxic to mammals on an acute basis, and the Agency considers the likelihood of mammalian acute mortality to be low for all of the modeled uses.

e) Synthesis of Risk Ranking from RQs and Environmental Loading

In general, the mitigation measures proposed by the registrants would be reflected in somewhat lower RQs for aquatic and terrestrial wildlife, but in many cases, those reductions would be insufficient to address concerns for non-target species. In addition, the fate and transport characteristics of PCNB and its metabolites intensify the risk to non-target organisms. The overall impact of the fate and transport characteristics of PCNB on the RQs cannot be quantified and thus contributes to an underestimation of ecological risk expressed only as RQs.

The combined effect of the fate characteristics on the amount of the pesticide and its metabolites entering, translocating, and remaining in the environment is referred to in this document as "environmental loading." Environmental loading varies with the different use sites for a pesticide, and is a function of how much of the pesticide is introduced into the environment and remains in the environment, as measured by:

- Usage (pounds applied on an annual basis)—a measure of the amount of PCNB introduced into the environment *as a whole* and available for potential exposures to wildlife immediately after application; and the amount of parent and metabolites available for these exposures in the long-term, and available for bioaccumulation in the food chain and long-range transport to other ecosystems and species outside the treatment area

- Percent crop treated (what proportion of a given use site is treated in a year)—a measure of how environmental inputs of PCNB are distributed *within areas where the crop is grown*, suggestive of how likely wildlife living in close association with a given crop are to be exposed to harmful levels of PCNB and its metabolites at the time of application and, through the persistent nature of PCNB and its metabolites, in the long-term

- Application rates—reflect the concentration of toxic material present *on individual food items and in water bodies* within or in close proximity to a treated area at the time of application and during the time it takes for residues to dissipate or travel off-site. Application rates are a factor in calculating RQs, unlike usage and percent crop treated, but applied material not consumed or otherwise taken up by non-target organisms can persist in the environment, and is available for long-range transport or other off-site movement.

- Application methods--for a volatile pesticide like PCNB, a foliar application may result in more volatilization and a greater potential for long-range transport. In contrast, incorporated treatments, including seed treatments, may be more likely to result in persistent residues in soil or water bodies near the area of application or contiguous areas.

Usage, percent crop treated, and application rate for each use site were compared to the range of values for all the use sites, and identified as high-end, midrange-, or low-end within the range. Distinctions between high-end and midrange and between midrange and low-end values

were based, where possible, on natural gaps within the ranges. Usage, percent crop treated, and application rates were categorized as in Tables 43-45, with use sites listed from high to low.

Table 43. Domestic Usage of PCNB

Use site and Usage Category	Annual Usage, lbs ai
High-end	
Turf (tees, greens, and fairways)	>400,000
Cotton	400,000
Midrange	
Potato	60,000
Green beans	30,000
Cole crops	23,000
Low-end	
Peanuts	5,000
Dry beans and peas	2,000
Peppers	2,000
Others	<500

Table 44. Domestic Percent Crop Treated for PCNB

Use site and PCT Category	Percent Crop Treated
High-end	
Green beans	15-20%
Midrange	
Cotton	up to 10%
Cole crops	up to 10%
Low-end	
Peppers	up to 5%
(New Mexico chile peppers reported up to 13%)	
Potatoes	up to 5%
Peanuts	<2.5%
Dry beans and peas	<2.5%
Turf (tees, greens, and fairways)	NA
Others	NA

NA = Information not available

Table 45. Maximum Application Rates for PCNB

Use site and Application Rate Category	Application Rate, lbs ai/A
High-end	
Turf (tees, greens, and fairways)	32.67 (twice/season)
Cole crops	22.5
Potato	22.5
Garlic	20.0
Peppers	16.5
Ornamentals	Variable but generally high
Midrange	
Tomato	7.0
Low-end	
Cotton	1.5
Green beans	1.0
Peanuts	1.0
Dry beans and peas	1.0

The placement of individual use sites within the ranges for usage, percent crop treated, and application rates, with consideration of the application method (foliar, incorporated) together were used to describe the environmental loading associated with each use, as shown in Table 46.

Table 46. Potential Environmental Loading for PCNB Use Sites

Use Site	Usage Category	PCT Category	Application Rate Category	Notes	Environmental Loading
Cole Crops	Midrange	Midrange	High-end		Medium
Tees, greens, and fairways	High-end	NA	High-end	Foliar application	High
Cotton	High-end	Midrange	Low-end		Medium
Potatoes	Midrange	Low-end	High-end	Some "over the top" applications	High
Peanuts	Low-end		Low-end		Low
Seed Treatments	NA	NA	Low-end		Low
Green Beans	Midrange	High-end	Low-end		Medium
Dry beans, peas	Low-end	Low-end	Low-end		Low
Garlic	Low-end	NA	High-end		Medium
Tomatoes	Low-end	Low-end	Midrange		Low
Peppers					
Chile peppers	Low-end	Midrange	High-end	Up to 13 PCT in NM	Medium
Other peppers	Low-end	Low-end	High-end		Medium
Ornamentals					
Bulbs	Low-end	NA	High-end		Medium
Other	Low-end	NA	High-end		Medium

The Agency assigned a risk ranking to each PCNB site based on the interplay of risk quotients (where available) and environmental loading, and on the idea that risk quotients exceeding levels of concern are the starting point, and that environmental loading adds to the risk concerns suggested by the RQs. The magnitude of the risk quotients also plays a role. Where risk has not been quantitatively assessed as risk quotients, the risk ranking relies on measures of environmental loading alone. The risk rankings for PCNB use sites are shown in Table 47. Use sites represent non-seed treatment uses unless otherwise noted.

