



Pentachloronitrobenzene

Proposed Final Registration Review Decision Case Number 0128

September 2022

Approved by: _____

A handwritten signature in blue ink, appearing to read "Mary Elissa Reaves".

Mary Elissa Reaves, Ph.D.
Director
Pesticide Re-evaluation Division

Date: 9/19/2022

Table Of Contents

I. INTRODUCTION	3
A. Summary of PCNB Registration Review	7
B. Summary of Public Comments on the Draft Risk Assessments and Agency Responses	9
II. USE AND USAGE	19
III. SCIENTIFIC ASSESSMENTS	20
A. Ecological Risks	20
1. Risk Summary and Characterization.....	20
2. Ecological Incidents.....	37
3. Outstanding Ecological and Environmental Fate Data	37
B. Human Health Risks	38
1. Risk Summary and Characterization.....	39
2. Human Incidents and Epidemiology.....	47
3. Tolerances	48
4. Outstanding Human Health Data	48
C. Benefits Assessment	49
IV. PROPOSED FINAL REGISTRATION REVIEW DECISION	50
A. Proposed Regulatory Rationale	50
1. Proposed Cancellation of the Registrations of PCNB.....	52
2. Potential Impacts of Proposed Cancellation	53
3. Environmental Justice.....	53
B. Tolerance Actions	54
C. Proposed Final Registration Review Decision	55
D. Data Requirements	57
V. NEXT STEPS AND TIMELINE	57
A. Proposed Final Registration Review Decision	57
Appendix A: Summary of Proposed Actions for PCNB	59

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Proposed Final Registration Review Decision (PFD) for pentachloronitrobenzene (PCNB; PC Code 056502, case 0128). In a registration review decision under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Agency determines whether a pesticide continues to meet FIFRA's registration standard.¹ A final registration review decision addresses all aspects of the registration review, as necessary, including considerations under the Endangered Species Act (ESA) and for the Endocrine Disruptor Screening Program (EDSP) under the Federal Food, Drug and Cosmetic Act (FFDCA)² as amended by the Food Quality Protection Act (FQPA). For more information on PCNB see EPA's public docket (EPA-HQ-OPP-2015-0348) at www.regulations.gov.

FIFRA³ mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. In 2006, the Agency began implementing the registration review program in which EPA reviews each registered pesticide every 15 years. Through the registration review program, the Agency intends to verify that all registered pesticides continue to meet the registration standard as the ability to assess and mitigate risks evolves and as policies and practices change. By periodically re-evaluating pesticides as science, public policy, and pesticide-use practices change, the Agency ensures that the public can continue to use products in the marketplace that do not present unreasonable adverse effects on human health or the environment. For more information on the registration review program, see <http://www.epa.gov/pesticide-reevaluation>.

The Agency is issuing a PFD for PCNB before issuing a final decision in registration review, as required under 40 CFR 155.58. EPA is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (the Services) to improve the consultation process for federally listed threatened and endangered (listed) species for pesticides under the ESA.⁴ The Agency has not fully evaluated PCNB's risks to federally listed species. However, as detailed below, the Agency is proposing to cancel all registrations of PCNB. If EPA's final decision is that all PCNB registrations must be cancelled, the potential for exposure to listed species and their designated critical habitat would be eliminated, and consultation with the Services would not be needed. Likewise, if the registrations of PCNB are cancelled, the potential for any endocrine effects would be addressed.

PCNB is an organochlorine fungicide that was first registered for use as a conventional pesticide in the United States in 1964. Organochlorine pesticides such as PCNB represent an older pest control technology; most organochlorine pesticides that were previously registered by the Agency have been cancelled, primarily based on concerns about environmental persistence, bioaccumulative potential, and potential ecological and/or human health risks. Organochlorine

¹ Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57.

² Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).

³ As amended by the Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489.

⁴ Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.

pesticides that have been cancelled include aldrin, chlordane, DDT, dicofol, dieldrin, endosulfan, endrin, lindane, and toxaphene. Organochlorine compounds share similar environmental fate and toxicity characteristics; many satisfy international criteria for Persistent, Bioaccumulative and Toxic (PBT) chemicals and Persistent Organic Pollutants (POPs). The PCNB technical-grade product and the end-use products formulated from it contain manufacturing impurities that are considered to be PBT chemicals and POPs.

PCNB is a contact fungicide that is currently registered for use on certain field crops (potatoes and cole crops), turf (golf course tees, greens, and fairways; landscaping for industrial parks; college and professional athletic fields, and sod farms), and production ornamentals and bedding plants (flowering bulbs, Southern magnolia trees, Southern pine, woody ornamentals, and ornamental cole crop bedding plants). It can be used as a soil or foliar treatment. PCNB acts by inhibiting lipid and fungal membrane synthesis in fungi.⁵ PCNB and its degradates are somewhat systemic and can be taken up by roots and translocated to other parts of the plant, as evidenced by their presence in commodities from treated crops. There are currently five registered end-use products and one registered technical product that contain PCNB.

Historical Context

The Reregistration Eligibility Decision for PCNB

A Reregistration Eligibility Decision (RED) for PCNB was issued in 2006.⁶ During the decision-making process, EPA identified potential ecological risks of concern, including risks associated with the environmental fate characteristics of PCNB and risks to mammals, birds, fish, and aquatic invertebrates. EPA also identified potential human health risks of concern, including risks associated with the residential use of products containing PCNB and risks to occupational handlers. At the same time, the Agency also evaluated the benefits of PCNB use. The RED identified uses that were eligible and ineligible for reregistration based on the interplay of risks and benefits. **Table 1** is reproduced from the RED with some added notation. For more detail on how the potential risks and benefits were determined, see the RED.

⁵ *Pentachloronitrobenzene (PCNB) (PC Code 056502) Registration Review: Assessment of Use, Usage, Potential Impacts of Cancellation, and Response to Public Comments on the Draft Risk Assessments*, June 27, 2022, available on the registration review docket for PCNB.

⁶ *Reregistration Eligibility Decision for Pentachloronitrobenzene*, June 2006, available at <https://www.regulations.gov/document/EPA-HQ-OPP-2004-0202-0057>

Table 1. Determinations of 2006 Reregistration Eligibility Decision (RED) for Pentachloronitrobenzene (PCNB) Uses.

Use Site	Risks/Benefits	Eligibility
Green beans*	Medium/Low	Not eligible
Cole crops:		
<i>For treatment of wirestem</i>	High/Low	Not eligible
<i>For treatment of clubroot</i>	High/High	Eligible
[Golf course] Tees, greens, and fairways	High/Low	Not eligible
Cotton*	Medium/Low	Not eligible
Potatoes	High/Low	Not eligible
Turf other than tees, greens, and 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:*		
<i>Chile peppers</i>	Medium/Low	Not eligible
<i>Other peppers</i>	Medium/Low	Not eligible
Production ornamentals:		
<i>Flowering bulbs</i>	Medium/High	Eligible
<i>Other ornamentals***</i>	Medium/Low	Not eligible
Seed treatments*	Low/High	Eligible

* PCNB is no longer registered for use on these sites

** PCNB is registered for use on industrial turf, sod farms, and collegiate and professional athletic fields; it is not registered for use on residential lawns and related sites, as recounted later in this section.

***PCNB is no longer registered for use on ornamentals in residential areas

October 2008 Scientific Advisory Panel Meeting and Findings

In October 2008, EPA convened the FIFRA Scientific Advisory Panel (SAP) on the Agency’s approach to assessing risks from PBT pesticides. PBT pesticides are persistent in the environment, have potential for bioaccumulation in aquatic and/or terrestrial food chains, and are toxic to multiple taxa. PCNB was one of several pesticides used as case studies for the October 2008 SAP meeting. PCNB is prone to volatilization and is subject to long-range transport. The 2010 follow-up memorandum from the SAP meeting⁷ reported that the panelists were generally supportive of EPA’s presented approach and that it was well supported by scientific evidence. The Agency has since adopted the approach for general use in its pesticide risk assessments. See additional information on this subject in Section III.

Product Cancellations and Use Terminations after Issuance of the RED

In the years after the RED was issued, some uses of PCNB were terminated and removed from PCNB product labels. On July 15, 2009, AMVAC’s PCNB manufacturing and end-use product

⁷ 2008 Science Advisory Panel Meeting Follow Up: Assessment of the Bioaccumulation and Long-Range Transport Potential (LRTP) and of Pentachloronitrobenzene (PCNB) and Associated Ecological Risks, available at <https://www.regulations.gov/document/EPA-HQ-OPP-2004-0202-0265>

registrations were amended, subsequent to a voluntary request, to terminate uses on golf course roughs; residential sites including lawns, yards, and ornamental plants and gardens around homes and apartments; grounds around day care facilities; school yards; parks (except industrial parks); playgrounds; and athletic fields (except professional and college fields) (74 FR 34337). For the purposes of the PCNB registration review, golf courses and athletic fields are considered to be “residential uses” in the context of post-application exposures to golfers and users of athletic fields who potentially are exposed to PCNB residues after application.

On March 13, 2014, the technical PCNB product registration was amended after a request from AMVAC to terminate all seed treatment uses (including potato seed piece treatment) of PCNB and to cancel several product registrations, including all PCNB end-use products registered for use as seed treatments (79 FR 14247).

On August 21, 2019, pursuant to requests from both registrants, the PCNB end-use product registrations of Lesco and Drexel were cancelled; these were the last PCNB products registered for the turf sites listed above (*i.e.*, golf course roughs; residential sites including lawns, yards, and ornamental plants and gardens around homes and apartments; grounds around day care facilities; school yards; parks (except industrial parks); playgrounds; and athletic fields (except professional and college fields)) (84 FR 43593).

On October 2, 2020, in response to a request from AMVAC, the following uses of PCNB were terminated: beans, cotton, garlic, peanuts, peppers, tomatoes, and bedding plants (except for the ornamental cole crops like flowering cabbage). These products were the last PCNB products registered for these uses (85 FR 52347). The technical product registration was amended to prohibit formulation of products to be used on these sites.

At present, PCNB end-use products are registered for the following sites only: the field crops of cole crops and potatoes; golf course tees, greens, and fairways; professional and collegiate athletic fields; sod farms; landscaping around industrial parks; and certain ornamentals in commercial production (*i.e.*, flowering bulbs, Southern pine and Southern magnolia trees, woody ornamentals, and ornamental cole crop bedding plants such as ornamental cabbage). The PCNB technical product registration prohibits the formulation of products for use on any other sites. The end-date for the existing stocks provisions related to the registrants and distributors for these amendments and cancellations have all passed; they may no longer sell or distribute cancelled products subject to these notices or products with labels that include uses that have been terminated. Under the existing stocks provisions, any old stocks in the hands of users were permitted to be used until exhausted, but given the amount of time that has passed, it is unlikely that there are appreciable amounts of these materials still remaining.

Stop Sale, Use, or Removal Order

In 2010, EPA issued a Stop Sale, Use, or Removal Order (SSURO) to AMVAC for all its products containing PCNB because the composition of the technical-grade PCNB product did not match its Confidential Statement of Formula (CSF). New conditions of registration were established in 2011 to limit the concentration of impurities of toxicological concern in the technical-grade product. The CSF was amended and sales of technical-grade PCNB subsequently

resumed; although, as noted in the previous section, some uses were removed from product labels and some end-use product registrations were voluntarily cancelled prior to initiation of the registration review (these are the actions documented in 85 FR 52347).

Organization of this Document

This document is organized in five sections:

- *Introduction* (summarizing the registration review milestones and responding to public comments);
- *Use and Usage* (discussing how and where PCNB is used);
- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);
- *Proposed Final Registration Review Decision* (presenting EPA's proposed decision, regulatory rationale, and any mitigation measures to address risks of concern); and
- *Next Steps and Timeline* (discussing how and when EPA intends to complete registration review).

A. Summary of PCNB Registration Review

On April 11, 2016, the Agency formally initiated registration review for PCNB with the opening of the registration review docket for the case.⁸ The following summary highlights the docket opening and other significant milestones that have occurred in relation to the Endocrine Disruptors Screening Program (EDSP) and thus far during the registration review of PCNB:

- June 2015 – The Agency completed its review of the EDSP Tier I assays for PCNB. EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a “naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” Under FFDCA § 408(p), the Agency must screen all pesticide chemicals. The review concluded:

“There is no evidence of potential interaction of PCNB with the estrogen pathway in the mammals. However, PCNB may potentially interact with the estrogen pathway in wildlife based on the complementarity effects observed within the FSTRA [Fish Short-Term Reproduction Assay] along with the results of the Tier 1 steroidogenesis assay. For the androgen pathway, there [is] no convincing evidence of potential interaction of PCNB with the mammals or wildlife. Additionally, there is no evidence of potential interaction of PCNB with the thyroid pathway in amphibians. However, there is evidence of potential interaction of PCNB with the thyroid pathway in mammals, although it is noted that the observed thyroid effects were consistently associated with alterations in the liver.”

The review is available on the public docket at
<https://www.regulations.gov/document/EPA-HQ-OPP-2015-0348-0010>.

⁸ 40 C.F.R. § 155.50

- April 2016 – EPA posted the PCNB *Preliminary Work Plan (PWP)* (March 30, 2016), *Pentachloronitrobenzene (PCNB). Human Health Assessment Scoping Document in Support of Registration Review* (March 11, 2016), and *Registration Review: Preliminary Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Human Health Drinking Water Exposure Assessments for Pentachloronitrobenzene (PCNB)* (March 6, 2016), and other supporting documents to the public docket for a 60-day public comment period.
- January 2017 – EPA posted the *Pentachloronitrobenzene Final Work Plan (FWP)* (September 10, 2016) to the public docket. The Agency received three comments on the PWP. None of these comments resulted in changes to the schedule or risk assessment needs in the PWP. The anticipated data requirements changed relative to what was included in the PWP: some anticipated data requirements for the PCNB metabolite pentachloroaniline (PCA) were deleted because EPA determined that the data needs could be satisfied by another guideline study.
- March 2017 – EPA issued a Generic Data Call-In (GDCI-056502-1608) for PCNB to AMVAC, the only technical registrant, to obtain data needed to conduct the registration review risk assessments. To date, numerous data requirements have not been satisfied. For more information on the outstanding required data, see Sections III.A.3 and III.B.4.
- November 2021 – EPA posted *Pentachloronitrobenzene (PCNB): Draft Human Health Risk Assessment in Support of Registration Review* (the 2021 HH DRA) and *Pentachloronitrobenzene: Draft Environmental Fate and Ecological Risk Assessment for Registration Review* (the 2021 Eco DRA) to the public docket for a 60-day public comment period, along with several other supporting documents. During the public comment period, which was subsequently extended for another 30 days, the Agency received comments from 15 commenters. The Agency has summarized all substantive comments and responded to these comments in Section I.B., below. The comments helped EPA to refine the human health risk assessment conclusions for the impurities of PCNB but did not change the registration review timeline. Based on these refinements, some risk estimates have changed. Potential cancer risks for golfers exposed to the impurities in PCNB and for occupational post-application exposures are no longer of concern. Other cancer/impurity risk estimates, for users of collegiate and professional athletic fields, are reduced in magnitude but remain of concern. The risks are discussed in more detail below and also in *Pentachloronitrobenzene (PCNB): Addendum to “Pentachloronitrobenzene (PCNB): Confidential Supplement to Draft Human Health Risk Assessment for Manufacturing Impurities (D463503)*. The addendum itself has been deemed confidential and is not available to the general public on the docket.
- September 2022 – EPA completed the PFD for PCNB and made it available in the public docket for a 60-day public comment period. Along with the PFD, EPA plans to post the following documents to the public docket:

- *Pentachloronitrobenzene: Response to Public Comments on the Draft Ecological Risk Assessment and Drinking Water Assessment for Registration Review*, June 30, 2022.
- *Pentachloronitrobenzene (PCNB): Response to Comments on the Draft Human Health Risk Assessment for Registration Review*, August 29, 2022.
- *Pentachloronitrobenzene (PCNB) (PC Code 056502) Registration Review: Assessment of Use, Usage, Potential Impacts of Cancellation, and Response to Public Comments on the Draft Risk Assessments*, June 27, 2022.

As noted above, the Agency also has prepared *Pentachloronitrobenzene (PCNB): Addendum to “Pentachloronitrobenzene (PCNB): Confidential Supplement to Draft Human Health Risk Assessment for Manufacturing Impurities (D463503)*, September 7, 2022. However, this document has been deemed confidential because it contains information related to the composition of the technical-grade product, and is not available to the general public on the docket. The Agency has based its proposed decision on information on PCNB and its degradates and on the impurities of toxicological concern.

B. Summary of Public Comments on the Draft Risk Assessments and Agency Responses

During the 60-day public comment period for the PCNB Draft Risk Assessments (November 1, 2021 to January 27, 2022), the Agency received comments from 15 entities. Comments were submitted by AMVAC, the United States Department of Agriculture (USDA) Office of Pest Management and Policy (OPMP), Golf Course Superintendents Association of America (GCSAA), the Inter-regional Project 4 (IR-4) Project, the Center for Biological Diversity (CBD), and representatives of several golf courses and country clubs. The Agency has summarized and responded to all substantive comments and comments of a broader regulatory nature below. More detailed responses can be found in *Pentachloronitrobenzene: Response to Public Comments on the Draft Ecological Risk Assessment and Drinking Water Assessment for Registration Review*, *Pentachloronitrobenzene (PCNB): Response to Comments on the Draft Human Health Risk Assessment for Registration Review*, and *Pentachloronitrobenzene (PCNB) (PC Code 056502) Registration Review: Assessment of Use, Usage, Potential Impacts of Cancellation, and Response to Public Comments on the Draft Risk Assessments*. The Agency thanks all commenters for participating and has considered these public comments in developing this PFD.