Table 47. Use-specific risk characterization--RQs and environmental loading [1,2]

Use site	Aquatic Risk Quotients exceeding LOCs	Terrestrial Risk Quotients exceeding LOCs	Environmental loading	Risk Ranking
Uses for which RQs have been calculated				
Cole crops	**Acute RQs:** FW fish, ES 0.36 FW invertebrate, ES 0.05 EM invertebrate 3.0	**Chronic RQs:** Avian up to 9.0 **Mammalian up to 234**	Medium	High
Golf course tees, greens, and fairways	**Acute RQs:** FW fish, ES 0.34 EM invertebrate 2.8	**Chronic RQs:** Avian up to 33 Mammalian up to 1858	High	High
Cotton	**Acute RQs:** FW fish, ES 0.12 EM invertebrate 1.0	**Chronic RQs:** Mammalian RQs up to 16	Medium	Medium
Potatoes	**Acute RQs:** FW fish, ES 0.08 **EM invertebrate 0.64**	**Chronic RQs:** Avian up to 6.6 Mammalian up to 375	High	High
Peanuts	**Acute RQs:** FW fish, ES 0.08 EM invertebrate 0.68	**Chronic RQs:** Mammalian RQs up to 10	Low	Medium
Seed treatments		Chronic LOCs exceeded for all seed types; Cotton (highest RQ) 11; assumes diet of seeds only	Low	Low
Uses for which RQs have not been calculated				
Green beans			Medium	Medium
Dry beans, peas			Low	Low
Garlic			Medium	Medium
Tomatoes			Low	Low
Peppers			Medium	Medium
Ornamentals (commercial)			Medium	Medium

The Agency undertook an analysis of the benefits of PCNB use in order to examine the relationship between ecological risks and benefits, on a use-by-use basis.

f) Benefits of PCNB Use

1 The turf and potato RQs for terrestrial wildlife based on ELL-FATE Version 1.4a; all others based on T-REX Version 1.22

2 FW = freshwater; E/M = estuarine/marine; ES = endangered species

The May 22, 2006 document, "Benefits and Cost Analysis of PCNB and Alternatives for Use on Golf Course Turf (Tees, Greens, Fairways), Cotton, Potatoes, Green Beans, and Cole Crops (Cabbage, Brussels Sprouts, Cauliflower), the Agency examined the major uses of PCNB not proposed for termination by the registrants. This document has been posted on the PCNB docket and may be accessed at http://www.regulations.gov/ in Docket Number OPP-2004-0202. From this examination, the Agency concluded that, with the exception of the use of PCNB on cole crops for clubroot, all the major uses of PCNB are associated with minimal benefits, because the target pests could be managed with comparable efficacy by alternative pesticides, at no or minimally greater cost.

The Agency has not quantitatively assessed benefits for the minor uses of PCNB. For these uses, the Agency made assumptions about benefits based on the qualitative assessment of public comment, comments solicited by USDA through the Regional IPM Centers, Crop Profiles posted at http://www.ipmcenters.org/Crop Profiles/, anecdotal information about how users value PCNB, and usage and percent crop treated information as indicators of benefits. In an effort to better understand the relationship between the risks and benefits of these minor uses, the Agency is at this time actively soliciting comments relating to benefits,. The sites for which the Agency is soliciting benefits information are: dry beans and peas, peanuts, tomatoes, peppers (all types), and ornamentals in commercial production (all types except for flowering bulbs).

Types of information which would be useful in this regard include data from comparative efficacy trials for different pesticides used to control diseases on these sites, information about the relative costs of using PCNB and potential alternatives, production cost data, information on why registered alternatives are not appropriate for specific diseases in a particular State or under particular climatic conditions, and documentation of the lack of alternatives for controlling a particular disease.

The Agency ranked the benefits (assessed or assumed) of the PCNB uses as either high or low, to represent the two ends of a spectrum. These rankings are shown in Table 48. Use sites represent non-seed treatment uses unless otherwise noted. "Uses not quantitatively assessed for benefits" do not include turf other than tees, greens, and fairways, or garlic, because the registrants have proposed to terminate those uses. The risk/benefit balance for uses not quantitatively assessed for benefits could be reconsidered if substantive benefits information is made available during the comment period after release of this RED. It is possible that a change in the risk/benefit balance for any of these uses could result in amendment of the RED.

Table 48. Benefits characterization of uses of PCNB

Use site	Usage, percent crop treated	Other benefits information	Benefits ranking
Uses quantitatively assessed for benefits (as per May 16, 2006 document)			
Green beans	30,000 lbs ai/yr, 15-20% crop treated	Numerous effective and economical alternatives for both target diseases	Low
Cole crops	23,000 lbs ai/yr, up to 10% crop treated	Several effective and economical alternatives for control of wirestem	For wirestem, Low
		Lack of feasible alternatives for control of clubroot	For control of clubroot: High
Golf course turf (tees, greens, and fairways)	400,000+ lbs ai/yr	Numerous highly effective, economically feasible alternatives with lesser risk of phytotoxicity	Low
Cotton	400,000 lbs ai/yr, up to 10% crop treated	Several alternatives of comparable efficacy and cost	Low
Potatoes	60,000 lbs ai/yr, up to 5% crop treated.	Several equally effective alternatives of comparable cost	Low
Uses not quantitatively assessed for benefits; benefits information being solicited			
Turf other than tees, greens, fairways	100,000 lbs ai/yr (approximate)	Benefits for tees, greens, and benefits represent conservative estimate of benefits for other turf, since the tolerance for disease damage on tees, greens, and fairways is very low relative to other turf sites (registrants have proposed to terminate)	Low
Dry beans and peas	2,000 lbs ai/yr, <2.5% crop treated	Assumed to be Low benefit, based on limited use. No USDA respondents cited use as critical.	Low
Peanuts	5,000 lbs ai/yr, <2.5% crop treated	Assumed to be Low benefit, based on limited usage. USDA respondent in TX cited extensive use, mainly in tank mixes; respondent in OK cited declining use	Low

Use site	Usage, percent crop treated	Other benefits information	Benefits ranking
Garlic	Limited usage	Assumed to be Low benefit, based on limited usage (registrants have proposed to terminate)	Low
Tomatoes	Limited usage	Assumed to be Low benefit because no USDA respondents cited use as critical.	Low
Peppers	2,000 lbs ai/yr, up to 5% crop treated	EPA seeks specific information on benefits to *all* types of peppers	
		NM Crop Profile says PCNB used on 13% *chile pepper* acreage	Low
		Other peppers: Only USDA respondent to mention peppers says use is important in DE	Low
Ornamentals in commercial production	Limited usage	EPA seeks specific information on benefits to *all* types of ornamentals in commercial production.	
		Anecdotal information suggests PCNB is important in production of *flowering bulbs*.	High
		CA Crop Profile indicates 29% of *containerized nurseries* use PCNB as a soil drench, numerous alternatives are cited	Low
Seed treatments	(Application rates much lower than rates for corresponding soil applications, typically <10%)	Assumed to be High benefit, based on input of USDA; use on rice and safflower seed may be less critical	High

4. Determination of Eligibility for Reregistration

Based on the assessment of human health risks associated with the PCNB uses, the Agency has determined that post-application risks associated with residential and related uses are unacceptable. These uses are not eligible for reregistration because the Agency cannot make a determination that the tolerance reassessment for PCNB meets the FQPA safety finding based on the contribution of these uses to the aggregate risks for PCNB. In addition, the registrants have proposed to terminate the turf uses of PCNB other than golf course tees, greens, and fairways. The following uses are not eligible for reregistration:

The Agency has evaluated the relationship of risks and benefits for all PCNB uses on a use-by-use basis. The uses of PCNB which do not demonstrate a favorable risk/benefit relationship are not eligible for reregistration. For most of the minor uses of PCNB, where benefits could not be quantified, the Agency believes that there may be publicly-held information on benefits that could affect our understanding of this relationship, and the reregistration eligibility decisions for these uses. The Agency has solicited information that could better inform the decisions on these uses.

The risk/benefit comparisons and the reregistration eligibility decisions for all the uses of PCNB for which these comparisons have been made are shown in Table 49. Decisions which could potentially be affected by the submission of benefits information during the comment period following the release of the RED are shown in italics.

Table 49. Determinations of Reregistration Eligibility for PCNB uses

Use Site	**Risk/Benefit**	**Eligibility**
Green beans	Medium/Low	Not eligible
Cole crops (PCNB is used to control two different diseases of cole crops)		
For treatment of wirestem	High/Low	Not eligible
For treatment of clubroot	High/High	**Eligible**
Tees, greens, fairways	High/Low	Not eligible
Cotton	Medium/Low	Not eligible
Potatoes	High/Low	Not eligible
Turf other than tees, greens, fairways*	High /Low	Not eligible
Dry beans/peas	Low/Low	*Not eligible*
Garlic	Low/Low	Not eligible
Peanuts	Medium/Low	*Not eligible*
Tomatoes	Low/Low	*Not eligible*
Peppers		
Chile peppers	Medium/Low	*Not eligible*
Other peppers	Medium/Low	*Not eligible*
Production ornamentals		
Flowering bulbs	Medium/High	**Eligible**
Other ornamentals	Medium/Low	*Not eligible*
Seed treatments	Low/High	**Eligible**

* Residential turf and ornamentals, and turf on school grounds, and in parks, playgrounds

The uses of PCNB with risks rated higher than benefits are not eligible for reregistration. Uses with benefits ranked higher than risks are eligible for reregistration.

One use of PCNB appears in Table 49 with both high risks and high benefits. Because the use of PCNB to control clubroot on cole crops is a subset of the overall use of PCNB on cole crops, the usage and percent crop treated figures cited here may be overstated. The Agency believes that the environmental loading associated with the clubroot use is probably lower than that associated with overall use. In addition, the use of PCNB on cole crops when applied via chemigation poses occupational risks that cannot be adequately mitigated with PPE or engineering controls. The Agency has determined that the use of PCNB on cole crops, if labeled for control of clubroot only, and to prohibit applicaton via chemigation, is eligible for reregistration.