Comments Submitted by CBD (Docket ID: EPA-HQ-OPP-2015-0348-0027)

Comment: CBD focused on EPA’s duty to consult with the Services with respect to effects on federally listed species and their designated critical habitat during the registration review of pesticides, in accordance with the ESA. The comments also addressed other aspects of registration review, including evaluating the effects on listed species when they are simultaneously exposed to PCNB and other pesticides. CBD suggested that in the absence of information that allows EPA to determine whether PCNB will act synergistically with other ingredients, the Agency must take action to prevent co-application of PCNB and other pesticides to the same area during a growing season. For PCNB products that may affect listed species,

CBD recommended generic labeling requiring the user to follow the prescribed measures contained in relevant Endangered Species Protection Bulletins. In addition, CBD expressed concern about effects on pollinators and other beneficial insects, and effects on human health or environmental safety concerning endocrine disruption associated with the use of products containing PCNB.

EPA Response: The Agency is proposing to cancel all registrations of PCNB. If EPA's final decision is that all PCNB registrations must be cancelled, the potential for exposure to listed species and their designated critical habitat would be eliminated and effects need not be assessed further. Likewise, if the registrations of PCNB are cancelled, potential risks associated with synergism and to pollinators and other beneficial insects will be resolved. If all registrations of PCNB are cancelled, the potential for any endocrine effect is also addressed.

Comments Submitted by IR-4 (Docket ID: EPA-HQ-OPP-2015-0348-0028)

Comment: IR-4 was established by the USDA to assist with the identification and registration of pesticides for specialty crops (e.g., fruits, vegetables, nuts, herbs, ornamentals) and low volume "minor uses" on major row crops, particularly through the development of residue data. IR-4 commented that PCNB is an effective management tool for the control of many plant diseases. According to IR-4, in multiple cases, the use of products containing PCNB rescued a variety of food crop industries, thus, restricting the utilization of this active ingredient may cause greater damage than the damage caused by the pests alone. IR-4 noted that although PCNB is an older fungicide, it is still of interest to growers, with recent requests to support its use on specialty crops and in 2019, IR-4 was asked to develop data to support the use of products containing PCNB on hemp.

EPA Response: EPA acknowledges the valuable role played by the IR-4 Program. Information on the role of PCNB in disease management has been considered in development of this PFD, see Section III.C.

Comments Submitted by USDA OPMP (Docket ID: EPA-HQ-OPP-2015-0348-0029)

Comment: In its comments, USDA OPMP provided information about the benefits of PCNB use on potatoes, turfgrass, and ornamental bulbs. OPMP commented that EPA identified a potential risk of concern for handlers performing manual dip applications with ornamental bulbs, based on the default assumption of 100 gallons of solution and, per the product label, a maximum concentration of 0.045 lb ai/gallon. OPMP noted that this application rate represents the high end of the approved rate range, and that actual rates are likely to vary based on the severity of infection.

EPA Response: The Agency utilized the information provided in USDA's comments while drafting *Pentachloronitrobenzene (PCNB) (PC Code 056502) Registration Review: Assessment of Use, Usage, Potential Impacts of Cancellation, and Response to Public Comments on the Draft Risk Assessments*, available on the public docket. This information also has been considered in development of this PFD, see Section III.C. Information on benefits in the production of ornamental bulbs was especially useful. As for the manual bulb dip operation,

assumptions about the amount handled for manual dip applications to ornamental bulbs are based on the Health Effects Division's Science Policy Council for Exposure (ExpoSAC) Policy 9.2, *Standard Values for Daily Amount Handled/Area Treated Assumptions for Use in Occupational Handler Assessments*. Per this policy, the values recommended for the assessment are "typical to high-end." The Agency welcomes any additional information specific to assessing exposures to occupational manual dip applications of ornamental bulbs in PCNB solution, including the amount handled. The Agency thanks USDA for its past and future outreach to user communities.

Comments Submitted by GCSAA (Docket ID: EPA-HQ-OPP-2015-0348-0030)

Comment: GCSAA noted the importance of PCNB in golf course management due to its efficacy against snow mold and affordability. GCSAA also noted that PCNB is especially important in regions that get a lot of snow, such as the Mountain West, Snowbelt Regions, and Great Lakes area. GCSAA indicated that two or three other active ingredients would be needed to achieve the results PCNB affords by itself. GCSAA provided information regarding the economic impact the golf course industry has in the United States, which is largely dependent on the quality of the turfgrass.

EPA Response: The Agency appreciates GCSAA's comment. The Agency used the information provided by GCSAA in its assessment of the benefits of PCNB on golf courses. See Section III.C.

Comments Submitted by Glendale Country Club (WA, Docket ID: EPA-HQ-OPP-2015-0348-0031), The Oregon Golf Club (OR, -0032), Treetops Resort (MI, -0033), The Pepper Pike Club (OH, -0034), Waupaca Country Club (WI, -0035), The Club at Arrowcreek (NV, -0036), Laurel Valley Golf Club (PA, -0037), Wildwood Golf Club (PA, -0038), Upper Montclair Country Club (NJ, -0039), and Bedford Golf and Tennis Club (NY, -0040)

Comment: Representatives of these golf courses stated that they have used PCNB as an effective and economical means for controlling snow mold, anthracnose, and other fungal diseases. They noted that PCNB can provide protection from snow mold over the course of an entire winter season after just one application. They explained that, as a fungicide with a multi-site mode of action and the only group 14 fungicide⁹ they use, PCNB helps prevent the development of fungicide resistance.

EPA Response: EPA appreciates the perspective of users of PCNB on golf course turf. These comments are consistent with information used in developing this PFD, although the Agency has also identified suitable, efficacious, and cost-effective alternatives to the use of PCNB on golf course turf, as discussed below.

Comments Submitted by AMVAC (Docket ID: EPA-HQ-OPP-2015-0348-0041, -0042, and -0043)

⁹ Refers to Fungicide Resistance Action Committee (FRAC) mode of action grouping
https://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2022--final.pdf?sfvrsn=b6024e9a_2

Comment: AMVAC indicated that PCNB is particularly important for resistance management in potatoes and cole crops as alternatives pose a high risk of developing resistance. AMVAC emphasized the efficacy of PCNB for controlling snow mold and anthracnose diseases in turfgrass. AMVAC also noted the benefits of PCNB use in ornamentals crops, nursery-grown conifers, flowering bulbs, and greenhouse-grown flowering plants.

EPA Response: The Agency thanks AMVAC for the comment and acknowledges that PCNB confers certain benefits. Information provided by AMVAC was integrated into the previously cited *Pentachloronitrobenzene (PCNB) (PC Code 056502) Registration Review: Assessment of Use, Usage, Potential Impacts of Cancellation, and Response to Public Comments on the Draft Risk Assessments* and used in drafting this PFD; see Section III.C.

Comment: AMVAC deduced from information in the open literature that the photodegradation of PCNB and its degradates would likely result in the production of numerous mono- and polychlorinated aromatic compounds whose half-lives can be inferred from published studies.

EPA Response: EPA agrees with AMVAC that the photodegradation pathway of PCNB is likely to be a complex, branching process that results in the formation of a range of different mono- and polychlorinated aromatic compounds; however, the Agency concludes that half-lives derived from published non-guideline studies should not be used quantitatively.¹⁰ In addition, since there are numerous PCNB Residues of Concern (ROCs), the degradation rate of a subset of the compounds cannot be used to predict the overall degradation rate of the ROCs.

Comment: AMVAC acknowledged that fully compliant guideline aerobic and anaerobic soil metabolism studies have not been submitted as required by the registration review DCI.¹¹ AMVAC provided EPA with many literature references and position papers on the environmental fate of polychlorinated aromatic compounds, a group to which PCNB belongs, and indicated it is endeavoring to conduct additional studies to address the data gaps.

AMVAC did not disagree with the assertion in the 2021 Eco DRA that PCNB is not likely to degrade extensively in the aquatic environment, either through chemical or biological means, except for the reversible reduction of PCNB to PCA. EPA's guidelines call for the application of test substances in an unacclimated soil and sediment, where metabolism is even less likely. AMVAC contended that the true long-term environmental fate of PCNB in aquatic systems cannot be defined by simple laboratory studies.

EPA Response: While the position papers and literature references provided by AMVAC help characterize the risk picture, they do not meet the standard for use in quantitative modeling. As the Agency explained in its September 10, 2020 response to AMVAC's request to waive the soil and aerobic aquatic metabolism data requirements, the registrant's rationale for the request relied on data it had submitted previously to the Agency, including information from the open literature. The Agency characterized these data as inadequate to support the waiver request.¹² While it is true that aerobic and anaerobic aquatic metabolism study guidelines require

¹⁰ *Pentachloronitrobenzene: Draft Environmental Fate and Ecological Risk Assessment for Registration Review*

¹¹ The Agency waived the requirement for anaerobic soil metabolism studies in September 2020.

¹² DP Barcode 453946

unacclimated test systems, there are examples from the open literature of microbes that can degrade PCNB in aerobic aquatic systems, yet there is uncertainty as to the *extent* to which acclimation affects aquatic metabolism. In the absence of suitable aquatic metabolism data, EPA will continue to make conservative assumptions about the persistence of PCNB in aquatic environments, as it has done in previous assessments.

Comment: AMVAC disagreed with the Agency’s conclusions about bioaccumulation in aquatic food chains and risk to aquatic-dependent wildlife, reiterating its position that there is “...clear and convincing data that PCNB is not bioaccumulative.” AMVAC indicated that the Agency has not considered these factors.

AMVAC suggested numerous refinements to the Agency’s assessment in support of its position on bioaccumulation. The refinements addressed AMVAC’s views that:

- Estimated Environmental Concentrations (EECs) in water for the major uses of PCNB were overestimated
 - Refinements were based the use of a 25’ buffer and a coarse to very coarse spray droplet size distribution, HUC2-level Percent Cropped Area (PCA) values, typical PCNB application rates, the field dissipation measured value rather than aerobic soil half-life, and the practice of “wetting-in” applications, and accounting for soil volatilization.
- Aquatic-dependent wildlife are primarily exposed to PCTA rather than the parent compound
- PCNB is metabolized by fish and other aquatic organisms, limiting the potential for bioaccumulation through the food chain
- The chronic NOAEL EPA selected for mammals overestimates risk

EPA Response: In general, the Agency disagrees with the foundations of AMVACs alternative analysis. Specifically, EPA notes that some PCNB product labels direct the user to use at least *one* of the following options to address spray drift, under specific circumstances (*e.g.*, for applications via chemigation with overhead sprinklers):

1. apply only when there is sustained wind away from fish-bearing waters,
2. use a 25-foot buffer between the treatment area and fish-bearing waters, or,
3. spray with a coarse or very coarse droplet size distribution.

The label restriction on applications near “fish-bearing waters” is unclear in its scope; nevertheless, EPA’s 2021 Eco DRA provided results for modeling EECs both with and without a 25-foot buffer to evaluate the potential effect. If all three options delineated above were applied uniformly for liquid spray applications with PCNB, incorporating them into the risk assessment would be appropriate.

Because ecological risk assessments are conducted on a field scale, rather than a watershed scale, the Agency does not use cultivated or treated area-based scaling factors (*e.g.*, percent crop treated or PCAs) or typical application rates when calculating EECs.

Due to the nature and limitations of field dissipation studies, including the inability to quantify the various routes of dissipation and inability to account for material balance of the applied pesticide, the use of field dissipation data is inappropriate for modeling aquatic exposure. The Agency explored the impact of watering-in PCNB after application and found it results in only a very small decrease in EECs that would not substantively alter EPA's risk conclusions.

EPA agrees that volatilization can be a route of dissipation for PCNB and has factored volatilization into its modeling of concentrations in the aquatic environment. However, the volatilization algorithm in the Pesticide in Water Calculator (PWC) is not validated for foliar applications. Modeling results for bare ground applications using the algorithm resulted in a ~50% reduction in estimated environmental concentrations (EECs). Data are not available for volatilization from cropped areas, but it is unlikely that volatilization would sufficiently reduce the EECs such that risk estimates would fall below the acute or chronic risk levels of concern (LOCs) for aquatic taxa when PCNB is applied to foliage.

EPA does not agree that using PCTA as the model chemical for the KABAM analysis is appropriate because of inconsistencies between the empirical data and KABAM estimates based on the PCTA Log K_{ow} . There is better agreement between the empirical data and the model estimates based on the PCNB Log K_{ow} . However, EPA acknowledges that depuration in fish, and possibly other organisms, is likely to be slower than estimated based on the PCNB Log K_{ow} because PCTA is the primary metabolite in fish. Consequently, EFED expects that bioaccumulation and risk to aquatic wildlife would fall between the estimates from KABAM based on the PCNB Log K_{ow} and the PCTA Log K_{ow} .

AMVAC's assessment used a less sensitive endpoint than the Agency used. According to AMVAC, the reductions in body weight observed in the selected rabbit study at 125 mg ai/kg bw/day are not statistically significant; AMVAC proposed a NOAEL of 125 mg ai/kg bw/day and a LOAEL of 250 mg ai/kg bw/day. Because there is an apparent dose-dependent decrease in terminal body weight at 125 mg ai/kg bw/day (while control animals gained weight at the same time), the Agency has concluded that these effects constitute a biologically significant response and represent a reasonable measurement endpoint for evaluating chronic risk to mammals. Alternative mammalian endpoints were discussed in the 2021 Eco DRA. Registered use patterns for PCNB are expected to result in exposure at levels that caused the reductions in rabbit body weight (*i.e.*, the study LOAEL) and also decreased offspring body weight in the two-generation reproduction study in rats. These findings indicate that growth effects are likely to occur in mammals at doses approximating residues of PCNB present in aquatic prey. Risk quotients describe the relationship between toxicity endpoints and environmental concentrations and are used to describe the potential for adverse effects as a result of exposure. Small discrepancies in the EECs for aquatic prey species are likely explained by the Agency's use of pre-rounded values; the Agency failed to update the EECs after rounding for significant figures. The updates result in minor changes to the EECs and do not qualitatively alter the conclusions of the assessment.

Finally, the Agency continues to acknowledge the uncertainties in the bioaccumulation component of its past and current assessments. To address these uncertainties, EPA required an Aquatic Food Chain Transfer study (OCSPP 850.1850) with the March 2017 DCI. AMVAC

requested a waiver of this data requirement, and the Agency rejected that request in 2018 because the four studies submitted by AMVAC in support of its waiver request did not adequately address uncertainties regarding the potential for biomagnification of PCNB and its metabolites.¹³ The required data have not been submitted.

Comment: AMVAC questioned the relevance of environmental monitoring data, noting that PCNB residue concentrations observed in the Canadian Arctic are very low, and suggesting that their presence may be due to local use of PCNB. AMVAC noted that it is very difficult to affirm that PCNB products were not used near regions where the monitoring data were collected.

EPA Response: The Agency views the Arctic monitoring data as an important line of evidence showing that PCNB is capable of long-range transport and that residues can enter food chains distant from actual use sites. EPA does not interpret the observed concentrations to be the maximum concentrations of the compound present in the environment. Thus, the monitoring data indicate only that PCNB residues are present in water, air, soil, and animals in the Arctic and EPA has not employed the data in a quantitative fashion. The Agency concludes that the presence of these residues is the result of long-range transport, since it appears there is little or no agricultural land in the Canadian Arctic or other local use of the fungicide. For context, PCNB monitoring data was collected in Resolute Bay, Nunavut, within the Arctic Circle. There appears to be very little crop production in Nunavut, and the distance between Resolute Bay and the agricultural regions of neighboring provinces Saskatchewan and Manitoba is over 1,000 miles. Although it cannot be definitively concluded that PCNB has not been used in areas near where the monitoring data were collected, it seems unlikely given the remoteness of Resolute Bay.

Comment: AMVAC cited several studies of aqueous photolysis as evidence that EPA greatly overestimated the half-life of PCNB in the atmosphere.

EPA Response: EPA does not consider the aqueous photolysis studies referenced by AMVAC to be predictive of atmospheric photolysis, and air monitoring data collected in the Canadian Arctic indicate that PCNB is sufficiently persistent in the air to undergo long-range atmospheric transport.

Comment: AMVAC disagreed with the Agency's risk conclusions for aquatic-phase amphibians based on the application of an incorrect acute-to-chronic ratio (ACR).

EPA Response: AMVAC is correct that the 2021 Eco DRA used an ACR for aquatic-phase amphibians that was incorrectly based on toxicity data from two different species. The correct ACR, based on studies with the Rainbow Trout studies, is 25, rather than of 7.7, as reported previously. The Agency concludes that the ACR approach likely overestimates acute toxicity in aquatic-phase amphibians, and the extent to which PCNB poses acute risks to aquatic-phase amphibians is uncertain. However, the Agency notes that the chronic risk estimate for aquatic-phase amphibians is potentially of concern.

¹³ *EFED Review of Data Waiver Request*, June 18, 2018 (D446863)

Comment: AMVAC put forth an alternative pollinator assessment for PCNB with refinements based on the chronic larval toxicity endpoint, empirical residue data, the degradation of PCNB over time, pollinator attractiveness, and timing of applications. Based on their refined assessment, AMVAC concluded that PCNB use poses low acute and chronic risks to bees both on and off the use site.