Several uses of PCNB have both low risks and low benefits. Because the ecological risks for PCNB are assumed to be underestimated, due to the significant but unquantified impact of environmental loading, and because the Agency is willing to consider the reregistration decision in light of information which supports greater benefits for these uses, they are not eligible for reregistration, pending consideration of such information submitted during the comment period after release of the RED.

Based on the risk-benefit comparisons, and the other considerations discussed above, the Agency has determined that the following uses of PCNB are not eligible for reregistration:

- green beans
- cole crops (if not labeled for control of clubroot only and to prohibit application via chemigation)
- turf
- cotton
- potatoes
- dry beans and peas
- garlic
- peanuts
- tomatoes
- peppers
- ornamentals in commercial production (except for flowering bulbs)
-

The Agency has determined that the following uses of PCNB are eligible for reregistration:

- cole crops (labeled for control of clubroot only and to prohibit application via chemigation)
- flowering bulbs (labeled for commercial use only)
- seed treatments

5. Labeling Requirements

In order to be eligible for reregistration, all products containing PCNB must bear specific use and safety information on their labeling. In addition, certain generic and product-specific data will be required for PCNB products. The specific label statements and a list of outstanding data requirements are found in Section V of this RED document.

6. Endangered Species Considerations

Risk Quotients for PCNB, reflecting mitigation measures proposed by the registrants, indicate a potential for acute and chronic risks to listed species associated with the modeled use sites, as noted below:

<u>Terrestrial organisms</u>
Mammals
- Chronic RQs exceed LOCs for cole crops, peanuts, cotton, and potatoes for all mammals feeding on short grass, tall grass, and broadleaf plants and insects
- Chronic RQS exceed LOCs for turf for all mammals feeding on all forage items

Birds (reptiles, terrestrial-phase amphibians)
- Chronic RQs exceed LOCs for cole crops and potatoes for birds feeding on short grass, tall grass, and broadleaf plants and insects
- Chronic RQs exceed LOCs for turf for birds feeding on all forage items
- Chronic RQs exceed LOCs for seed-eating birds for all modeled seed treatments

Seed treatments
- Chronic RQs exceed LOCs for treated seeds of barley, cotton, oats, peas, rice, soybean, and sugar beet for seed-eating birds
- Chronic RQs exceed LOCs for treated seeds of all types for seed-eating mammals

<u>Aquatic organisms</u>
Freshwater fish (aquatic-phase amphibians)
- Acute RQs exceed LOCs for all sites

Freshwater invertebrates
- Acute RQs exceed LOCs for cole crops

Estuarine/marine invertebrates
- Acute RQs exceed LOCs for all sites

Although the reregistration decisions for PCNB uses will eliminate or reduce exposures in many instances, endangered species LOCs associated with the remaining uses of PCNB may still be exceeded for aquatic and terrestrial species.

To address concerns about risks to endangered species from pesticide use, the Agency has developed the Endangered Species Protection Program (ESPP). The assessments of risk for aquatic and terrestrial wildlife described in this RED serve as a screening tool to determine the need for any species-specific assessments for listed species, in accordance with the ESPP. Such assessments would refine the screening level assessment by taking into account such factors as the geographic areas of pesticide use in relation to the listed species and the habits and habitat requirements of the listed species. If the Agency's species-specific assessments result in the need to modify the use of the pesticide in specific geographic areas, those changes will be undertaken through the process described in the Agency Federal Register Notice (54 FR 27984) on implementation of the ESPP.

7. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, we will continue to work with all interested parties on this important issue. From its assessment of PCNB, as summarized in this document, the Agency concludes that certain drift mitigation measures are needed to address the risks from off-target drift for PCNB. Label statements implementing these measures are listed in Section V of this document.

V. What Registrants Need to Do

The Agency has determined that certain uses of PCNB are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect those measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Summary Table in Section D below. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

A. Submissions for Technical-Grade Active Ingredient Products

1. Within 90 Days of Receipt of the Generic DCI

For each PCNB technical grade active ingredient product, the registrant needs to submit the following items within 90 days of receiving the Generic DCI:

- completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form);
- submit any time extension and/or waiver requests with a full written justification); and
- compositional analysis of registered PCNB technical materials, accounting for PCNB and all contaminants present in those materials. Materials of the same composition must be used to develop the toxicity data required by the DCI.

2. Within Generic DCI Deadlines

Within the time limit specified in the generic DCI, the registrant must cite any existing generic data which address data requirements or submit new generic data responding to the DCI. Please contact Jill Bloom at (703) 308-8019 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/SRRD)
Jill Bloom
US EPA (7508P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Jill Bloom
Office of Pesticide Programs (7508P)
4th Floor, One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202

B. Submissions for End-Use Products Containing PCNB

1. Within 90 Days

Within 90 days from the receipt of the product-specific data call-in (PDCI), the registrant must submit, for each product:

- completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
- any time extension or waiver requests with a full written justification.

2. Within Product DCI Deadlines

Within eight months from the receipt of the PDCI, the registrant must submit:

- two copies of the confidential statement of formula (EPA Form 8570-4);
- a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";
- five copies of the draft label incorporating all label amendments outlined in Table 47 of this document;
- a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); and
- if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
- the product-specific data responding to the PDCI.