AMVAC suggested that the chronic endpoint selected by the Agency for larval honey bees was too low because the effects on larval and pupal were not biologically significant. PCNB-specific residue data for pollen and nectar are not available, but AMVAC cited the empirical residue data in the Bee-REX white paper¹⁴ as evidence that the Bee-REX defaults overestimate exposure. AMVAC used the relative difference between default and empirical data to develop its own nectar and pollen residue exposure estimates and pollinator risk. AMVAC also attempted to refine the pollinator risk assessment by averaging exposure measurements to replicate the exposure period in the adult and larval chronic honey bee toxicity studies, and by arguing that bees are unlikely to forage within certain PCNB use sites so that opportunities for exposure are limited.

EPA Response: EPA is confirming that its selection of the chronic endpoint for larval bees as noted in the 2021 Eco DRA is appropriate because the observed increase in mortality is statistically significant compared to the negative control, and the difference ranges from 10 to 21% after correcting for control mortality. The study also demonstrated a clear dose response.

With regard to AMVAC's inferences from the Bee-REX paper, the commenter does not explain how the residue data cited therein should be viewed as representative of residues resulting from typical PCNB use. The Agency notes that the exposure assumptions in Bee-REX are purposely conservative but considers them to be warranted for PCNB in the absence of chemical-specific residue data. The Agency does not agree with the use of empirical residue data for chemicals that are unrelated to PCNB to refine the PCNB pollinator risk assessment. Based on conclusions from the Tier 1 pollinator dataset, EPA has identified chemical-specific pollen and nectar residue data as information that would be needed to address the uncertainties in pollinator exposure and to facilitate a complete pollinator risk assessment.

EPA disputes AMVAC's reasoning that residue concentrations should be averaged to represent the in-life duration of the pollinator studies, because Bee-REX estimates risk based on a single application and assumes exposure occurs when the residues are at their highest concentration. Consequently, dissipation is not considered in the Tier 1 pollinator assessment. Additionally, PCNB is known to be systemic in plants to some extent, thus, exposures may derive not only from foliar deposition, but also potentially from residues translocated into pollen and nectar.

EPA acknowledges that certain crops will only be attractive to certain bees and will be less attractive when other sources of pollen/nectar are available or when crops are allowed to bloom. All these factors limit the potential for pollinator exposure. However, there remain opportunities for direct exposure, for example, when cole crops are grown for seed and for potatoes which,

¹⁴ *White Paper in Support of the Proposed Risk Assessment Process for Bees*, September 2012. <https://www.regulations.gov/document/EPA-HQ-OPP-2012-0543-0004>

under certain conditions, are attractive to foraging bumble bees and solitary bees. Exposure may also result from bees foraging on flowering weeds on the field, and from exposure via drift outside the treated field. The latter is also true for turf and other plants sprayed with PCNB-containing products.

Although it is true that applications of PCNB for managing snow mold in turfgrass generally are made at cooler times of the year (*e.g.*, October to March), bees may be foraging to some extent at the beginning and end of that period. PCNB may also be applied to turf to control other fungal pathogens of turfgrass during warmer months when bees are foraging. EPA agrees that golf course turf and sod farms are generally well-manicured, and grasses are wind-pollinated, not likely to go to seed, and not a source of nectar. This well-maintained turf is not expected to be attractive to bees, but other PCNB turf use sites, such as industrial parks, are not as closely maintained and may contain flowering weeds or could result in pollinator exposure due to drift.

In summary, the Agency concurs with elements of AMVAC's qualitative characterization, but maintains that there is a reasonable expectation of potential pollinator exposure on PCNB-treated use sites or via drift.

Comment: AMVAC summarized an alternative approach for estimating the dermal absorption of impurities of toxicological concern present in PCNB. AMVAC's approach is based on adjustments to account for rat-to-human differences using a dermal flux ratio and a correction factor to account for the difference between the duration of exposure in empirical studies and the default occupational exposure timeframe of eight hours.

EPA Response: The Agency re-evaluated the available data on dermal absorption of the impurity from the published literature and concluded that the 30% dermal absorption factor (DAF) is appropriate for human dermal exposure. The Agency does not agree with the proposed use of the dermal flux ratio due to two limitations of this approach: (1) it does not account for the amount of test substance deposited across the different skin layers and (2) the dosing in the *in vitro* and *in vivo studies* AMVAC uses as the basis for its conclusions about the dermal flux ratio is very different, and the high dose in the *in vitro* component potentially exceeds saturation of the dermal absorption process.

Relative to the duration of exposure in the empirical studies, the Agency identified an additional study from the published literature that directly supports the appropriateness of a 30% DAF for assessing occupational human exposure during an 8-hour workday. The Agency also considered whether the available data were appropriate for use in an alternative approach to dermal absorption that combines rat and human skin data to estimate a human DAF. Because the dose in the relevant *in vitro* study is more than 20,000 times greater than the dose in the relevant *in vivo* experiments, the data are not conducive to refinement of a DAF.

Comment: AMVAC commented that the Agency improperly concluded that the impurities of toxicological concern in PCNB do not dissipate from leaf surfaces after application of the fungicide. AMVAC cited three foliar dissipation studies in support of its conclusion.

EPA Response: Based on the studies cited by AMVAC in its comments on the human health risk assessment, the Agency acknowledges that environmental factors likely contribute to foliar residue dissipation of the impurities of toxicological concern in PCNB. Two of the literature studies cited by AMVAC (Nash, 1980¹⁵ and Jensen, 1983¹⁶) reported a range of dissipation rates for the dioxin congener TCDD after application of the herbicide 2,4,5-trichlorophenoxy acetic acid to grass, including a residue half-life of 52 days when residues were measured up to 112 days. The study author posited that this half-life is related to a slower dissipation after the initial residue concentrations have declined to a certain point and that a longer half-life was not observed in some of the studies because the herbicide was applied at extremely high levels. Because of the exaggerated application rate (six to 12 times normal rates) and associated uncertainty, the Agency cannot directly rely on such studies for risk assessment purposes, although they are considered evidence supporting the likelihood of dioxin dissipation in the field. Other uncertainties arise from the referenced literature. For example, early post-application residue measurements (less than 28 days) either are not reported or differ from those approved by the Agency to quantify turf transferable residues (TTR). A third literature study (Kaup, 2000¹⁷) was not considered useful since the residues measured were deposited under ambient conditions rather than from a known application rate.

Nevertheless, the Agency has considered these uncertainties and the limitations of the available literature and has concluded that the 52-day half-life allows for a health protective risk assessment. The Agency has refined its residential and occupational post-application risk assessments accordingly and the results are reported in Section III and the confidential supplements to the risk assessment.

Comment: In its assessment of post-application risks to golfers, EPA utilized only the worst-case TTR data, from trials in Missouri, and disregarded the data from the California and Oregon sites. AMVAC stated that excluding the data from the other two study sites is inappropriate as the elimination of data without due cause creates a bias and reduces the statistical significance of the overall study data. Additionally, the Agency based its estimation of post-application golfer risks on an assumption that a golfer would play one round of golf per week over the course of the year. AMVAC cited a recent survey from the National Golf Foundation indicating that golfers typically play 20 times per year.

EPA Response: The Agency typically uses the highest predicted Day-0 value from TTR data across the geographic sites; however, the use of first-order dissipation kinetics has the potential to underestimate initial concentrations of total PCNB TTR, so EPA relied on measured TTR values for risk quantitation purposes. Since the assessment is based on measured TTR data as opposed to relying on first-order dissipation kinetics, averaging of the TTR data from all sites is not appropriate.

¹⁵ Nash, R. G.; Beall, M. L., Jr. (1980) *Distribution of Silvex, 2,4-D, and TCDD Applied to Turf in Chambers and Field Plots*, J. Agric. Food Chem. 28, 614-623.

¹⁶ Jensen, D. J.; Getzendaner, M. E.; Hummel, R. A.; Turley, J. (1983) *Residue Studies for (2,4,5-Trichlorophenoxy)acetic Acid and 2,3,7,8-Tetrachlorodibenzo-p-dioxin in Grass and Rice*, J. Agric. Food Chem. 31, 118-122.

¹⁷ Kaupp, H.; Blumenstock, M.; McLachlan, M. S. (2000) *Retention and Mobility of Atmospheric Particle-Associated Organic Pollutant PCDD/Fs and PAHs in Maize Leaves*, Research New Phytol. 148, 473-480.

EPA welcomes further information on the National Golf Foundation survey, for example, what type of player was included in the survey (recreational, professional, ages, *etc.*), if there are additional years of data available, what geographical areas were represented, and other information that potentially could be utilized to refine the Agency's assessment. The Agency considers the current assumption of 52 exposures per 365 days to be appropriate because it is protective of a wide range of golfers, including recreational and professional players.

Comment: Based on communications with GCSAA, AMVAC contended that golf course workers are exposed to PCNB used only at the golf course where they are employed and assumed that they would be exposed once a year during mixing/loading or application activities, and thereafter to post-application exposure from working at the golf course. Based on these assumptions, AMVAC recalculated potential exposures for golf course workers to impurities in PCNB products.

EPA Response: Labels of PCNB products registered for use on golf courses do not restrict use to one application per year, so AMVAC's exposure estimates cannot be verified. The Agency welcomes AMVAC to provide more details relating to its correspondence with GCSAA on this subject or otherwise provide additional evidence to support the claim that golf course workers will use PCNB only once yearly. In absence of further information, EPA has made the reasonable assumption that some golf course workers may make multiple applications yearly.

II. USE AND USAGE

PCNB is an organochlorine contact fungicide registered for use as soil and foliar treatments on certain field crops (potatoes and cole crops), turf (golf courses tees, greens, and fairways only; landscaping for industrial parks; college and professional athletic fields, and sod farms), and production ornamentals (flowering bulbs, Southern magnolia trees, Southern pine, ornamental cole crop bedding plants, and woody ornamentals).

There are currently five registered end-use products containing PCNB. These products are formulated as flowable concentrates (FC; EPA Reg. Nos. 5481-8992 and 5481-585) and granules (G; EPA Reg. Nos. 5481-614, 5481-8988, and 34704-1087). AMVAC Chemical Corporation is the registrant for the technical registration and four of the end-use products; Loveland Products is the registrant for the remaining end-use product.

PCNB may be applied at planting or transplant, pre-emergent to the crop, or post-emergence (either at mid-season for potatoes or ornamentals; or at the first appearance of disease on turf). Broadcast and soil drench applications are also permitted for ornamental seedlings in nurseries or greenhouses prior to transplanting in the field or retail sale, and ornamental bulbs can be treated with dip solutions. Applications of PCNB are made by airblast (Southern magnolia only), groundboom (ornamentals and turf), chemigation (ornamentals and foliar potato applications only), drench and soil-directed with mechanically-pressurized handgun, backpack applications to soil media, and dip (flowering bulbs). Aerial application of PCNB is prohibited, and the use of handheld equipment is prohibited except for use in greenhouses. Maximum single application

rates range from 1.5 lb ai/A to as high as 114 lb ai/A for the registered FC formulations and up to 43.6 lb ai/A for the G formulations.

Cole crops (broccoli, cabbage, cauliflower, Brussels sprouts, collards, kale, and mustard greens) and potatoes are the only registered field crop uses of PCNB. Usage of PCNB for foliar applications to potatoes has been variable from year to year but peaked over fifteen years ago and usage in potato production has been in overall decline since. From 2016 to 2020, about 43,000 pounds of PCNB were applied annually to around 14,000 acres of potato. Less than 2.5% of national potato acreage was treated with PCNB annually during this time. The annual average of pounds applied between 2016-2020 represents a slight increase in pounds of PCNB used in potato compared to the previous five-year period (2011-2015). However, usage has remained consistently low over the ten-year period with an annual average percent crop treated of <2.5% and the slight increase in pounds applied observed was not indicative of any trend of increasing PCNB usage in potato. Broccoli, cabbage, and cauliflower are surveyed for pesticide usage, but no usage of PCNB has been reported recently, and USDA National Agricultural Statistics Service (NASS) data suggest that few growers are applying PCNB to these crops.

Additional details and relevant citations on the use and usage of PCNB are found in *Pentachloronitrobenzene (PCNB) (PC Code 056502) Registration Review: Assessment of Use, Usage, Potential Impacts of Cancellation, and Response to Public Comments on the Draft Risk Assessments*, posted to the public docket.

III. SCIENTIFIC ASSESSMENTS

A. Ecological Risks

The Agency has summarized the 2021 Eco DRA below. The Agency used the most current science policies and methodologies to prepare a risk assessment in support of the registration review of PCNB.¹⁸ For additional details, see *Pentachloronitrobenzene: Draft Environmental Fate and Ecological Risk Assessment for Registration Review* and *Pentachloronitrobenzene: Response to Public Comments on the Draft Ecological Risk Assessment and Drinking Water Assessment for Registration Review* in EPA's public docket (EPA-HQ-OPP-2015-0348). The Agency's conclusions about the ecological risks associated with the use of products containing PCNB have not changed substantially since the time of the RED.

1. Risk Summary and Characterization

The Agency identified potential risks of concern across nearly all evaluated taxa from exposure to PCNB and its residues of concern, including its degradates. EPA has identified environmental fate properties of PCNB and its degradates that cannot be fully represented by calculating RQs, including the potential overlapping risks pertaining to bioaccumulation/bioconcentration, persistence in the environment, and the potential for long-range atmospheric transport.

¹⁸ The 2021 Eco DRA only addresses potential risks to species not listed as threatened or endangered under the Endangered Species Act.

In this discussion of ecological risks, the term “PCNB” generally refers to the following Residues of Concern (ROCs): the parent compound, and the degradates PCA, PCTA, pentachlorothioanisole sulfoxide (PCTASO), pentachlorothioanisole sulfone (PCTASO₂), pentachlorophenol (PCP) and pentachlorobenzene, all of which are structurally similar to the parent and are expected to be persistent.

In addition to these ROCs, the PCNB technical product and end-use products formulated from it contain impurities of toxicological concern, including hexachlorobenzene, pentachlorobenzene (also, a PCNB degradate), polychlorinated dibenzodioxins (PCDDs), and polychlorinated dibenzofurans (PCDFs), the latter two collectively referred to as “dioxins”. A number of the impurities of toxicological concern found in PCNB are on the Stockholm Convention list of Persistent Organic Pollutants, or POPs.¹⁹

PCNB is not itself addressed by the Stockholm Convention, and is not the only source of hexachlorobenzene, pentachlorobenzene, or dioxin releases into the environment. Other organochlorine compounds, including chemicals that have since been cancelled as pesticides, including aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, hexachlorobenzene, mirex, toxaphene, are also addressed under the Stockholm Convention.

While PCNB is not the only source of dioxins in the environment, the Agency has assessed the potential ecological risks associated with the maximum permitted concentrations of dioxins in PCNB products. The Agency has concluded that terrestrial vertebrates whose diets include aquatic organisms are potentially at risk from dioxin exposure based on the maximum concentrations permitted in PCNB products. For further details, see the 2021 Eco DRA and the *2008 Science Advisory Panel Meeting Follow Up: Assessment of the Bioaccumulation and Long-Range Transport Potential (LRTP) and of Pentachloronitrobenzene (PCNB) and Associated Ecological Risks* (EPA-HQ-OPP-2015-0348).

Impacts of Long-Range Transport, Bioaccumulation, and Persistence on Ecological Risk

The environmental fate characteristics of the PCNB ROCs, and the contaminants in PCNB, may increase the scope and magnitude of the potential ecological risks beyond what is represented in the Agency’s usual means of quantifying ecological risk, *i.e.*, the RQ method. These features, as well as a broad discussion of the ecological hazards associated with PCNB, are summarized below in the context of characterizing the risks.

¹⁹ Parties to the Stockholm Convention on POPs have committed to eliminate or restrict the production and use of chemicals listed on Annexes A and B of the Convention and to reduce the release of chemicals listed on Annex C of the Convention, including a number of organochlorine pesticides and by-products. The United States is a signatory to the Convention and though not a party, participates as an observer in the meetings of the parties and in technical working groups. See the list and related information at <http://www.pops.int/TheConvention/ThePOPs/The12InitialPOPs/tabid/296/Default.aspx>

Long-Range Transport

The Agency has determined that PCNB and its degradates have the potential for long-range transport, as reported at the time of the RED, after the 2008 SAP, and in the 2021 Eco DRA.

PCNB is expected to exist primarily in the vapor phase while in the atmosphere. Henry's Law constants for the degradates PCA, PCTA, pentachlorobenzene, and PCP (on the order of 10^{-7} to 10^{-4} atm/m³-mol) indicate that volatilization may also be an important environmental fate process for these compounds. Aquatic modeling for bare ground applications of PCNB showed a ~50% reduction in the estimated environmental concentrations of PCNB in surface water when volatilization was taken into account, suggesting that significant amounts of surface-applied PCNB may be transported from the treated field via volatilization.

Based on empirical data, PCNB is intermediately to highly volatile from dry non-absorbing surfaces under field conditions, and volatile from water surfaces. Field studies indicate that spray-applied PCNB and its degradate PCA can volatilize from the treated field. There are no data on the field volatility of granular or soil-incorporated PCNB. However, field dissipation studies can help inform the effects of the different formulations and incorporation on the volatilization of PCNB. Based on field dissipation data, granular and broadcast applications of PCNB dissipated at a similar rate, indicating that any differences in volatilization of the different formulations is expected to be small. The incorporated applications tended to dissipate at a slower rate than the surface applications, potentially due to decreased volatilization of the incorporated compound.

PCNB is expected to be persistent in the atmosphere based on an estimated atmospheric half-life of >1,400 days. Other information on degradation of PCNB ROCs once present in the atmosphere is not available, but the limited existing monitoring data show that PCNB itself has been found in places where local use of the fungicide is unlikely. The means of transport (atmospheric or otherwise) is not known.

Studies of long-range transport between 1994 and 2004 were summarized in *2008 Science Advisory Panel Meeting Follow Up: Assessment of the Bioaccumulation and Long-Range Transport Potential (LRTP) and of Pentachloronitrobenzene (PCNB) and Associated Ecological Risks* (previously cited in Section I of this PFD). PCNB was detected in air samples from Saskatchewan, British Columbia, and Alberta, Canada. Authors of the Saskatchewan study noted that the registered uses of PCNB in Canada at that time (ornamentals, ginseng, and turf) were not "major crops" grown in that part of the province. The British Columbia and Alberta study locations were within national parks, where PCNB use is not expected to have taken place.

The presence of PCNB residues in pristine areas also has been documented more recently. PCNB was detected in air samples collected in Nunavut in the Canadian Arctic between 2006 and 2009. PCNB was detected in air, snow, meltwater, and seawater in the Resolute Passage (Nunavut) during the 2012 winter-summer transition. In a study in the Bathurst Region of Nunavut in 2008-2009, PCNB was detected in plant material, and in the muscle and liver tissue of wolves and caribou (at frequencies of 57% and 83% in wolf and caribou livers, respectively). A 2016

monitoring study of PCNB and other pesticides (including endosulfan, chlorpyrifos, chlorothalonil, and dacthal), reported that residues of PCNB were found in seawater, plant material, and fish and mammalian tissue.²⁰ Findings from these studies are summarized in the 2021 Eco DRA. While the source of PCNB residues in these remote areas are not definitively known, they are far from areas of agricultural crop or other plant cultivation where the use of PCNB could occur, so that long-range transport via the atmosphere or other media is a reasonable assumption.

These monitoring efforts have focused on the parent PCNB and were not designed to detect or quantify any of the other residues of concern. The presence and potential impact of these other compounds is another uncertainty. Additionally, whether these residues are the result of past or more recent usage is unknown.

The Agency has not conducted a comprehensive risk assessment for listed species at this time, but LOC exceedances for non-listed species suggest that listed species also may be at risk. Since PCNB may be transported over long distances, residues from long-range transport of PCNB are likely to co-occur with listed species in remote areas.

The impurities of toxicological concern that are found in PCNB have likewise been found in pristine areas, although the Agency acknowledges that these compounds are present in the environment predominantly from sources other than pesticide use, such as the manufacture of industrial-use chemicals, industrial waste, and processes such as combustion.

Bioaccumulation

The Agency required the registrant to submit aquatic food chain transfer data in the March 2017 registration review DCI, but these data are still outstanding (they were due 12 months after the registrant's receipt of the DCI). The bioconcentration of PCNB was examined in previously submitted guideline studies. In a study of Bluegill Sunfish (*Lepomis macrochirus*) exposed to PCNB for 28 days, PCNB and its degradates bioconcentrated in fish tissues, with Bioconcentration Factors (BCFs) of 370X for edible tissue, 1,800X for viscera, and 960X for whole fish tissues. In another bioaccumulation study, sunfish were exposed to PCNB for 35 days. BCFs were 400X for edible tissues, 1,800X for viscera, and 1,100X for whole fish tissues.

Several other relevant fish studies are described in the open literature. Studies in various species yielded BCFs for Rainbow Trout (*Oncorhynchus mykiss*, BCFs of 114 to 261X), Topmouth Gudgeon (*Pseudorasbora parva*, BCF of 238X), and Guppy (*Poecilia reticulata*, BCFs ranging from 363 to 1,030X). Studies of aquatic plants yielded BCFs of 3,100X and 4,508X. Although studies show that PCNB can depurate when the fish are no longer exposed, the extent of depuration in other aquatic taxa is uncertain.

²⁰ Morris A.D., Muir C.G.D., Solomon K.R., Letcher R.J., McKinney M.A., Fisk A.T., McMeans B.C., Tomy G.T., Teixeira C., Wang X., Duric M. (March 2016). Current-use pesticides in seawater and their bioaccumulation in polar bear–ringed seal food chains of the Canadian Arctic. *Environmental Toxicology and Chemistry*. 35:7 (1695-1707). <https://setac.onlinelibrary.wiley.com/doi/full/10.1002/etc.3427>

While the Agency currently has no uniform, definitive criteria for identifying bioaccumulative potential based on BCFs, BCFs are used in some regulatory contexts. For example, per Section 313 of the Emergency Planning and Community Right-to-Know Act²¹ (EPCRA), manufacturing facilities are required to report releases and waste management data for specifically listed chemicals. EPA has set reporting thresholds for chemicals of special concern, based on a BCF criterion of 1,000. To be clear, PCNB, as a pesticide, it is not subject to the reporting requirements under EPCRA. Rather, the EPCRA threshold is cited here to give context to the BCFs for PCNB. For reference, international criteria have been established for bioaccumulative potential—a chemical generally is considered to have a high potential for bioaccumulation if it has a BCF of 5,000 or more.²²

While still problematic, PCNB does not have the highest BCFs of all the organochlorine pesticides; DDT has a BCF of 42,000 and dicofol has a BCF of 17,500. It should be noted that on the basis of their environmental persistence and potential to bioaccumulate, some of the chemicals for which EPA has set a lower reporting threshold for reporting under EPCRA are PCNB degradates and impurities of toxicological concern. The typical reporting threshold is 100 lbs annually, while the threshold for hexa- and pentachlorobenzene is 10 lbs and the threshold for the dioxins is 0.1 gram.

As noted above, EPA convened the Scientific Advisory Panel (SAP) in October 2008 to present and get feedback on the Agency's approach to assessing risks from pesticides that are persistent in the environment, have potential for bioaccumulation, are toxic, and are prone to long-range transport. In the 2010 follow-up memorandum to the SAP meeting,²³ EPA reported that the SAP was generally supportive of EPA's presented approach and that the approach was a "leap forward" for the Agency that was well-rooted in the science. The Agency used several pesticides as case studies for illustrating its approach, and one of them was PCNB while another (*i.e.*, endosulfan) was subsequently cancelled.

The SAP specifically supported the Agency's proposed use of a food web bioaccumulation model to assess the risks associated with PBT chemicals and subsequent to the SAP meeting, the Agency finalized the first iteration of its K_{ow} -based Aquatic Bioaccumulation Model (KABAM) for use in pesticide risk assessment. KABAM analysis is now a common feature of the Agency's ecological risk assessments. EPA has used KABAM to assess the risks posed to mammals and birds by residues of PCNB that have concentrated in aquatic prey. Risks of concern from these residues are identified using the same criteria as those associated with ingestion of terrestrial food sources (*i.e.*, an RQ above the chronic risk LOC of 1.0 represents a potential risk of concern).

As detailed in the 2021 Eco DRA and summarized in **Table 2**, the Agency used KABAM to calculate chronic RQs for eight species of mammalian predators feeding on aquatic species. The species of mammalian predators included, in order of increasing size are shrews, rats, moles, mink, and otters. The prey species ranged from plankton to fish. The Agency found that the

²¹ Text at <https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap116.pdf>

²² *Synopsis of Pentachloronitrobenzene Environmental Loading and Ecological Risk*, April 26, 2006.
<https://www.regulations.gov/document/EPA-HQ-OPP-2004-0202-0053>

²³ Available at <https://www.regulations.gov/document/EPA-HQ-OPP-2004-0202-0265>

chronic risk LOC of 1.0 was exceeded for predators consuming any of the prey species for exposures based on the application of PCNB to cole crops, turf, and ornamentals, with RQs ranging from 1.2 to 22; the highest risk estimates are associated with the use on turf. Risk estimates from ingestion of aquatic species by six species of predatory birds were also calculated. RQs of 1.0 to 2.1 were calculated for cranes, rails, herons, small osprey, and white pelicans based on the application parameters for turf. An RQ of 1.1 was calculated for white pelicans only based on the use parameters for ornamentals. Potential risks of concern generated using KABAM are consistent with findings of PCNB monitoring in the Canadian Arctic. As noted in the 2021 Eco DRA and above, PCNB residues have been found in aquatic invertebrates and fish, seals, and polar bears. The highest biomagnification factors were observed in fish species.

There is information that supports the potential for the ROCs to bioaccumulate in terrestrial food webs as well. Estimated and experimentally derived Log octanol-air partition coefficients (K_{OA}) for PCNB ROCs range from 6.7 to 11 and Log octanol-water partition coefficients ($\text{Log } K_{OW}$) range from 3.8 to 5.8. According to published reviews summarized by EPA²⁴, chemicals with a $\text{Log } K_{OA} > 5$ and a $\text{Log } K_{OW} > 2$ have a greater potential for bioaccumulating and biomagnifying through terrestrial food webs. As described in the 2010 follow-up memorandum from the October 2008 SAP meeting, the bioaccumulative potential of PCNB ROCs in a terrestrial food chain was evaluated by the Agency using a simplified exposure paradigm. The concentration of total PCNB ROCs in soil and residues taken up from the soil by earthworms were used to estimate bioaccumulative potential in terrestrial vertebrates that consume earthworms. The Agency concluded that the ingestion of earthworms did not pose risks of concern for birds and mammals. No other prey types were evaluated, and, aside from the monitoring data cited here, no new, relevant data or models have been submitted or developed since that time to advance our understanding of the accumulation of PCNB within a terrestrial food web. Two studies from the from the Canadian Arctic provide qualitative evidence of PCNB biomagnification in terrestrial food webs in the Arctic.

Persistence in the Environment

The PCNB parent compound has laboratory-based aerobic soil metabolism half-lives ranging from approximately one to six months and is classified as slightly persistent to persistent in soil. However, PCNB degrades and/or transforms into numerous identified compounds, many of which are organochlorines and represent potential residues of concern for human health and ecological effects. These residues of concern are structurally and toxicologically similar and have similar fate characteristics to the parent material, although some degradates/metabolites of PCNB can be more persistent than the parent compound. The half-life of PCNB plus the four major degradates is approximately one to 1.3 years. Volatilization is expected to represent a relevant dissipation route for PCNB, and PCNB is expected to be persistent in the atmosphere based on an estimated atmospheric half-life of $>1,400$ days.

²⁴ *White paper on Methods for Assessing Ecological Risks of Pesticides with Persistent, Bioaccumulative, and Toxic Characteristics*, October 7, 2008. Available at <https://www.regulations.gov/search?filter=EPA-HQ-OPP-2008-0550>.

Additional evidence of the persistence of PCNB ROCs in the environment comes from submitted residue chemistry data. While the residue chemistry data base is incomplete, the limited available data show that PCNB ROCs can be detected in commodities from crops that are not themselves treated with PCNB, but that are planted following the harvest of treated crops. At an application rate less than half of the maximum allowable application rate, quantifiable residues were found in rotational crops 365 days after treatment of the preceding crop with PCNB (365 days was the only plant-back interval tested). These data suggest that PCNB ROCs can remain in fields one year or more after application of PCNB at less-than-maximum rates in sufficient quantity to be taken up by a subsequently planted, untreated crop and appear as residues in the harvested commodities from that untreated crop.

The Interplay of Ecological Hazard and the Fate Characteristics of PCNB

While the impact of PCNB's unique fate characteristics on potential risks is important, potential risks are also dependent on toxicity. Information on the toxicity of PCNB is folded into the discussions of ecological risks in this document, and a high-level summary is provided here to give context. More detail can be found in the 2021 draft risk assessments.

PCNB ROCs display toxicity in many species for multiple exposure durations and via numerous routes of exposure. This summary focuses on the most-sensitive endpoints from studies with definitive endpoints and without deficiencies that compromise the utility of study results for quantifying risk (for example, when the limit of solubility in aquatic testing is in question). Although some of the adverse effects manifest in the ecological toxicity chronic toxicity database are relatively low in magnitude, their real-world impact cannot be disregarded, because they could adversely affect fitness and survival.

Hazard for Terrestrial Species

PCNB is practically non-toxic to mammals and birds on an acute exposure basis. Toxicity tests for adult honey bees characterize PCNB as “practically non-toxic” and no more than “moderately toxic” to larval honey bees on an acute basis.

In mammals, the selected chronic endpoint was a small reduction in body weight. For birds, the endpoint from the chronic testing was based on reproductive effects, including number of 14-day survivors. On a chronic exposure basis, the endpoint for larval honey bees was a 40% to 80% increase in pupal and larval mortalities, respectively. Testing in terrestrial plants resulted in relatively minor reductions in dry weight.

Hazard for Aquatic Species

For fish, acute toxicity studies resulted in a designation of PCNB as “very highly toxic.” PCNB is highly and very highly acutely toxic to aquatic invertebrates.

The endpoint derived from a chronic toxicity study with PCNB in a freshwater fish species included small reductions in length and weight, while exposure to PCA resulted in small reductions in growth. In an estuarine/marine fish, the chronic endpoint for PCNB exposure was a

91% reduction in hatching success. Effects observed in chronic testing for aquatic invertebrates include a 25% or 58% reduction in the number of offspring (depending on the test species) and decreases in dry weight (16-18%). Aquatic plant testing resulted in decreases in a variety of growth parameters.

Overall, the Agency's ecological toxicity database shows that the PCNB ROCs is toxic to a variety of wildlife taxa for different exposure durations and pathways.

Terrestrial Risks Associated with the PCNB ROCs (wildlife and plants)

Mammals

On-field risks

Risks associated with residues in terrestrial food sources were assessed for PCNB products applied as liquids. Although sublethal effects were reported, acute RQs were not calculated for mammals from acute exposure to terrestrial dietary items because no mortalities were observed in the acute toxicity study up to the highest dose tested. Acute exposure from dietary items on the field is, however, expected to be up to 5 times greater than the highest dose tested in the laboratory acute toxicity study.

The Agency identified potential chronic risks of concern to mammals for exposure to residues of PCNB on terrestrial food items. The endpoint for chronic risk estimates is a decrease in adult body weight (8% decrease). As shown in **Table 2** below, the highest RQs are associated with the use of products containing PCNB on woody ornamentals. Risk estimates exceed the chronic risk LOC of 1.0 across all uses.

The RQs presented in **Table 2** cover exposures from dietary items on or near the treated field, using the Terrestrial Residue Exposure Model (T-REX) and ingestion of bioaccumulated residues in aquatic prey, using KABAM. T-REX uses the Kenaga nomogram to predict the distribution of pesticide residue concentrations in/on terrestrial food items. Risk estimates exceed the chronic risk LOC of 1.0 across all uses. Note that upper-bound Kenaga RQs are between 2 to 3 times higher than mean Kenaga RQs.

As shown in **Table 2** below, as few as 20 granules of PCNB can pose potential risks of concern for the small mammals.

Using the default foliar half-life and the No Observed Adverse Effect Level (NOAEL), residues on food items result in risk estimates which exceed the Agency chronic risk LOC for up to 316 days, based on upper-bound dose-based exposure estimates, and 263 days, based on mean dose-based exposure estimates. Additionally, upper-bound exposure estimates exceed the Lowest Observed Adverse Effects Level (LOAEL) up to 199 days after application, suggesting that residue concentrations on many of the on-field food items may exceed the NOAEL and the LOAEL for more than half a year after application. This persistence of residues increases the likelihood of exposures and subsequent potential risks of concern for mammals that forage for at least a portion of their diet on the field.

Off-field risks

Off-field risks associated with terrestrial food sources can be characterized as the distance from the field edge at which the RQ no longer exceeds the LOC. These effects distances apply to PCNB products applied as liquids. Risk estimates depend on the application rate, method of application, release height (applies to groundboom only) and spray droplet spectrum. PCNB is only applied by ground; the effects distances shown in **Table 2** represent groundboom applications, low boom height (except high boom for Southern magnolia), and fine to medium/coarse droplet size distribution. As shown in **Table 2** below, RQs based on upper-bound dose-based exposure estimates exceed the Agency’s chronic risk LOC up to 280 feet from the field edge.

Risks to mammalian predator species ingesting aquatic prey

Chronic Dose-based RQs are derived using KABAM version 1.0. The highest risk estimates are associated with the use of PCNB on turf and outdoor ornamentals at the maximum application rate.

Table 2. PCNB Chronic Risk Estimates¹ for Mammals Based on the NOAEL/NOAEC

On-Field Dose-Based RQs, terrestrial food items	RQ Range, Upper-Bound Kenaga²	RQ Range, Mean Kenaga³
Use Site	Risk Estimates⁴	
Cole crops	0.64 to 100	0.3 to 36
Potatoes	0.14 to 22	0.07 to 8.0
Woody ornamentals	3.3 to 510	1.5 to 180
Hardwood (S. magnolia)	1.1 to 180	0.53 to 64
Conifers	1.2 to 200	0.58 to 69
Turf	1.7 to 260	0.77 to 92
On-Field Dietary-Based RQs, terrestrial food items	RQ Range, Upper-Bound Kenaga	RQ Range, Mean Kenaga
Use Site	Risk Estimates⁴	
Cole crops	0.82 to 14	0.38 to 4.6
Potatoes	0.18 to 2.9	0.08 to 1.0
Woody ornamentals	4.2 to 66	1.9 to 24
Hardwood (S. magnolia)	1.5 to 23	0.68 to 8.2
Conifers	1.6 to 25	0.74 to 9.0
Turf	2.1 to 34	0.98 to 12
On-Field, range of number of intact granules to reach chronic NOAEL		
Animal Size	Number of Granules	
Small mammals	10-21	
Medium-sized mammals	19-39	
Large mammals	230-480	
Off-Field Effects Distance (distance from field edge at which the RQ no longer exceeds the LOC) based on upper-bound Kenaga residue values		

Use Site	Number of Feet
Cole crops	37 feet
Potatoes	6.6 feet
Woody ornamentals	280 feet
Hardwoods (S. magnolia)	140 feet
Conifers	86 feet
Turf	120 feet
RQs for Mammals that Consume Aquatic Organisms , range for fog and water shrews, rice rats and star-nosed moles, minks, and river otters (smallest to largest) ⁵	
Use Site	Risk Estimates
Potatoes	0.04 to 0.15
Cole crops	1.2 to 4.1
Turf	6.4 to 22
Ornamentals	3.1 to 11

¹ **Bolded** values indicate RQs exceed EPA's chronic risk level of concern (LOC) of 1.0 for non-listed mammals.