Please contact Bonnie Adler at (703) 308-8523 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Bonnie Adler

By express or courier service:
Document Processing Desk (PDCI/PRB)
Bonnie Adler

US EPA (7508P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

Office of Pesticide Programs (7508P)
4th Floor, One Potomac Yard.
2777 S. Crystal Drive
Arlington, VA 22202

C. Manufacturing-Use Products—Data Requirements and Labeling

1. Generic Data Requirements

Fulfillment of the data requirements identified in the risk assessments and listed below is necessary to confirm the reregistration eligibility decision documented in this RED. The Agency will consider waiving or modifying some of these data requirements in light of this RED, which designates most uses of PCNB as ineligible for reregistration.

Table 50. Generic Data Requirements for the Reregistration Eligibility Decision on PCNB

Guideline or Special Study Name or Description	OPPTS Guideline No.
Direct Photolysis Rate of Parent and Degradates in Water [1]	835.2240
Aerobic Aquatic Metabolism Study[2]	835.4300
Anaerobic Aquatic Metabolism Study[2]	835.4400
Invertebrate Acute Toxicity Test, Freshwater Daphnids[1]	850.1010
Gammarid Acute Toxicity Test[1]	850.1020
Estuarine/marine Mollusk (Oyster) Acute Toxicity Test (Shell Deposition)[1]	850.1025
Estuarine/marine Mysid (Shrimp) Acute Toxicity Test[1]	Special Study (old guideline 72-3F)
Penaeid Acute Toxicity Test[1]	850.1045
Bivalve Acute Toxicity Test (Embryo Larval)[1]	850.1055
Fish Acute Toxicity Test, Freshwater (Bluegill Sunfish)[1]	850.1075
Fish Acute Toxicity Test, Rainbow Trout [1]	850.1075
Daphnid Chronic Toxicity Test (early life stage in fish)[1]	850.1300
Mysid (Shrimp) Chronic Toxicity Test (life cycle in aquatic invertebrates– estuarine/marine species) (parent plus PCA)	850.1350
Early-life Stage Estuarine Fish (parent plus PCA)	850.1450
Terrestrial Plant Toxicity, Tier 1 (Seedling Emergence)	850.4100

Guideline or Special Study Name or Description	OPPTS Guideline No.
Terrestrial Plant Toxicity, Tier 1 (Vegetative Vigor)	850.4150
Aquatic Plant Toxicity Test Using *Lemma* spp.	850.4400
Semi-aquatic Plant Toxicity Test	Special Study
Foliar Dissipation—for use in determining potential exposures to terrestrial wildlife (*not* dislodgeable residues)	Special Study
Radiolabeled common moiety analytical method for plants and animal commodities, as discussed in Section IV of this RED	860.1340
Enforcement analytical method—reserved pending approval of analytical method	Special Study
Magnitude of Residues in Meat, Milk, Poultry and Eggs--reserved pending approval of analytical method	860.1480
Crop Field Trials (Magnitude of Residues in Plants)—reserved pending approval of analytical method	860.1500
Analytical Reference Standards—reserved pending approval of analytical method	860.1650
90-day Subchronic Inhalation Toxicity Test, Rat [3, 4]	870.3465
Dermal Absorption (Dermal Penetration), Rat [3, 5]	870.7600
Iodide Uptake, Rat	Special Study, protocol to be proposed by registrants
Comparative Thyroid Test [3, 6]	Special Study
Bioaccumulation of PCNB and metabolites; determination of biological half-life [3, 7]	Special Study
Data on toxicological significance of consistent, dose related decreases in AST/ALT in PCNB toxicity tests [3, 8]	Special Study

[1] Test material is PCA.

[2] Soil metabolism studies must be conducted to determine conditions which favor the formation of pentachlorophenol from PCNB and to track the production/further metabolism/degradation of pentachlorophenol over time.

[3] Since small differences in impurities may result in differences in the toxicity of test materials, these studies must be conducted with materials identical to marketed technicals. The compositional analysis of test materials for each study must be verified and the Agency will compare this documentation to the compositional analyses of each technical product required to be submitted for within 90 days of receipt of the DCI, as noted above.

[4] In addition to guideline requirements, interim thyroid hormone analyses required at 7, 14, 30, and 90 days. Histopathology assessment to include thyroid analysis.

[5] Conditionally required; in absence of data, Agency will continue to assume 33% dermal absorption by default.

[6] Registrants must submit a protocol for Agency approval. A draft protocol has been developed by the Agency for another pesticide, and it may be useful as a basis for this study. Registrants must assess thyroid toxicity in adults vs. offspring. For already-submitted thyroid metabolism studies (MRIDs 440966-01 and 440966-02), deficiencies have been noted in reviews and must be addressed. For MRID 440966-02, raw data for the study were reported as missing by the testing facility and information on the purity and lots of the labeled thyroxine was not provided. For MRID 440966-01, registrant must submit (1) data on the fate of individual animals and verification of the number of treated animals that died prior to assignment to the experimental groups, (2) clarification of the different compound consumption values given in the study report, and (3) verification that the test diets were prepared and used within the time of demonstrated stability,

[7] Submission must include required guideline items of the metabolism/kinetics study. The tier II level study must be performed. Registrant must report circulating blood levels of key metabolites and PCNB that relate to key end-points of toxicity and dose levels in other studies; dosing regimen based on thyroid study (may be combined with comparative thyroid study if based on accepted protocol).

[8] Registrant may propose to submit study to assess toxicological significance of these findings, or may propose to address data requirement with narrative explanation. The AST/ALT finding in question are reported in MRIDs 43015801 (rat), and 41718600 and 41718601 (dogs).