² Residues on food items result in risk estimates which exceed the Agency chronic risk LOC for up to 316 days, based on upper-bound dose-based exposure estimates.

³ Residues on food items result in risk estimates which exceed the Agency chronic risk LOC for up to 263 days, based on mean dose-based exposure estimates.

⁴ Highest RQs across all sizes of mammals and all dietary items

⁵ The largest mammals have the highest RQs.

Birds, Reptiles, and Terrestrial-Phase Amphibians

On-field risks

Residues in terrestrial dietary items

Acute RQs were not calculated for birds (which serve as a surrogate for reptiles and terrestrial-phase amphibians in the absence of taxa-specific data) because no clinical signs of toxicity or mortalities were observed in the acute toxicity study up to the highest dose tested. Acute exposure from dietary items on the field however, is expected to be up to 16 times above the highest dose tested in the laboratory acute toxicity studies. Birds would need to ingest 510 or more granules to reach the highest acute dose tested.

The Agency identified potential chronic risks of concern to birds from exposure to PCNB. The endpoint is a 7% reduction in adult body weight in a study of Bobwhite Quail (*Colinus virginianus*). In another study with quail there was a 43% reduction in 14-day hatchling survival relative to controls at the lowest dose tested. The RQs presented here cover exposures from terrestrial dietary items (T-REX) and the ingestion of bioaccumulated residues in aquatic prey (KABAM). As seen in **Table 3** below, the highest RQs are associated with the use of PCNB on woody ornamentals. Risk estimates from exposure to terrestrial dietary items exceed the chronic risk LOC of 1.0 for all uses.

As shown in **Table 3** below, as few as 14 granules of PCNB can pose chronic risks of concern for the smallest birds.

Using the default foliar dissipation half-life of 35 days, residues on terrestrial food items are expected to result in risk estimates which exceed the Agency chronic risk LOC for up to 194 days.

Off-field risks

As with mammals, off-field avian risks depend on the method of application, release height, and spray droplet spectrum. PCNB is primarily applied by ground. RQs exceed the Agency’s chronic risk LOC up to up to 14 feet from the edge of the treated field.

Risks to avian predator species ingesting aquatic prey

Risk estimates were derived using KABAM version 1.0. Some species whose diets include aquatic organisms are potentially at risk from exposure to bioaccumulated residues in aquatic prey resulting from PCNB uses on turf and ornamental plants.

Table 3. PCNB Chronic Risk Estimates¹ for Birds, Reptiles, and Terrestrial-phase Amphibians Based on the NOAEL/NOAEC

On-Field Dietary-Based RQs, terrestrial food items	Range, Upper-Bound Kenaga²	Range, Mean Kenaga
Use Site	Risk Estimates³	
Cole crops	0.6 to 9	0.3 to 3.2
Potatoes	0.1 to 2	0.1 to 0.7
Woody ornamentals	2.9 to 46	1.3 to 16
Hardwood (S. magnolia)	1 to 16	0.5 to 5.7
Conifers	1.1 to 17	0.5 to 6.2
Turf	1.5 to 23	0.7 to 8.2
On-Field, range of number of intact granules to reach chronic NOAEL		
Animal Size	Number of Granules	
Small birds	14-28	
Medium-sized birds	85-170	
Large birds	1,200-2,400	
Off-Field Effects Distance (distance from field edge at which the RQ no longer exceeds the LOC) based on upper-bound Kenaga residue values		
Use Site	Number of Feet	
Cole crops	3.3 feet	
Potatoes	3.3 feet	
Woody ornamentals	14 feet	
Hardwoods (Low Boom)	6.6 feet	
Hardwoods (High Boom)	10 feet	
Conifers	6.6 feet	
Turf	6.6 feet	
RQs for Birds that Consume Aquatic Organisms , range for sandpiper, crane, rail, heron, small osprey, and white pelican (smallest to largest) ⁴		

Use Site	Risk Estimates
Potatoes	0.01 to 0.02
Cole crops	0.17 to 0.39
Turf	0.92 to 2.1
Ornamentals	0.46 to 1.1

¹ **Bolded** values indicate the RQ exceeds the Agency's chronic risk level of concern (LOC) of 1.0 for non-listed birds, terrestrial-phase amphibians, and reptiles.

² Residues on food items result in risk estimates which exceed the Agency chronic risk LOC for up to 194 days, based on upper-bound dose-based exposure estimates.

³ Highest RQs across all species and all dietary items

⁴ The highest RQs are attributed to the largest birds.

Terrestrial Invertebrates

EPA relies on honey bee (*Apis mellifera*) data as a surrogate for both *Apis* and non-*Apis* bees and, in the absence of other data, for terrestrial invertebrate species. Based on the available data, EPA determined that PCNB uses present potential risks of concern to bees and other terrestrial invertebrates.

Tier 1 Assessment

On-field Risks

Acute RQs for larval honey bees were not calculated due to non-definitive endpoints. Twenty-five percent mortality was observed at the highest dose tested, and oral EECs are as high as 161 times above the highest dose tested in the study. Therefore, acute risks of concern are expected for larval bees.

Acute RQs for adult honey bees also were not calculated due to non-definitive endpoints. Mortality was not observed in either the acute contact or oral study; however, EECs for uses on turf and ornamental are up to 42 times higher than the highest doses tested in the acute contact and oral toxicity studies, respectively. Therefore, acute adult bee risk is expected but quantitatively uncertain for these uses.

The Agency identified potential risks of concern to larval honey bees for chronic exposure to PCNB. The endpoint is a 2.4-fold increase in pupal mortality relative to the untreated control. The chronic dietary-based RQs range from 40 to 900 and exceed the chronic risk LOC of 1.0 for larval bees for all registered PCNB uses. Oral exposure is also expected to exceed levels which reduced adult bee emergence by 82% in laboratory-based studies.

The Agency identified potential risks of concern to adult honey bees for chronic exposure to PCNB. Despite evidence of solvent interference (*i.e.*, solvent "acetone" control had 15% lower food consumption than the negative "untreated" control), the Agency identified a chronic toxicity endpoint based on a decrease in body weight; however, the dose values in the study likely overestimate exposure. The chronic dietary-based RQs range from 5.9 to 140 and exceed the chronic risk LOC of 1.0 for adult bees for all registered PCNB uses when evaluating residues from the single maximum application rate. See **Table 4**, below, for chronic RQ values.

Off-field Risks

RQs exceed the chronic risk LOC up to 53 feet from the field edge.

Table 4. PCNB Tier I Chronic Dietary Risk Estimates¹ for Honey Bees

On-field Risk Estimates		
Use Site	RQs for Adult Nectar Forager	RQs for Larval Worker
Cole Crops	28	180
Potatoes	5.9	40
Woody Ornamentals	140	900
Hardwood	40	260
Conifers	52	340
Turf	40	260
Off-Field Effects Distance (distance from field edge at which the RQ no longer exceeds the LOC)		
Use Site	Number of Feet (Adults)	
Cole Crops	10 feet	
Potatoes	3.3 feet	
Woody Ornamentals	53 feet	
Hardwoods (Low Boom)	14 feet	
Hardwoods (High Boom)	20 feet	
Conifers	17 feet	
Turf	14 feet	

¹**Bolded** RQ values exceed LOC (Chronic risk LOC=1.0)

Higher-Tier Data

At present, no higher-tier data are available for PCNB, including data on residues of PCNB and its degradates in pollen and nectar. PCNB may be applied to foliage, but the extent to which PCNB and its residues of concern are systemic in plants is uncertain. Residues of PCNB and its degradates in the soil may also be a source of exposure if taken up by plants and translocated to pollen and nectar and for ground nesting bees.

Attractiveness of PCNB Use Sites to Pollinators

Most of the registered PCNB use sites are attractive to honey bees and social or solitary non-*Apis* bees (e.g., bumble bees in the genus *Bombus* and mason bees in the genus *Osmia*). The cole crops (e.g., cabbage, cauliflower, broccoli) are highly attractive to honey bees when they are allowed to flower. Typically, they are allowed to flower only if they are grown for seed, in which case growers utilize managed pollinators; however, only a small proportion of these crops are grown for seed. Potatoes also rely on pollination when grown for breeding purposes only; only

about 1% of the acreage is grown for breeding. Turf to which PCNB is applied is typically mowed frequently and is not often allowed to flower. When it does flower, turf is wind-pollinated and serves as a source of pollen for bees only when no other food source is available.

Table 5 below summarizes relevant information from the 2018 USDA compendium of pollinator-attractive plants.²⁵ USDA does not report on attractiveness for ornamentals, but the Agency expects that bees will be attracted to most of the ornamental plant species for which PCNB is registered when they are flowering. Additionally, EPA expects that bees will forage on flowering plants in and adjacent to any treated field.

Table 5. Attractiveness of Pentachloronitrobenzene (PCNB) Use Sites to Bees

Use site	Total U.S. Acreage (seed & non-seed)	Attractiveness To:		
		Honey Bees	Bumble Bees	Solitary Bees
Cauliflower and broccoli	~164,700	++	+	+, some genera
Other cole crops	up to 60,000	++	+	+
Potatoes	1,000,000+	-	+	+, some genera
Grass	35,000,000+	+	-	-

The degree to which pollen and nectar are attractive is listed using a scale where "-" = not attractive, "+" = attractive under certain conditions, and "++" = high attractiveness

Based on the attractiveness of these use sites particularly when grown for seed, and application methods and timing of PCNB applications, there is a reasonable expectation that both *Apis* and non-*Apis* bees will be exposed to PCNB while foraging on or adjacent to the treated field.

Terrestrial Plants

Seedling emergence and vegetative vigor studies are available for PCNB typical end-use products (containing 41.2% PCNB). Terrestrial monocots and dicots appear to be more susceptible to pre-emergence exposure than after emergence. While a definitive endpoint could not be identified, negative effects on growth and survival were observed in seedling emergence and vegetative vigor studies. Notably, the maximum application rate for PCNB is higher than the highest dose tested in the vegetative vigor study, so the impact of PCNB on seedlings at the maximum application rate is uncertain.

Terrestrial plant RQs are below the LOC for all scenarios except non-listed monocots in wetland areas as the result of combined runoff and spray drift exposures associated with PCNB application to woody ornamentals, where the RQ is equivalent to the LOC of 1.0. No other potential risks of concern were identified for terrestrial plants.

Manufacturing Impurities in PCNB--Risks to Terrestrial Predator Species Ingesting Aquatic Prey

²⁵ USDA. *Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen*, 2018, https://www.ars.usda.gov/ARUserFiles/OPMP/Attractiveness%20of%20Agriculture%20Crops%20to%20Pollinating%20Bees%20Report-FINAL_Web%20Version_Jan%202018.pdf

Potential risks to mammals ingesting aquatic prey from exposure to the dioxin impurities originating in PCNB were assessed in 2010 and reported again in the 2021 Eco DRA. Risks posed by these impurities for avian piscivores were not assessed because the manner of dosing in the available avian toxicity studies on the dioxins was not relevant for assessing risk from dietary exposures (the impurities were introduced via intraperitoneal injection). Based on the NOAEL, chronic RQs for piscivorous mammals ranged from 0.09 to 380 relative to an LOC of 1.0. The LOC also was exceeded for the turf and cole crops uses when based on the LOAEL.

Aquatic Risks Associated with the PCNB ROCs

Freshwater Fish

The Agency identified potential acute risks of concern to freshwater fish (which serve as surrogates for aquatic-phase amphibians) for acute and chronic exposure to PCNB. The acute RQ range is 0.03 to 2.9; RQs above 0.5 exceed the acute risk LOC for non-listed species. The acute risk LOC is exceeded across all uses except potatoes.

The Agency identified potential chronic risks of concern to freshwater fish. The chronic toxicity endpoint for freshwater fish is reductions in length (2%) and wet weight (9%). Chronic RQs based on the NOAEC exceed the LOC for all use sites except potatoes. Exposure from use on turf and ornamentals is expected to exceed the LOAEC. See **Table 6** for risk estimates for freshwater fish.

Aquatic-phase Amphibians

Freshwater fish typically serve as surrogates for aquatic-phase amphibians in EPA risk assessments; however, in the case of PCNB, experimental chronic toxicity data are also available for the African clawed frog (*Xenopus laevis*). These data were submitted by the registrant under the EDSP. No acute toxicity data are available for the African clawed frog, but the Agency approximated acute RQs by applying an ACR based on freshwater fish acute toxicity data. As noted previously, the Agency erred in its conclusions about acute risks to aquatic-phase amphibians and the extent which PCNB poses acute risks of concern to aquatic-phase amphibians is uncertain.

In the chronic toxicity study with the African clawed frog, a definitive NOAEC could not be established because adverse developmental effects were observed at all PCNB exposure concentrations. The endpoint is based on statistically significant reductions in the median development stage, an 8% reduction in snout-to-vent body length, and a 19% reduction in wet weight. Chronic risk quotients based on the LOAEC exceed the LOC for all PCNB use sites. EECs for all uses except the use on potato exceed the highest concentration tested in the chronic toxicity study. See **Table 6** for risk estimates for the African Clawed Frog.

Estuarine/Marine Fish

The Agency found no potential acute risks of concern associated with exposures of estuarine/marine fish to PCNB. The Agency identified potential chronic risks of concern for

estuarine/marine fish. The chronic toxicity endpoint is a 91% decrease in the hatching success. Only the chronic RQ for turf exceeds the chronic risk LOC when based on the NOAEC. See **Table 6** for risk estimates for estuarine-marine fish.

Table 6. Acute and Chronic Risk Estimates¹ for Freshwater Fish, Aquatic-phase Amphibians, and Estuarine/Marine Fish Associated with the Current Uses of PCNB.

Use Site	Acute RQ	Chronic RQ
Freshwater Fish (chronic RQs based on the NOAEC)		
Potatoes	0.03	0.04
Cole Crops	0.65	1.5
Turf	2.9	5.5
Ornamental	1.4	3.7
Aquatic-phase Amphibians (chronic RQs based on the LOAEC)		
Potatoes	<i>The extent to which exposure to PCNB poses acute risks to aquatic-phase amphibians is uncertain.</i>	2.9
Cole Crops		110
Turf		400
Ornamental		270
Estuarine/Marine Fish (chronic RQs based on the NOAEC)		
Potatoes	<0.01	0.01
Cole Crops	0.04	0.30
Turf	0.19	1.1
Ornamental	0.09	0.75

¹ **Bolded** RQ values exceed LOC (acute risk LOC=0.5, chronic risk LOC=1.0)

Freshwater Invertebrates

Potential risks for aquatic invertebrates are assessed for species in the water column and the benthos.

In the water column

The Agency found no acute risks of concern associated with exposures of freshwater invertebrates to PCNB in the water column.

The Agency identified potential chronic risks of concern for freshwater invertebrates from water column exposure to PCNB. The chronic toxicity endpoint is a 25% reduction in number of offspring. The RQs exceed the chronic risk LOC across all use sites except potatoes. The RQs for turf and ornamental uses also exceed the Agency’s chronic risk LOC when calculated based on the LOAEC. See **Table 7** for risk estimates for aquatic invertebrates.

In the benthos

Based on its environmental fate properties, parent PCNB that enters aquatic systems is expected to partition to the sediment and persist in this environmental compartment. Similar partitioning and persistence behavior is expected from other PCNB ROCs that form either on the field or in water.

There were no data available for acute effects on sediment-dwelling (benthic) freshwater invertebrates; however, by using acute toxicity data for freshwater invertebrates in the water column compared to sediment pore water concentrations, the Agency identified potential acute risks of concern for benthic invertebrates for all uses but potatoes.

Due to exposure uncertainties in the chronic sediment toxicity studies for all benthic invertebrates, the Agency used the chronic endpoint for freshwater invertebrates in the water column and compared to concentrations in sediment pore water concentrations to assess risk to freshwater benthic invertebrates. On this basis, the Agency identified potential chronic risks of concern to freshwater benthic invertebrates. The chronic RQs for ornamentals and turf exceed the LOC. The RQs for turf and ornamental uses also exceed the Agency's chronic risk LOC when calculated based on the LOAEC for freshwater water-column invertebrates. See **Table 7** for RQ values.

Estuarine/Marine Invertebrates

In the water column

The Agency identified potential acute risks of concern to estuarine/marine invertebrates in the water column for PCNB used on all sites except potatoes.

The Agency also identified potential chronic risks of concern to estuarine/marine invertebrates for water column for PCNB used on all sites except potatoes. The chronic toxicity endpoint is a NOAEC above which there were 16 – 18% reductions in weight and 3 - 6% reductions in length (3-6%) in weight, 21% reductions in survival, 58% reductions in the number of offspring per female, and a 32% increase in the time until first brood at the LOAEC. The chronic RQ range is 0.09 to 14 and exceed the chronic risk LOC of 1.0 for all uses except potatoes. The RQs for cole crops, turf, and ornamental uses exceed the Agency's chronic risk LOC when calculated based on the LOAEC. See **Table 7** for RQ values.

In the benthos

The Agency identified potential acute risks of concern to benthic estuarine/marine invertebrates for exposure to PCNB in sediment pore water. The acute RQs range from 0.04 to 4.6 and exceed the acute risk LOC of 0.5 across all uses except potatoes. See **Table 7** for RQ values.

The Agency identified potential chronic risks of concern to benthic estuarine/marine invertebrates for exposure to PCNB to sediment pore water. Due to exposure uncertainties in the chronic sediment toxicity studies for all benthic invertebrates, these risk estimates are based on the water-column based NOAEC for estuarine/marine invertebrates. The chronic RQs range from

0.05 to 5.4 and exceed the chronic risk LOC of 1.0 across all uses except potatoes. The RQs for the turf and ornamental uses exceed the Agency’s chronic risk LOC when calculated based on the LOAEC at which there were 21% reductions in survival and 58% reductions in the number of offspring per female for estuarine/marine water-column invertebrates.

Table 7. Acute and Chronic Risk Estimates¹ for Aquatic Invertebrates Exposed to PCNB ROCs in the Water Column and in Benthic Sediments.

Use Sites	Freshwater RQs				Estuarine/Marine RQs			
	Water Column		Benthic		Water Column		Benthic	
	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic
Potatoes	<0.01	0.05	<0.01	0.03	0.24	0.09	0.04	0.05
Cole Crops	0.08	1.4	0.02	0.89	5.4	2.5	1.3	1.6
Turf	0.38	7.8	0.07	3.1	24	14	4.6	5.4
Ornamental	0.18	3.7	0.05	2.2	12	6.6	3.4	3.9

¹**Bolded** RQ values exceed level of concern (LOC) (Acute risk LOC=0.5, Chronic risk LOC=1.0)

Aquatic Vascular and Non-Vascular Plants

Toxicity testing with the aquatic vascular plant duckweed (*Lemna gibba*) did not identify a definitive endpoint, so RQs were not calculated.

The Agency identified potential risks of concern to non-vascular aquatic plants for exposure to PCNB based on data from the marine diatom *Skeletonema costatum*. The toxicity endpoint (*i.e.*, the concentration resulting in a 50% inhibition, or the IC₅₀) is based on reduced biomass (the area under the growth curve); reductions in yield and growth rate parameters also occurred at the same concentration. The RQs exceed the LOC for non-vascular aquatic plants from the use of products containing PCNB on turf only (RQ = 1.6, LOC=1.0).

2. Ecological Incidents

EPA reviewed PCNB-related incidents reported to the Incident Data System (IDS). As of EPA’s latest search on August 4, 2022, there are two incidents in the IDS. One incident, with a certainty index of “possible,” occurred in South Carolina in 2000, and was associated with damage to 655 acres of cotton after cotton seeds failed to germinate following application of a granular product that was not soil incorporated. The other incident, also with a certainty index of “possible,” occurred in Iowa in 2004, was the result of a misuse of products containing PCNB that led to damage in over 20,000 acres of soybeans. There are also eight incidents reported in Aggregate IDS.

The Agency intends to continue monitoring ecological incident reports for PCNB and will conduct additional analyses if necessary.

3. Outstanding Ecological and Environmental Fate Data

The ecological and environmental fate database for PCNB is incomplete. The Agency previously issued the following data requirements (via GDCI-056502-1608, issued in March 2017) that have not been satisfied:

- Photodegradation in Water (OCSPP Guideline # 835.2240)
- Aerobic Soil Metabolism (two soils) (OCSPP Guideline # 835.4200)
- Aerobic Aquatic Metabolism (OCSPP Guideline # 835.4300)
- Anaerobic Aquatic Metabolism (OCSPP Guideline # 835.4400)
- Aquatic Food Chain Transfer (OCSPP Guideline # 850.1850)
- Environmental Chemistry Method/Independent Laboratory Validation in Water OCSPP Guideline # 850.6100)
- Environmental Chemistry Method/Independent Laboratory Validation in Soil/Sediment (OCSPP Guideline # 850.6100)

EPA identified potential risks of concern for honey bees. Additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators, based on the *Guidance for Assessing Pesticide Risks to Bees* (June 2014).²⁶ In the 2017 registration review DCI, the Agency required the full suite of pollinator studies, consistent with that guidance. Based on risk concerns for pollinators as described in the 2021 Eco DRA, the Agency has determined that were it not proposing to cancel all registrations, the following Tier 2 data would continue to be needed to facilitate a comprehensive pollinator risk assessment:

- Semi-field Toxicity Testing (OECD Guidance Document 75, tunnel/enclosure or colony feeding)
- Field Trial of Residues in Pollen and Nectar

The need for Tier 3 pollinator data would be determined based on the results of lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.

B. Human Health Risks

The Agency has summarized the 2021 HH DRA below. The Agency used the most current science policies and risk assessment methodologies to prepare this risk assessment in support of the registration review of PCNB. For additional details on the 2021 HH DRA for PCNB, see *Pentachloronitrobenzene (PCNB): Draft Human Health Risk Assessment in Support of Registration Review* in EPA's public docket (EPA-HQ-OPP-2015-0348). Also summarized in this section are the results of the human health risk assessment for the dioxin impurities in PCNB; risk estimates are provided in a way that does not compromise the confidentiality of information on the composition of PCNB products. A more detailed accounting is provided in the confidential appendix.

A supplementary memo to the 2021 HH DRA, *Pentachloronitrobenzene (PCNB): Confidential Supplement to Draft Human Health Risk Assessment for Manufacturing Impurities* (September 17, 2021), was classified as confidential because it contains information that relates to the

²⁶https://www.epa.gov/sites/production/files/2014-6/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

composition of the PCNB technical-grade product, including information on manufacturing impurities of toxicological concern, which include dioxin compounds. A more recent memo that shows refinements to the impurities risk assessment in response to public comments on the 2021 HH DRA, *Pentachloronitrobenzene (PCNB): Addendum to “Pentachloronitrobenzene (PCNB): Confidential Supplement to Draft Human Health Risk Assessment for Manufacturing Impurities (D463503), 09/7/22*, is classified as confidential for the same reason.

Neither of these documents are available on the public docket. If a request is made for either document under the Freedom of Information Act, the Agency can release only redacted versions with the confidential information obscured or removed. The Agency has prepared a summary of these two memos in a confidential appendix to this PFD, which also is not available to the public. Any discussion of the impurities in the publicly available version of this PFD is restricted to information that cannot be used to identify the amounts of specific components of in PCNB products, which is protected as a trade secret. Since the confidential information in the two memos and the confidential appendix is related to AMVAC’s technical product, copies have been provided to AMVAC.

The human health risk assessment non-cancer endpoint for PCNB and its degradates is based on effects in the thyroid. A suite of effects was seen after subchronic and chronic oral exposures in the thyroid of male and female rats, including hypertrophy and hyperplasia of the thyroid follicular epithelium, thyroid colloid vacuolation, and altered thyroid hormone levels. Subchronic inhalation exposure resulted in decreased thyroxine (T4) levels in male rats and subchronic dermal exposure caused hypertrophy of the thyroid follicular epithelium and dilation of thyroid follicles in male rats. Although thyroid toxicity is seen in both sexes, male rats are more sensitive than females and several studies observed thyroid effects in males only. Thyroid follicular adenomas were seen in male and female rats in a chronic exposure study.

PCNB is classified as a “Possible Human Carcinogen (Group C)” based on the presence of thyroid follicular cell adenomas in rats. The Agency determined that for the purpose of risk characterization, the Reference Dose (RfD) approach should be used to quantify human risk.

1. Risk Summary and Characterization

Dietary (Food + Water) Risks

In support of PCNB registration review, the following three dietary risk assessments were conducted: (1) dietary exposure to PCNB and metabolites/degradates determined to be toxicologically similar to PCNB; (2) dietary exposure to pentachlorophenol (PCP), which was identified in the environmental fate and plant metabolism studies and is itself a pesticide; and (3) a confidential dietary assessment of the dioxin manufacturing impurities in PCNB.

Because of concerns about bioaccumulation in aquatic food webs, the Agency looked at potential human dietary and aggregate risks associated with subsistence fishing. For subsistence fishing based on the consumption of fish and shellfish, the chronic dietary risk estimates were $\leq 20\%$ of the chronic population-adjusted dose (cPAD) and are not of concern; aggregate risk estimates also were not of concern. Based on the assumptions incorporated into the subsistence fishing

dietary assessment and the available PCNB environmental monitoring data, the subsistence fishing risk assessment is protective of potential dietary exposures to populations, such as some in the Arctic, whose diet may rely to some extent on marine mammals and terrestrial wildlife species.

PCNB and Toxicologically Similar Metabolites/Degradates

The Agency determined that there are no dietary risks of concern for PCNB and its toxicologically related metabolites/degradates. The parent and these degradates are residues of concern for the human health risk assessment.

Pentachlorophenol

PCP, an ROC of PCNB that itself is a pesticide, and is classified as a B2 carcinogen, was identified in the potato (peel only) and rotational crop (root crops only) PCNB metabolism studies.²⁷ PCP also has been identified in anaerobic metabolism studies with PCNB, but it is not expected to reach ground or surface water in significant concentrations. Thus, potential dietary risks would be associated with residues of PCP in food only. The resulting food-only cancer risk estimate is 2×10^{-8} . Based on low potential exposure to PCP, the Agency has concluded that the non-cancer dietary assessment conducted for PCNB is protective of potential exposure to PCP.

Incidentally, in February 2022, the Agency announced its Final Registration Review Decision on PCP as a pesticide. Its use is associated with potential risks of concern to occupational handlers engaged in pressure-treating wood (the sole use of the pesticide). The Agency was unable to make a finding that the benefits of pentachlorophenol use outweigh the potential risks and concluded that it does not meet the FIFRA registration standard.²⁸

Dioxins

Based on the available data, the dioxin contribution from PCNB use to drinking water exposure is expected to be negligible based on the low concentrations of dioxins in PCNB and the propensity for the compounds to sorb to soil and sediment. Analysis of the available water monitoring data does not indicate that there are higher measured concentrations of these manufacturing contaminants in drinking water in regions with high PCNB usage; however, due to the infrequent sampling intervals, the monitoring likely could have missed the peak concentrations in water resulting from PCNB application. The food-only dietary risk estimates for the dioxins in PCNB are not of concern. Details are captured in *Pentachloronitrobenzene (PCNB): Addendum to "Pentachloronitrobenzene (PCNB): Confidential Supplement to Draft Human Health Risk Assessment for Manufacturing Impurities (D463503)*, which, as explained above, is not available on the public docket.

Residential Handler Risks

²⁷ <https://www.epa.gov/fera/risk-assessment-carcinogenic-effects>

²⁸ <https://www.regulations.gov/document/EPA-HQ-OPP-2014-0653-0071>

Registered PCNB product labels with residential use sites (including golf courses, collegiate and professional athletic fields) require that handlers wear specific clothing (*e.g.*, long sleeved shirt/long pants) and/or PPE (including chemical resistant gloves and a PF10 respirator). The Agency has thus assumed that PCNB is not permitted for homeowner use, and, therefore, the Agency has not conducted a quantitative residential handler assessment. Residential handler exposures to PCNB ROCs and the manufacturing impurities in PCNB are not expected.

Residential Post-Application Risks—PCNB ROCs

Use of products containing PCNB is prohibited on lawns and related sites; however, use is permitted on golf courses and collegiate and professional athletic fields. In this context, EPA assessed the potential post-application risks to golfers and users of those athletic fields. Chemical-specific TTR data are available for three geographic trial sites (CA, MO, and OR). The LOC for post-application risks to golfers and users of collegiate and professional athletic fields is 300.

Golfers

Potential risks are not of concern for adults and children exposed from golfing activities following golf course turf applications of PCNB on Day 0, even using the high-end (MO) TTR data.

Collegiate and Professional Athletic Fields

Potential risks are of concern for adults exposed on PCNB-treated collegiate and professional athletic fields, using TTR data from all three geographic trials, for Day 0 and Day 1 with Margins of Exposure (MOEs) ranging from 62 to 220, relative to an LOC of 300. On Day 3, MOEs increased to 790 to 2,000 and are not of concern.

Labels for PCNB products permit use on these fields to treat snow mold only, and applicators must ensure that the treated area will be idle for at least two days after application. Applicators are directed to make the first application of the season for snow mold prior to first snowfall or when temperatures consistently are below 60°F and extended wet conditions are expected.

Residential Post-Application Non-cancer Risks--Manufacturing Impurities in PCNB

Golfers—The Agency determined that non-cancer residential post-application risks are potentially of concern (*i.e.*, MOEs are < the LOC =30) for adults and children exposed to dioxins on the day PCNB is applied to golf course turf for granular formulations only, based on the use of TTR data for the MO test site.

Collegiate and Professional Athletic Fields— The Agency determined that non-cancer post-application risks associated with the dioxins are potentially of concern (*i.e.*, MOEs < LOC = 30) for adults following exposure on collegiate/professional athletic field turf treated with PCNB, based on data from all three TTR test sites. As noted above, labels for PCNB products permit use

on these fields under certain circumstances only, so risks based on the MOEs only may be overestimated.

Residential Post-Application Cancer Risks--Manufacturing Impurities in PCNB

Golfers— Cancer risks were calculated for adults only, with the assumption of golfing once a week over the course of the year. Based on revised assumptions about the rate at which dioxins may degrade over time, potential risks are not of concern.

Collegiate and Professional Athletic Fields—Cancer risk estimates for adults exposed to dioxins following applications to these athletic fields of PCNB were assessed based on revised assumptions about foliar dissipation. Risk estimates derived in this way are potentially of concern. As noted above, labels for PCNB products permit use on these fields under certain circumstances only, so these risks may be overestimated to some extent.

Aggregate Risks—PCNB and ROCs

In an aggregate assessment, EPA considers the combined pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. The Agency sums the exposures from these sources and compares the aggregate risk to quantitative estimates of hazard. EPA considers the route and duration of exposure when assessing aggregate risks. Other residential exposure scenarios (from applications to golf course with granular PCNB products and applications to collegiate and professional athletic fields) resulted in short- and intermediate-term risks of concern and, therefore, have not been included in the cancer aggregate assessment.

Potential short- and intermediate-term aggregate risks (based on food and drinking water exposures plus post-application risks to golfers from PCNB use on golf course turf) are not of concern for adults, youth 11 to <16 years old, and youth 6 to <11 years old (*i.e.*, the estimated MOEs are > the LOC of 300). Post-application exposure scenarios relating to users of professional and collegiate athletic field uses resulted in potential risks of concern (*i.e.*, MOEs < LOC) and were not included in the short-term aggregate assessment. If these scenarios are effectively mitigated and the potential risks are no longer of concern, (*i.e.*, MOEs ≥ LOC) they will be reconsidered for the aggregate assessment. The chronic aggregate exposures are equivalent to dietary exposure estimates and are therefore not of concern.

Aggregate Risks—PCP

Residential exposure to PCP from PCNB is expected to be negligible. Therefore, aggregate exposures are equivalent to dietary exposure estimates and are therefore not of concern for PCP.

Aggregate Risks—Manufacturing Impurities in PCNB

The short- and intermediate-term non-cancer aggregate risks for the dioxins in PCNB identified as not being of concern at the time of the draft risk assessment. New assumptions about the

dissipation of dioxins after PCNB application result in reduced risk estimates, so these risks are not of concern.

The Agency has revised its cancer aggregate risk assessment for the manufacturing impurities based on the new assumptions about the dissipation of the dioxins after the application of PCNB. The aggregate includes dietary exposures and exposures to golfers playing on courses where liquid formulations of PCNB have been applied. Other residential exposure scenarios (from applications to golf course with granular PCNB products and applications to collegiate and professional athletic fields) resulted in short- and intermediate-term risks of concern and, therefore, have not been included in the cancer aggregate assessment.

Bystander Risks—PCNB ROCs

The Agency examined potential exposures for people near treated sites due to spray drift following application of PCNB. The potential for drift is influenced by many factors, including groundboom release height (aerial applications of PCNB are prohibited) and spray droplet size distribution. The smaller the droplet size or the greater the release height, the greater the potential for drift. Current labels of PCNB products applied in spray form do not set uniform, definitive requirements for droplet size distribution or boom height.

The Agency identified no potential adult bystander risks of concern for PCNB. For children 1 to <2 years old, there are potential combined dermal and incidental oral risks of concern at the field edge for three exposure scenarios (*i.e.*, following groundboom applications to golf course turf and ornamental cole crops in nurseries; and airblast applications to Southern magnolias). Risks are no longer of concern 10 feet from the field edge. Risk estimates for these scenarios are shown in **Table 8** below. Other uses of PCNB do not pose bystander risks of concern (MOEs are greater than the LOC at the field edge).

Table 8. Potential Bystander Risks for Children (1 to < 2 years old) from Applications of PCNB (LOC = 300)

Use Site	Application via	Spray Parameters	MOE at Field Edge	MOE 10 Feet from Field Edge
Golf Course Turf	Groundboom	High boom/very fine to fine droplets	160	330
Ornamental cole crop bedding plants in nurseries, before transplant			240	490
Southern Magnolia	Airblast	Sparse foliage	210	370

Bystander Risks—Manufacturing Impurities in PCNB

For adults, non-cancer dermal spray drift risks are potentially of concern at the edge of the field for some use sites, application methods and application parameters (*e.g.*, boom height, droplet

size spectrum). For children 1 to <2 years old, there also are potential combined dermal and incidental oral non-cancer risks of concern at the field edge for several scenarios.

Cumulative Risks

EPA has not made a common-mechanism-of-toxicity-to-humans finding for PCNB and any other substance. PCNB does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has premised this PFD and the underlying risk assessments on the belief that PCNB does not have a common mechanism of toxicity with other substances.