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 47.

D. End-Use Products—Data Requirements and Labeling

1. Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. A product-specific data call-in, outlining specific data requirements, will be issued separately from this document.

2. Labeling for End-Use Products

In order to be eligible for reregistration, all product labels must be amended to incorporate the risk mitigation measures outlined in Section IV. Table 47 describes how language on the labels of end-use products should be amended.

E. Existing Stocks

Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. Specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

F. Required Labeling Changes

In order to be eligible for reregistration, all product labels must be amended to incorporate the risk mitigation measures outlined in Section IV. Table 51 details how language on the labels should be amended.

Table 51. Labeling Changes for Products Containing PCNB

Description	Amended Labeling Language	Placement on Label
Manufacturing-Use Products		
For All Manufacturing- Use Products	"This product may be formulated into a fungicide for the following use(s) only: soil-directed applications for treatment of clubroot on cole crops; soil-directed or bulb-soak applications for commercial production of flowering bulb plants and bulbs; and treatments to seeds of barley, beans, corn, cotton, oats, peas, peanut, rice, safflower, sorghum, soybeans, sugar beets, and wheat." "This product may not be formulated into end-use products labeled for use on cole crops (unless labeled solely for treatment of clubroot), turf (including lawns), green beans (unless labeled solely for treatments to seeds), cotton (unless labeled solely for treatments to seeds), potatoes, dry beans and peas (unless labeled solely for treatments to seeds), garlic, peanuts (unless labeled solely for treatments to seeds), tomatoes, peppers, or ornamentals (except commercial production of flowering bulb plants and bulbs)." "This product may not be formulated into end-use products, unless the end-use products are labeled to prohibit aerial applications." "This product may not be formulated into end-use products with directions for use on cole crops, unless the end-use products are labeled to prohibit chemigation applications on cole crops." "This product may not be formulated into end-use products with directions for use for commercial production of flowering bulb plants or bulbs, unless the end-use products are labeled to prohibit applications directed at foliage or flowers and to prohibit broadcast applications." "This product may be formulated into wettable powders only if packaged in water-soluble packaging." "This product may not be formulated into granular products, unless these products are labeled to prohibit application with a chest-mounted rotary spreader (belly-grinder)."	Directions for Use

Description	Amended Labeling Language	Placement on Label
	"This product may be formulated into dust products only for seed treatment applications." "This product may not be formulated into end-use products labeled for seed treatment uses, unless seed treatments are the sole use on the end-use product labels." "This product may not be formulated into end-use products labeled for seed treatment uses, unless the end-use products are labeled to incorporate the following language:" "Seeds that have been treated with this product that are then packaged and offered for sale or distribution must contain the following labeling:" "This bag contains seed treated with PCNB. To avoid possible adverse health effects, when opening this bag or loading the treated seed, wear long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves, and a NIOSH-approved respirator equipped with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N, R, P, or HE filter. "Do Not Use for Food, Feed, or Oil." "After seeds have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. Exception: Once seeds are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the soil/media subsurface."	

Description	Amended Labeling Language	Placement on Label
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This chemical is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

End-Use Products		
NOTE: PPE established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.		
PPE Requirements Established by the RED for Liquid, Dry Flowable, or Water Dispersible Granule formulations (excludes products labeled for seed treatment use) NOTE: Products labeled for non-seed treatment uses must not be labeled for seed treatment use also. NOTE: When cole crops are not listed on the product label, references to this use may be removed from the respirator statement. NOTE: When greenhouse uses or bulb soak uses are prohibited on the product label, references to the corresponding use(s) may be removed from the respirator statement.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category *(registrant inserts A, B, C, D, E, F, G, or H*) on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and other handlers must wear: long-sleeved shirts and long pants, shoes plus socks, chemical-resistant gloves, except for applicators using groundboom equipment, and chemical-resistant apron when involved in bulb soak applications. In addition, all 1) mixers and loaders, 2) applicators making applications to cole crops, 3) applicators performing bulb soak applications, and 4) applicators making applications in greenhouses must wear a NIOSH-approved respirator equipped with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N, R, P, or HE filter." "See Engineering Controls for more options." Instruction to Registrant: Drop the "N" type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

End-Use Products		
PPE Requirements Established by the RED for Wettable Powder formulations (excludes products labeled for seed treatment use) NOTE: Wettable powder formulations must be packaged in water soluble packets. NOTE: Products labeled for non-seed treatment uses must not be labeled for seed treatment use also. . NOTE: When cole crops are not listed on the product label, references to this use may be removed from the respirator statement. NOTE: When greenhouse uses or bulb soak uses are prohibited on the product label, references to the corresponding use(s) may be removed from the respirator statement.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are *(registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category *(registrant inserts A, B, C, D, E, F, G, or H)* on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and other handlers must wear: long-sleeved shirts and long pants, shoes plus socks, chemical-resistant gloves except for applicators using groundboom equipment, chemical-resistant apron for all mixers and loaders and for all applicators involved in bulb soak applications. In addition, all 1) applicators making applications to cole crops, 2) applicators performing bulb soak applications, and 3) applicators making applications in greenhouses must wear a NIOSH-approved respirator with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N, R, P, or HE filter." "See Engineering Controls for more requirements and options." Instruction to Registrant: Drop the "N" type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil.	Immediately following or below Precautionary Statements: Hazards to Humans and Domestic Animals

End-Use Products		
PPE Requirements Established by the RED for Granular Formulations NOTE: When cole crops are not listed on the product label, references to this use may be removed from the respirator statement. NOTE: When greenhouse uses are prohibited on the product label, references to these uses may be removed from the respirator statement .	"Personal Protective Equipment (PPE)" "Loaders, applicators, and other handlers must wear: long-sleeved shirts and long pants, shoes plus socks, In addition, all 1) loaders, 2) applicators making applications to cole crops, and 3) applicators making applications in greenhouses must wear a NIOSH-approved respirator equipped with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N, R, P, or HE filter." "See Engineering Controls for more options." Instruction to Registrant: Drop the "N" type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED for Dust formulations labeled to treat seeds NOTE: Dust formulations are limited solely to seed treatment uses.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category *(registrant inserts A, B, C, D, E, F, G, or H*) on an EPA chemical-resistance category selection chart." "All loaders, applicators, handlers involved in clean-up of the seed treatment area, and handlers calibrating, maintaining, repairing, or cleaning seed treatment equipment must wear: long-sleeved shirts and long pants, shoes plus socks, chemical-resistant gloves, chemical-resistant apron when loading, or cleaning spills or equipment, a NIOSH-approved half-face, full-face or hood-style respirator with -- a dust/mist filtering cartridge (MSHA/NIOSH approval number prefix TC-21C), or -- a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

End-Use Products		
	-- a cartridge or canister with any N*, R or P or He filter. A quarter-face cup-style dust/mist filtering respirator is not permitted." "Persons drying or bagging treated seed, sewing or stacking bags containing treated seed, or operating a forklift within the seed treatment area are handlers and must wear: long-sleeved shirts and long pants, shoes plus socks, chemical-resistant gloves, except when sewing bags of treated seed, a NIOSH-approved respirator with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N, R, P, or HE filter. A NIOSH-approved quarter-face cup-style dust/mist filtering respirator is one type of respirator which is permitted." "See Engineering Controls for more options." Instruction to Registrant: Drop the "N" type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil.	
PPE Requirements Established by the RED for Liquid, Dry Flowable, and Water Dispersible Granule formulations labeled for seed treatment use NOTE: Products labeled for seed treatment uses must not be labeled for non-seed treatment use also.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category *[registrant inserts A, B, C, D, E, F, G, or H*] on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators, and handlers involved in clean-up of the seed treatment area and all handlers calibrating, maintaining, repairing, or cleaning seed treatment equipment must wear: long-sleeved shirts and long pants, shoes plus socks, chemical-resistant gloves, chemical-resistant apron when mixing, loading, cleaning up spills or equipment, a NIOSH-approved half-face, full-face or hood-style respirator with -- a dust/mist filtering cartridge (MSHA/NIOSH approval number prefix TC-21C), or	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

End-Use Products		
	-- a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or -- a cartridge or canister with any N*, R or P or He filter. A quarter-face cup-style dust/mist filtering respirator is not permitted." "Persons drying or bagging treated seed, sewing or stacking bags containing treated seed, or operating a forklift within the seed treatment area are handlers and must wear: long-sleeved shirts and long pants, shoes plus socks, chemical-resistant gloves, except when sewing bags of treated seed, a NIOSH-approved respirator with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N, R, P, or HE filter. A NIOSH-approved quarter-face cup-style dust/mist filtering respirator is one type of respirator which is permitted." "See Engineering Controls for more options." Instruction to Registrant: Drop the "N" type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil.	
PPE Requirements Established by the RED for Wettable Powder formulations labeled for seed treatment use NOTE: Wettable powder formulations must be packaged in water soluble packets.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category *[registrant inserts A, B, C, D, E, F, G, or H*] on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators, and handlers involved in clean-up of the seed treatment area and all handlers calibrating, maintaining, repairing, or cleaning seed treatment equipment must wear: long-sleeved shirts and long pants, shoes plus socks, chemical-resistant gloves, chemical-resistant apron when mixing, loading, cleaning up spills or equipment,	

End-Use Products		
	a NIOSH-approved half-face, full-face or hood-style respirator with -- a dust/mist filtering cartridge (MSHA/NIOSH approval number prefix TC-21C), or -- a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or -- a cartridge or canister with any N*, R or P or He filter. A quarter-face cup-style dust/mist filtering respirator is not permitted." "Persons drying or bagging treated seed, sewing or stacking bags containing treated seed, or operating a forklift within the seed treatment area are handlers and must wear: long-sleeved shirts and long pants, shoes plus socks, chemical-resistant gloves, except when sewing bags of treated seed, a NIOSH-approved respirator with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N, R, P, or HE filter. A NIOSH-approved quarter-face cup-style dust/mist filtering respirator is one type of respirator which is permitted." "See Engineering Controls for more options." Instruction to Registrant: Drop the "N" type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil.	
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls for Liquid Formulations (for labels where the use patterns make the use of an enclosed cab feasible)	"Engineering Controls" "When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4,5), the handler PPE requirements may be reduced or modified as	Immediately following User Safety Requirements