Occupational Handler Risks—PCNB

In general, PCNB product labels set out clothing and Personal Protective Equipment (PPE) requirements for occupational handlers of PCNB. Applicators are required to wear long-sleeved shirts, long pants, chemical-resistant glove, shoes and socks. For some products, these same requirements apply to mixer/loaders. For some other products, mixer/loaders additionally are required to wear, for exposures in enclosed areas (i.e., greenhouses), at minimum, a PF10 respirator, while for exposures outdoors, they must wear a minimum of a particulate filtering respirator.

For PCNB, the majority of occupational handler risks are not of concern either at the currently required level of clothing/PPE or if the handler wears additional PPE and/or utilizes Engineering Controls (ECs).

Certain PCNB product labels²⁹ restrict how much PCNB may be handled per day, which is not typical for pesticide product labeling. These restrictions were implemented in response to an earlier occupational cancer risk assessment for the impurities of PCNB. For example, in reference to the use on cole crops, the relevant labels indicate that mixers and loaders supporting applications of PCNB are not permitted to handle more than 600 lbs. ai/day and applicators are not permitted to apply more than 1,350 lbs. ai/day (tables in the 2021 HH DRA largely include these restrictions in terms of the equivalent maximum allowable area to be treated per day; the tables also provide alternate risk estimates based on the Agency's standard assumptions about acres treated on a daily basis). For PCNB, there are no non-cancer occupational risks of concern assuming handlers follow the amount handled restrictions (see Table E.1 in the 2021 HH DRA).

In **Table 9** below, risk estimates are shown for each use scenario based on EPA's standard assumptions about acres treated on a daily basis and for increasing levels of personal protection. The level of protection increases as one reads down the rows for a particular scenario (a combination of the handler type, application method, and use site). Reading down the rows for a particular scenario, dermal protection may progress from single layer clothing with gloves to double layer clothing or engineering controls with gloves; a chemical-resistant hat may be added for overhead airblast applications. For inhalation exposure, protection may progress from a Protection Factor 10 Respirator (PF10R), to engineering controls, to engineering controls plus a

²⁹ For EPA Registration Nos. 5481-585, 5481-8992, and 5481-8988

PF10 respirator. Note that there are no engineering controls that are feasible for use in the manual dip operation for ornamental bulbs.

An Aggregate Risk Index (ARI) is used to indicate risk estimates that are the result of dermal and inhalation exposures together; the LOC is an ARI of 1. An ARI was used for PCNB since the LOCs for dermal exposure (300) and inhalation exposure (100) are different. Although the total ARIs are represented in **Table 9**, the dermal exposures generally drive the overall risk estimates. The nursery acreage (60 acres) is reflective of a typical nursery, while orchard acreage (350 acres) reflects a large outdoor area similar to field grown crops acreage. In **Table 9**, ARIs below 1, which represent potential occupational handler risks of concern, are shown in boldface type, and when no additional protection can be added to achieve an ARI > 1, in boldface and italics. Two scenarios remain of concern even with the maximum possible protection afforded by the maximum feasible levels of protection; thus, the corresponding ARIs are shown in boldface and italics. These two scenarios are: mixer/loaders supporting chemigation with liquid formulations preplant for woody plants in an orchard and applicators of manual dip applications with liquid formulations on ornamental bulbs.

Table 9. Occupational Handler Non-Cancer Risk Estimates for PCNB

Application method	Use Site	Area Treated or Amount Handled/ Day	Level of Protection (dermal) ¹	Level of Protection (inhalation) ¹	Total ARI ²
Mixer/Loader					
Chemigation using a liquid formulation	Orchard (preplant): Woody plants	350 acres	SL/G	PF10R	0.046
			EC/G	EC/PF10R	<i>0.43³</i>
	Orchard (preplant): Southern pine seed/seedlings	350 acres	SL/G	PF10R	0.12
			DL/G	PF10R	0.16
			EC/No G	EC/No-R	0.15
			EC/G	EC/No-R	1.1
	Orchard (foliar application): Southern Magnolia	350 acres	SL/G	PF10R	0.16
			DL/G	PF10R	0.21
			EC/No G	EC/No-R	0.2
			EC/G	EC/No-R	1.5
	Nursery Trees (preplant): Woody Plants	60 acres	SL/G	PF10R	0.27
			DL/G	PF10R	0.33
			EC/No G	EC/No-R	0.33
			EC/G	EC/No-R	2.4
	Nursery Trees (preplant): Southern Pine Seed and Seedlings	60 acres	SL/G	PF10R	0.7
			DL/G	PF10R	0.89
EC/No G			EC/No-R	0.86	
EC/G			EC/No-R	6.5	
Groundboom application using a liquid formulation	Sod Farms	80 acres	SL/G	PF10R	0.7
			DL/G	PF10R	0.89
			EC/No G	EC/No-R	0.86
			EC/G	EC/No-R	6.2
Applicators					

Application method	Use Site	Area Treated or Amount Handled/ Day	Level of Protection (dermal) ¹	Level of Protection (inhalation) ¹	Total ARI ²
Airblast application using any starting formulation	Nursery Trees (Foliar app): Southern Magnolia Trees	20 acres	SL/G	No-R	0.065
			SL/G/CRH	No-R	0.42
			SL/G/CRH	PF10R	0.49
			DL/G/CRH	PF10R	0.71
			EC/G	EC/No-R	6.8
	Orchard (Foliar app): Southern Magnolia Trees	40 acres	SL/G	No-R	0.032
			SL/G/CRH	PF10R	0.24
			DL/G/CRH	No-R	0.29
			DL/G/CRH	PF10R	0.36
			EC/G	EC/No-R	3.5
Manual dip using a liquid formulation	Ornamental bulbs	100 gallons of solution	SL/G	No-R	0.29
			DL/G	No-R	0.6
			DL/G	PF10R	0.6³

¹ Key to levels of protection: SL = single layer of clothing (long-sleeved shirt, long pants, shoes/socks), DL = double layer of clothing (e.g., coveralls over long-sleeved shirt, long pants, shoes/socks), G = chemical-resistant gloves, CRH = chemical-resistant hat, EC = engineering controls (e.g., a closed mixing/loading system or an enclosed cab), PF10R = "protection factor 10" respirator

² ARI = Aggregate Risk Index = $1 \div [(\text{Dermal LOC} \div \text{Dermal MOE}) + (\text{Inhalation LOC} \div \text{Inhalation MOE})]$.

³ Two scenarios remain of concern even with the maximum possible protection afforded by the maximum feasible levels of protection; thus, the corresponding ARIs are shown in **boldface** and *italics*

For further details, see *Pentachloronitrobenzene (PCNB): Occupational and Residential Exposure and Risk Assessment for Registration Review*, available on the public docket.

Occupational Handler Risks--Manufacturing Impurities in PCNB

As noted above, some PCNB product labels restrict how much PCNB may be handled per day, which is not typical for pesticide product labeling. There are no non-cancer occupational risks of concern associated with the dioxins in PCNB assuming handlers follow these usage restrictions. When potential exposures are derived from the standard, default amounts handled, there are some potential risks of concern for handlers from exposure to the impurities.

For non-cancer risks, a number of scenarios do not achieve adequate protection without additional PPE or ECs. Some scenarios pose potential risks of concern even at the maximum feasible PPE/ECs. The same is true for potential cancer risks.

Occupational Post-Application Risks-PCNB

The current restricted entry interval (REI) for PCNB is 12 hours for the FC product (EPA Reg. No. 5481-8992) and the G product (EPA Reg. No. 5481-8988) with agricultural sites covered under the Worker Protection Standards (WPS). The other PCNB products, which are not registered for uses covered by the WPS, have no REIs.

Most occupational post-application crop/activity exposure scenarios result in no risks of concern. A potential risk of concern is identified for the ornamental trees (field grown and nursery):

Southern magnolia trees for moving hand-set irrigation equipment at Day 0 have an MOE of 230 (the LOC is 300). On Day 1, the MOE rises to 930.

Occupational Post-Application Risks—Manufacturing Impurities in PCNB

As discussed previously, the Agency has revised its assumptions about the dissipation of the dioxins in the field and on foliage after application of PCNB, and occupational post-application risk estimates have been revised accordingly. Potential non-cancer risks of concern have been identified for three scenarios.

For workers moving hand-set irrigation equipment in Southern magnolia trees on the day of product application, using the 52-day half-life assumption (1.3% daily residue dissipation), non-cancer risk estimates do not meet or exceed the LOC of 30 for more than 30 days after application.

Potential non-cancer risks of concern also were identified for workers performing golf course maintenance activities, based on the MO TTR data (the highest TTR of the three geographic sites where the experimental data were developed). For this scenario, the MOE did not reach the LOC for more than 13 days after application of PCNB. No risks of concern are identified for golf course maintenance with the use of either the CA or OR TTR data.

Additionally, potential non-cancer risks of concern were identified for sod farm workers performing maintenance, transplanting, and planting activities, regardless of which TTR data were used. For the risk estimates based on the three geographic sites, the LOC did not reach the MOE for more than 3 weeks.

The new half-life assumption was also used to re-evaluate potential cancer risks for post-application workers. For workers performing various tasks in Southern magnolias, golf course maintenance, and sod farms, potential cancer risks of concern have been identified.

2. Human Incidents and Epidemiology

EPA reviewed PCNB incidents reported to both the Incident Data System (IDS) and the Sentinel Event Notification System for Occupational Risk (SENSOR). As of EPA's latest search on January 6, 2021, Main IDS showed zero incidents reported and Aggregate IDS showed one minor-severity incident reported from January 1, 2016 to January 6, 2021.

A query of CDC/NIOSH Sentinel Event Notification System for Occupational Risks (SENSOR)-Pesticides covering the period 2012-2017 identified two cases involving PCNB. One case was high in severity; this case involved a patient who intentionally ingested ½ tablespoon of a granular product containing multiple active ingredients including PCNB and aldicarb, which is an *n*-methyl carbamate insecticide. This individual was hospitalized for four days with symptoms including vomiting, agitation/irritability, and muscle weakness. The registration of the product implicated in this case was cancelled in 2002; the case occurred in 2015. The second case was low in severity. The case involved a researcher who was exposed to PCNB via inhalation from

autoclave steam. The product in this case contained 40% PCNB and is no longer registered. The affected individual reported symptoms including dizziness, headache, irritability, and hot flashes.

In April 2021, the Agency conducted a search of the Agricultural Health Study (AHS) publications. No relevant publications were identified. Separately in an open literature search in April 2021, EPA identified one publication examining the association between PCNB exposure and pancreatic cancer. The study authors found no evidence of a significant positive relationship between PCNB exposure and pancreatic cancer.

The Agency intends to monitor human incidents for PCNB and will conduct additional analyses if necessary. For further details, see *Pentachloronitrobenzene (PCNB): Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment* in EPA's public docket (EPA-HQ-OPP-2015-0348).

3. Tolerances

The Agency has established tolerances for PCNB under 40 C.F.R. § 180.291. PCNB is registered for uses that result in residues in or on food. Generally, a tolerance or tolerance exemption must cover the residues present in food commodities or the affected food is considered adulterated.³⁰

During the risk assessment process, EPA determined that the tolerance expression for PCNB was outdated. Additionally, several tolerances are established for uses for which PCNB is no longer registered, the existing tolerance for potato is insufficient to represent the current potato use pattern, and the cole crop tolerances do not align current crop grouping designations. Furthermore, no tolerances for ruminant commodities have been established, and potential residues from treated commodities in the livestock diet are not represented.

This PFD proposes that all registrations of PCNB be cancelled. If the registrations are cancelled, the Agency anticipates proposing revocation of the associated tolerances at a later time, providing for sufficient time for commodities with residues of PCNB resulting from legal application to clear the marketplace. Any proposal to change (or revoke) tolerances is subject to a public comment period, so that potentially affected stakeholders will be able to provide input on those changes. If tolerances are revoked, other changes, such as increasing the potato tolerance or establishing tolerances for ruminant commodities, may not take place. A full accounting of potential changes to the PCNB tolerances may be found in the 2021 HH DRA, available on the public docket.

4. Outstanding Human Health Data

The human health database for PCNB is not complete. The Agency previously required data via GDCI-056502-1608. The registrant has not fulfilled some of these data requirements. Although not all human health data requirements have been completely satisfied, the available data were sufficient to conduct the 2021 HHRA DRA and to support this PFD because the Agency was able

³⁰ 21 U.S.C. §§ 342, 346(a).

to apply appropriate safety factors to account for uncertainty in the toxicology database and use conservative assumptions as needed.

The unfulfilled data gaps from GDCI-056502-1608 are, as follows:

- *Field Rotational Crop Study (OCSPP 860.1900)*: Field rotational crop studies are required for cereal grains, a leafy vegetable, and root and tuber vegetables. Pending submission of these data, the labels should indicate that within 1-year of application only a labeled crop may be rotated to a treated field. The Agency received a rebuttal to the 1-year plantback interval for non-labeled crops from AMVAC on June 20, 2022; this submission is currently under review.
- *Comparative Thyroid Assay (CTA)*: In April 2021, the registrant submitted a range-finding study to support dose selection for the definitive CTA and a protocol for the definitive CTA study. On August 4, 2021, the HED Hazard and Science Policy Committee (HASPOC) confirmed the need for the CTA but suggested that certain mitigation measures could potentially support a waiver of the data requirement. For more information, see *Pentachloronitrobenzene (PCNB): Summary of Hazard and Science Policy Council (HASPOC) Meeting on July 8, 2021: Recommendations on the Need for a Comparative Thyroid Assay (CTA)*.³¹ On October 28, 2021, the Agency provided a review of the protocol for the definitive CTA to the registrant. The Agency discussed the protocol review with the registrant on November 18, 2021, at which time the Agency informed the registrant that, given the PCNB risk assessment findings, these conditions could differ from what the Agency ultimately proposed for mitigating the risks.

In addition, the following data gap was noted in the 2021 HH DRA:

- *Analytical Standards*: The analytical standards for the PCNB metabolite PCA expired on 9/30/2021. A new PCA analytical standard needs to be submitted to EPA's National Pesticide Standards Repository (<https://www.epa.gov/pesticide-analytical-methods/national-pesticide-standard-repository>). Submission of these standards was not a requirement of the registration review DCI for PCNB.

C. Benefits Assessment

In 2006, EPA assessed the benefits of PCNB use and developed a cost analysis for alternatives to PCNB use on key sites: golf course tees, greens, and fairways; cotton; potatoes; green bean; and cole crops.³² The Agency used this work to categorize the benefits associated with the PCNB use sites for the RED compared to the potential risks of PCNB use, as shown in Table 1 above. At the time, the Agency determined that there were high benefits associated with the use of products containing PCNB to control clubroot on cole crops (cabbage, cauliflower, Brussel sprouts, broccoli, collard, kale, mustard greens), based on the lack of feasible pesticidal alternatives for

³¹ <https://www.regulations.gov/document/EPA-HQ-OPP-2015-0348-0021>

³² *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, available on the docket at <https://www.regulations.gov/document/EPA-HQ-OPP-2004-0202-0050>

control of clubroot. The Agency also concluded equally effective alternatives were available for tees, greens, fairways, cotton, potatoes, and green beans, and that the benefits of these uses of PCNB were low

In 2012, EPA reevaluated the benefits for PCNB use on flowering bulbs, for the control of snow mold on golf course turf, and for the control of clubroot on cole crops. At that time, the Agency concluded that there were cost-effective alternatives for all three uses. The seed treatment uses of PCNB were cancelled in 2014.

Quantitative data that are nationally representative of pesticide usage on golf course turfgrass and in ornamental production are not available. Due to the lack of recent surveys of pesticide usage for turfgrass and ornamentals, EPA requested information from USDA and GCSAA regarding the use of products containing PCNB on these sites, and while no quantitative usage data for these sites was submitted, the relevant information provided by USDA and GCSAA is discussed in the updated benefits assessment, *Pentachloronitrobenzene (PCNB) (PC Code 056502) Registration Review: Assessment of Use, Usage, Potential Impacts of Cancellation, and Response to Public Comments on the Draft Risk Assessments*, June 27, 2022, which has been posted to the public docket.

PCNB benefits users by controlling/suppressing plant diseases on registered use sites to prevent economic losses. Due to its multisite mode of action and persistence, it plays a role in resistance management and provides long lasting plant disease suppression/control. However, based on available information, efficacious alternatives are available to control fungal pests controlled by PCNB and the Agency expects that if all existing registrations were to be cancelled, impacts to users would be low. Available information indicates that most alternatives are comparable in cost to PCNB; however, some alternatives may be more expensive than PCNB. The Agency has concluded that the overall benefits of PCNB are low. For more information on the benefits and impacts of cancellation, see the updated benefits assessment mentioned above.

IV. PROPOSED FINAL REGISTRATION REVIEW DECISION

A. Proposed Regulatory Rationale

The Agency has reviewed the risks and benefits associated with the registered uses of PCNB in developing this Proposed Final Registration Review Decision and proposes that the risks of the use of PCNB outweigh the benefits of its use for all use sites and therefore all PCNB registrations present unreasonable adverse effects to the environment as defined in section 2(bb) of FIFRA. As such, EPA proposes that registrations of products containing PCNB do not meet the FIFRA standard for registration.

Exposures and risks associated with the use of products containing PCNB result from direct application of PCNB, spray drift, volatilization, long-range transport, run-off, ingestion of residues in the field, contamination of waters serving as habitat for aquatic life, concentration of residues of concern in the aquatic food chain (and potentially, the terrestrial food chain), contact of golfers and users of collegiate and professional athletic fields with treated turf, and occupational handler and worker exposures related to application and post-application activities.

Summary of Ecological Risks Associated with PCNB and its Degradates

Using the deterministic (point estimate-based) RQ approach, the Agency has identified potential risks of concern to terrestrial and aquatic animals (both vertebrates and invertebrates) and aquatic plants associated with the use of products containing PCNB. Since adverse effects have been observed for a wide range of taxa, it seems reasonable to assume that PCNB could pose risks beyond the species on which the Agency's ecological risk estimates are based. Since PCNB has been detected in areas far removed from PCNB use, it also is reasonable to assume residues from long-range transport of PCNB are likely to co-occur with non-target organisms, including those that are federally listed as endangered or threatened under the ESA in remote areas.

The Agency also has concluded that PCNB and its degradates are persistent in the environment. This and other environmental fate characteristics such as volatility and the tendency to partition to sediment contribute to a potential for long-range transport and bioaccumulation, which may be underestimated because monitoring studies tend to focus on the parent compound only and were not targeted to locations and times when PCNB is in use. Based on this persistence, the propensity for long-range transport and bioaccumulation coupled with the toxicity of the compound to multiple non-target species/taxa, the impacts of the use of products containing PCNB on the environment likely extend beyond the Agency's ability to fully quantify potential ecological risks. These characteristics (1) increase the scope of PCNB's adverse effects on the environment by affecting areas beyond where it is used, (2) increase the magnitude of these risks because residues accumulate in the environment and in food webs, and (3) increase duration of exposure and risk by retaining the potential for ecological exposure well after the time when PCNB is applied.

In addition, PCNB contains impurities of toxicological concern that also originate from other processes and the manufacture of other materials. The amount of these impurities in PCNB is relatively small compared to these other sources, and so they are not a focal point of the Agency's ecological risk assessment, but they nonetheless contribute to the larger risks. Based on their toxicity and fate characteristics that they have in common with PCNB, these impurities also can contribute to impact on the environment overall.

Summary of Human Health Risks Associated with PCNB and its Degradates

The Agency has identified potential risks of concern to human health from exposure to PCNB and its degradates. There are no dietary risks of concern for the general population associated with residues of PCNB and its degradates or for people with subsistence diets based on fish and shellfish. Potential risks of concern have been identified for golfers, users of collegiate and professional athletic fields, bystanders, occupational handlers, and people who work in areas where PCNB has been applied previously.

Summary of Human Health Risks Associated with Impurities in PCNB

The Agency determined that there are no dietary risks of concern for the dioxin impurities of PCNB. There are potential cancer and/or non-cancer risks of concern for golfers and users of

collegiate and professional athletic fields, cancer and non-cancer risks of concern for certain occupational handlers, and non-cancer risks of concern for certain occupational post-application exposures. Some of the occupational handler cancer risks cannot be wholly mitigated by additional PPE or engineering controls.

Summary of Benefits Associated with the Use of Products Containing PCNB

Benefits of the use of products containing PCNB include the efficacious and cost-effective control of plant diseases, and a multi-site mode of action that may forestall the development of fungicide resistance. In evaluating the benefits associated with the use of products containing PCNB overall and on a site-by-site basis, EPA determined the benefits from the use of products containing PCNB are low for all uses and that efficacious alternatives are available for all uses of products containing PCNB. The Agency estimates that the impacts from cost increases from using more expensive alternatives are not significant; for further details, see *Pentachloronitrobenzene (PCNB) (PC Code 056502) Registration Review: Assessment of Use, Usage, Benefits, Potential Impact of Potential Cancellation, and Response to Public Comments on the Draft Risk Assessments*.

Other Considerations in Formulating a Proposed Registration Review Decision for PCNB

The Agency considered a combination of risk mitigation measures to address these potential risks, including selective use terminations, prohibition of certain application methods or equipment, application rate reductions, spray drift restrictions, additional PPE and engineering controls, longer REIs, buffers and vegetative filter strips, and pollinator protection label statements. EPA determined that these measures, even when combined, do not adequately address the identified risks, especially considering the low benefits of continued PCNB use. In particular, the combination of these potential measures would not adequately address EPA's concerns with the persistence, bioaccumulation, toxicity, and long-range transport potential from the use of products containing PCNB. The Agency has concluded that these particular concerns cannot be adequately addressed unless all the uses of PCNB are cancelled. Therefore, after considering both the risks and the benefits, the Agency is proposing the cancellation of all PCNB registrations. The Agency has discussed its risk concerns with the registrant of technical-grade and most end-use products, AMVAC. At this time, AMVAC does not support the Agency's proposal and has not agreed to voluntarily cancel all PCNB registrations.

1. Proposed Cancellation of the Registrations of PCNB

The Agency is proposing to cancel all current PCNB registrations to address ecological and human health risk concerns. These risks are driven by the toxicity and environmental fate characteristics of PCNB and the other ROCs. Potential risks of concern were identified for humans and across nearly all wildlife taxa assessed during this registration review. Furthermore, PCNB and its degradates are collectively considered to be persistent in the environment, bioaccumulative in the aquatic food chain and possibly in the terrestrial food chain as well, highly to very highly toxic to aquatic organisms, and susceptible to long-range atmospheric transport. These characteristics result in the potential for widespread and long-lived exposure that cannot be accounted for fully using EPA's approaches to quantifying human health and

ecological risks. EPA finds that cancellation of these registrations is necessary to effectively mitigate the identified risks of concern to both human and ecological health.

The combination of fate characteristics and risks of concern presents a unique risk picture that requires a more holistic approach to mitigation efforts. Risk- and taxa-specific mitigation measures, short of cancellation, will not properly address the potential reach of PCNB. Its detected presence in remote, pristine areas presents a situation where any PCNB usage could result in residues, degradates, and impurities being transported in the atmosphere and/or accumulating in the aquatic and terrestrial food chains. Thus, the Agency is proposing that all PCNB registrations be cancelled to prevent such exposures from occurring.

The Agency's proposed decision is also based, as appropriate, on the consideration of benefits and the potential impacts of cancellation, as discussed in more detail below.

Process for Cancellation

After considering public comment on this PFD, the Agency intends to take the next step in the registration review process, which is to proceed with a final registration review decision for this case. See 40 CFR 155.40. Currently the final registration review decision for PCNB is scheduled for 2023. At that point, the Agency may initiate proceedings, in accordance with section 6(b) of FIFRA, to cancel the registrations of PCNB-containing pesticide products. There are no immediate use restrictions or limitations for users of products containing PCNB with the issuance of this proposed final decision.

2. Potential Impacts of Proposed Cancellation

Usage of PCNB (where data are available) has declined overall since the last benefits assessment and new alternative fungicides have been registered. From 2016 to 2020, quantitative usage of PCNB among surveyed agricultural crops was only reported for potatoes, and although usage on potatoes has been variable historically, the percent of crop treated consistently has remained low (<2.5 percent). Based on available information, EPA concludes that cancellation of all PCNB registrations is likely to result in low impacts on agricultural and non-agricultural users as efficacious and cost-effective alternatives are available to control the fungal pests controlled by PCNB.

3. Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. Throughout the registration review process, EPA has sought to include all communities and persons, including minority, low-income, and indigenous populations who may be disproportionately overburdened by exposure to PCNB.

Based on EPA's ecological risk assessment that concluded that PCNB has the potential to bioconcentrate in aquatic and possibly terrestrial food webs, a dietary risk assessment for

subsistence fishing was conducted. Based on consumption rates associated with subsistence fishing and residue data from the PDP monitoring, exposure estimates were calculated and incorporated into the dietary model. Subsistence dietary exposure was calculated for the population with the highest dietary exposure (all infants) and the populations with residential exposures (adults and children 6-19 years old). Dietary exposures from subsistence fishing and the consumption of fish and shellfish are not of concern. Based on the assumptions incorporated into the subsistence fishing dietary assessment and the available PCNB environmental monitoring data, the subsistence fishing risk assessment is protective of potential dietary exposures to populations, such as some in the Arctic, whose diet may rely to some extent on marine mammals and terrestrial wildlife species.

One group that is likely to experience disproportionate exposure to pesticides is agricultural farmworkers, golf course workers, and athletic field maintenance personnel. EPA has conducted assessments of risks to workers who handle PCNB or may be exposed during post-application activities to PCNB, its degradates, and manufacturing impurities, and has identified potential risks of concern for PCNB that would not be adequately addressed with additional PPE or engineering controls. EPA's proposal to cancel all registrations of PCNB would address these potential risks of concern.

When the PWP for the registration review of PCNB was issued, the Agency solicited information on "any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to PCNB compared to the general population." No responsive information was submitted at that time. In light of the potential risks discussed in this document, the Agency again seeks information on any groups or segments of the population who, as a result of their proximity and exposure to pesticides, unique exposure pathway (*e.g.*, as a result of cultural practices), location relative to physical infrastructure, exposure to multiple stressors and cumulative impacts, lower capacity to participate in decision-making, or other factors, may have unusually high exposure to PCNB compared to the general population or who may otherwise be disproportionately affected by the use of products containing PCNB as a pesticide.

B. Tolerance Actions

Since the Agency is proposing to cancel all registrations of PCNB, the revocation of PCNB tolerances may be considered. EPA's review of current tolerances also identified deficiencies with respect to currently registered uses, as summarized in Section III.B.3 of this Proposed Final Registration Review Decision (PFD). For further details, see the 2021 HH DRA in the public docket (EPA-HQ-OPP-2015-0348).

Table 10. Tolerance Summary for PCNB

Commodity/ Correct Commodity Definition	Established Tolerance (ppm)	Comments
40 CFR 180.291(a) General. Tolerances are established for residues of the fungicide pentachloronitrobenzene (PCNB), including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels is to be determined by measuring the sum of PCNB, pentachloroaniline (PCA), and pentachlorothioanisole (PCTA), calculated as the stoichiometric equivalent of PCNB, in or on the following commodities:		
bean	0.1	Registrations have been amended to terminate this use.
<i>Brassica</i> , head and stem, subgroup 5A	0.1	
cotton, undelinted seed	0.1	Registrations have been amended to terminate these uses.
garlic, bulb	0.1	
peanut	1.0	
potato	0.1	
soybean, forage	0.02	Registrations have been amended to terminate these uses.
soybean, hay	0.02	
soybean, seed	0.02	
vegetable, fruiting, group 8	0.1	
180.291(c) Tolerances with regional restrictions.: Tolerances are established for residues of the fungicide pentachloronitrobenzene (PCNB), including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels is to be determined by measuring the sum of PCNB, pentachloroaniline (PCA), and pentachlorothioanisole (PCTA), calculated as the stoichiometric equivalent of PCNB, in or on the following commodities:		
collards	0.2	
kale	0.2	
mustard, greens	0.2	

C. Proposed Final Registration Review Decision

The Agency is issuing this PFD in accordance with 40 C.F.R. § 155.58.³³ The Agency is proposing that PCNB does not meet the registration standard as currently registered, and it cannot satisfy the standard for registration at this time through implementation of risk mitigation measures short of cancellation.

The Agency conducted detailed ecological and human health risk assessments for PCNB. In these risk assessments, EPA identified potential risks of concern for the majority of taxa evaluated. Additionally, the Agency identified potential risks associated with the environmental fate characteristics of PCNB that increase the scope and magnitude of the potential ecological risks through bioaccumulation in the aquatic food chain, persistence in the environment, and long-range atmospheric transport. EPA also identified potential residential post-application,

³³ In a PFD, EPA sets out a proposed final decision that includes EPA's "proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings." 40 C.F.R. §155.58(b)(1).

bystander, occupational handler, and occupational post-application risks of concern associated with the continued registration of PCNB.

While federally listed threatened and endangered species are not addressed explicitly in the risk assessments, the magnitude of the ecological risks for non-listed species and the potential for widespread exposure to residues of PCNB suggest that there are potential risks of concern for listed species and for modification of designated critical habitat. Although endocrine disruption is not a focus of the registration review risk assessments, submitted data and other relevant scientific information indicates PCNB may interact with the estrogen signaling pathway in fish and the thyroid signaling pathway in mammals.

While some of these human health and ecological risks could potentially be addressed with a combination of specific risk mitigation measures, a risk management approach relying on such measures is inadequate for addressing the totality of the potential risks, particularly given the intrinsic characteristics of PCNB. Furthermore, the Agency has found that the overall benefits of PCNB use are low, especially given the development and adoption of new fungicides and non-pesticidal control options. In weighing the potential risks and benefits as required under FIFRA, EPA determined that the potential risks associated with the use of products containing PCNB outweigh the potential benefits. The Agency is proposing that all registrations of PCNB be cancelled to address this imbalance between potential risks and benefits. The immediate cancellation of all PCNB registrations also would negate concerns about risks to listed species and potential endocrine disruption.

During registration review, EPA considers whether a pesticide registration “continues to satisfy the FIFRA standard for registration.”³⁴ Here, EPA proposes that PCNB does not meet the FIFRA registration standard. In weighing the potential risks and benefits, EPA determined that the potential risks associated with the use of products containing PCNB outweigh the potential benefits. The Agency is proposing that all registrations of PCNB be cancelled to address this imbalance between potential risks and benefits.

In this PFD, the Agency is not making any definitive human health or environmental safety findings associated with the EDSP screening of PCNB. Similarly, the Agency is not making an endangered species effects determination. However, as discussed above, if the registrations of products containing PCNB are cancelled, no action will exist for which EPA has obligations under the ESA. Moreover, if the registrations of PCNB products are cancelled and PCNB tolerances are revoked, any potential endocrine effect would be eliminated. If the registrations are not cancelled, the Agency will complete any necessary ESA and EDSP requirements before issuing a final registration review decision for PCNB.

³⁴ 40 C.F.R. § 155.40(a); 7 U.S.C. § 136a(c)(5); *see also* 7 U.S.C. §§ 136(bb) (defining “unreasonable adverse effects on the environment” as encompassing both “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide” [FIFRA’s risk-benefit standard] **and** “a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FFDCA safety standard]”). In a PFD, EPA sets out a proposed final decision that includes EPA’s “proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings.” 40 C.F.R. § 155.58(b)(1).

D. Data Requirements

There are currently data requirements that remain unfulfilled. See **Table 11**, below, for a summary of data gaps.

Table 11. Status of PCNB GDCI-056502-1608 Outstanding Data Requirements and Submission of Analytical Standard

Study Title	Test Material(s)	OCSPP Guideline #	Due Date	Current Status
Aquatic Food Chain Transfer	PCNB	850.1850	3/9/2018	Submitted data are “supplemental;” requirement not satisfied
Honey Bee Colony-level study	TEP ¹	NonGDL	---	Risks identified based on Tier I data trigger Tier II studies
Full-field Pollinator Study	TEP	850.3040	---	Pending outcome of Tier II studies
Residues in Pollen and Nectar	TEP	NonGDL	---	Risks identified based on Tier I data trigger Tier II studies
Photodegradation in Water	PCNB & PCA	835.2240	3/9/2018	Requirement not satisfied
Aerobic soil metabolism (2 soils)	PCNB	835.4200	3/9/2019	Requirement not satisfied
Anaerobic Aquatic Metabolism	PCNB	835.4300	3/9/2018	Requirement not satisfied
Environmental Chemistry Method/Independent Laboratory Validation in Water	PCNB	835.6100	3/9/2018	Requirement not satisfied
Environmental Chemistry Method/Independent Laboratory Validation in Soil/Sediment	PCNB	835.6100	3/9/2018	Submitted data are “supplemental;” requirement not satisfied
Comparative Thyroid Assay	PCNB	SS-1033	3/9/2018	Requirement not satisfied
Field Rotational Crop Study	TEP	860.1900	3/9/2019	Requirement not satisfied
PCA Analytical Standards	PCA	---	Expired 9/30/2021	(not included in DCI)

¹TEP= Typical end-use product

V. NEXT STEPS AND TIMELINE

A. Proposed Final Registration Review Decision

A Federal Register Notice will announce the availability of the PCNB PFD and open a 60-day comment period. After considering public comments on this PFD, the Agency may issue a final registration review decision for this case. The Agency may then initiate proceedings to cancel the

Docket Number EPA-HQ-OPP-2015-0348
www.regulations.gov

registrations of pesticide products containing PCNB. See Section IV.A.1 of this document for further details on next steps.

Appendix A: Summary of Proposed Actions for PCNB

Affected Populations	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
<ul style="list-style-type: none"> • Birds • Mammals • Pollinators • Fish • Aquatic invertebrates • Aquatic plants 	<ul style="list-style-type: none"> • Water • Drift • Run-off • Residues on food items at site of treatment • Consumption of granules • Long-range transport • Bioaccumulation 	<ul style="list-style-type: none"> • Ingestion • Direct Contact 	<ul style="list-style-type: none"> • Acute • Chronic 	<ul style="list-style-type: none"> • Mortality • Reproductive /Developmental effects • Persistence • Bioaccumulation /bioconcentration • Long-range transport 	<ul style="list-style-type: none"> • Cancellation of all registrations
<ul style="list-style-type: none"> • Golfers • College/professional athletic field users 	<ul style="list-style-type: none"> • Residues on turf 	<ul style="list-style-type: none"> • Dermal absorption 	<ul style="list-style-type: none"> • Chronic • Lifetime (cancer) 	<ul style="list-style-type: none"> • Thyroid effects • Cancer 	
<ul style="list-style-type: none"> • Bystanders 	<ul style="list-style-type: none"> • Drift 	<ul style="list-style-type: none"> • Ingestion • Dermal absorption 			
<ul style="list-style-type: none"> • Occupational Handler 	<ul style="list-style-type: none"> • Handling PCNB 	<ul style="list-style-type: none"> • Inhalation • Dermal absorption 			
<ul style="list-style-type: none"> • Occupational Post-application 	<ul style="list-style-type: none"> • Residues on treated foliage 	<ul style="list-style-type: none"> • Dermal absorption 			