End-Use Products		
	specified in the WPS."	
Engineering Controls for Wettable Powder Formulations	"Engineering Controls" "Water-soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]." "Mixers and loaders using water-soluble packets must : -- wear the personal protective equipment required in the PPE section of this labeling for mixers and loaders, and -- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant footwear, and the type of respirator as specified in the PPE section of this label." Include this statement on labels where the use patterns make the use of an enclosed cab feasible: "When applicators use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(5), the handler PPE requirements may be reduced or modified as specified in the WPS."	Immediately following User Safety Requirements
Engineering Controls for Granular, Dry Flowable, and Dry Flowable Formulations (for labels where the use patterns make the use of an enclosed cab feasible)	"Engineering Controls" "If applicators use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(5), the handler PPE requirements may be reduced or modified as specified in the WPS."	Immediately following User Safety Requirements

End-Use Products		
Engineering Controls for Dust Formulations Labeled For Seed Treatments	"Engineering Controls" "If loaders and/or applicators use a closed system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people while it is being handled and if the system has a properly functioning dust control system that is used and maintained in accordance with the manufacturer's written operating instructions, handlers using the closed mixing/loading and/or application system must: -- wear long-sleeve shirt, long pants, shoes, socks, and chemical-resistant gloves, -- be provided, have immediately available, and wear, in case of emergency, such as a broken package or equipment breakdown, a NIOSH-approved respirator with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N, R, P or HE filter."	Immediately following User Safety Requirements
Engineering Controls for Liquid, Dry Flowable, or Water Dispersible Granule Formulations Labeled for Seed Treatments	"Engineering Controls" "If mixers/loaders or applicators use a closed system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people while it is being handled and if the system has a properly functioning dust control system that is used and maintained in accordance with the manufacturer's written operating instructions, handlers using the closed mixing/loading and/or application system must: -- wear long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron, -- be provided, have immediately available, and wear, in case of emergency, such as a broken package or equipment breakdown, a NIOSH-approved respirator with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N, R, P or HE filter."	Immediately following User Safety Requirements

End-Use Products		
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazard Statement	"This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark except as noted on appropriate labels. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash waters or rinsate. This pesticide is toxic to birds and mammals. Treated seed and granules on soil surface may be hazardous to terrestrial wildlife. Cover or collect any such materials spilled during loading."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS) (excludes products with directions for use as a seed treatment)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours. Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated areas without restriction if there will be no contact with anything that has been treated."	Directions for Use, Under Agricultural Use Requirements Box

End-Use Products		
Restricted-Entry Interval for products with directions for use as an on-farm, planter box, hopper box, or other at-plant seed treatment	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours." Exception: Once seeds are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the soil/media subsurface."	Directions for Use, Under Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material"	Direction for Use Agricultural Use Requirements box
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Directions for Use under General Precautions and Restrictions

End-Use Products		
Other Application Restrictions	**For all products:** "Use of this product on cole crops (unless labeled solely for treatment of clubroot), turf (including lawns), green beans (unless labeled solely for treatments to seeds), cotton (unless labeled solely for treatments to seeds), potatoes, dry beans and peas (unless labeled solely for treatments to seeds), garlic, peanuts (unless labeled solely for treatments to seeds), tomatoes, peppers, or ornamentals (except commercial production of flowering bulb plants and bulbs) is prohibited." **For all products for which aerial application is feasible (e.g., not on labels containing directions solely for use as seed treatment):** "Aerial applications prohibited." **For granular formulations:** "Application with a chest-mounted rotary spreader (belly-grinder) is prohibited." **For products labeled for use on cole crops:** "Use as a seed treatment is prohibited." **For products labeled for use on ornamentals:** "Use as a seed treatment is prohibited. Use on ornamentals is limited to commercial production of flowering bulb plants or bulbs in commercial greenhouses, nurseries, or field production facilities. Use in residential settings is prohibited. Application directed at foliage or flowers is prohibited. Broadcast applications are prohibited." **For products labeled for use as seed treatment:** "For seed treatment applications only. Application to soil or foliage is prohibited."	Directions for Use

End-Use Products		
Application Restrictions Associated with the Directions for Use on Cole Crops NOTE: Application rates must be listed as amounts of formulated product.	"Application by chemigation to cole crops is prohibited. This product may only be used for treatment of clubroot. Maximum seasonal application rate is 22.5 lb ai/A/season or (*registrant inserts application rate as amount of formulated product equivalent to 22.5 lb ai/A/season*)."	Directions for Use
Application restrictions for products used for commercial seed treatments	This product may not be used to treat seed unless the following language is placed on the pesticide label: "Seeds that have been treated with this product that are then packaged and offered for sale or distribution must contain the following labeling:" "This bag contains seed treated with PCNB. To avoid possible adverse health effects, when opening this bag or loading the treated seed, wear long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves, and a NIOSH-approved respirator equipped with: -- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or -- any N, R, P, or HE filter." "Do Not Use for Food, Feed, or Oil." "After seeds have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. Exception: Once seeds are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the soil/media subsurface."	Directions for Use

End-Use Products		
Spray Drift	"SPRAY DRIFT MANAGEMENT" "Avoiding spray drift at the application site is the responsibility of the applicator and the grower. The interactions of many equipment and weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering these factors when making decisions about spraying." "Apply only when the wind speed is less than or equal to 10 mph at the application site." "Apply as a medium or coarser spray (ASAE standard 527)." "Apply using a nozzle height of no more than 4 feet above the ground or crop canopy."	Directions for Use

Appendices